MINUTES OF 330TH MEETING OF REGISTRATIONBOARD HELD ON 24TH TO 26TH JULY, 2023

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

330th meeting of Registration Board was held on 24th to 26th July, 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.	Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, (HI-M, SI-M), Former Surgeon General Pakistan, Rawalpindi (On line)	Co-opted Member
2.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad.	Member
3.	Dr. Imranullah Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
4.	Dr. Ayesha Yaqoob, DDC, Rep of Director DTL, Govt. of Punjab	Member
5.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
6.	Mr. Ghulam Mujtaba, Rep. of IPO, Islamabad	Member
7.	Syed Adnan Rizvi, Director DTL. Govt. of Sindh. Karachi	Member
8.	Dr. Mahvash Ansari, Deputy Director, Rep. of Director, QA&LT, DRAP, Islamabad.	Member
9.	Mr. Muhammad Kashif, Deputy Director, Rep. of Director, Division of BE&R	Member
10.	Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
11.	Hafiz Muhammad Asif Iqbal, Deputy Director, Rep. of Director, MD&MC Division	Member
12.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member
13.	Dr. Khalid Ashfaque, Animal Husbandry Commissioner, M/o NFS, Islamabad.	Co-opted Member

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

Item No. I Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
2.	Dr. M. Haseeb Tariq	Evaluator PEC-III
3.	Mst. Farzana Raja	Evaluator PEC-IV
4.	Mst. Iqra Aftab	Evaluator PEC-V
5.	Mr. Adil Saeed	Evaluator PEC-IX
6.	Ms. Najia Saleem	Evaluator PEC-X
7.	Dr. Farhadullah	Evaluator PEC-XI
8.	Mr. Shahid Nawaz	Evaluator PEC-XIII
9.	Ms. Saima Hussain	Evaluator PEC-XV
10.	Ms. Sana Kanwal	Evaluator PEC-XX
11.	Mr. M. Tahir Waqas	Evaluator PEC-XXI
12.	Ms. Maham Misbah	Evaluator PEC-XXIII
13.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
14.	Mr. Salateen Waseem Philip	Deputy Director (PE&R)

Agenda of Evaluator PEC-II

Case no. 01: Contract manufacturering applications applied on Form-5F from a manufacturer whose product development and stability data is already approved on Form 5F, by the Registration Board:

Apixaban

1.	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 Novamed Pharmaceuticals (Pvt.)Ltd ., 28km Ferozepur Road Lahore
	GMP status of the manufacturer	GMP certificate garnted on 31/08/2021.
	Evidence of approval of manufacturing facility	License granted on 08/04/2006 and renewed on 08/04/2021 General tablet section approved and
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7965 dated 25-03-2022 Rs.75,000/- dated 28-02-2022
	The proposed proprietary name / brand name	**Linara 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Apixaban …… 5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Apixaban (Anticoagulant and direct inhibitor of factor Xa.
	Reference to Finished product specifications	In-House
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Eliquis Tablet, Company: Bristol Myers Squibb,USA
	For generic drugs (me-too status)	Apixaget tablet by Getz Pharma
	Name and address of API manufacturer.	Changzhou Pharmaceuticals Factory**,** 518 Laodong East Road,Changzhou,Jianngsu Province,China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Novamed Pharmaceuticals(Pvt.) Ltd., 28km Ferozepur 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 Novamed Pharmaceuticals(Pvt.)Ltd ., 28km Ferozepur Road Lahore Manufacturer firm: M/s Novamed Pharmaceuticals(Pvt.)Ltd ., 28km Ferozepur Road Lahore Brand Name: Apixo Tablet 5 mg	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
2.	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 Novamed Pharmaceuticals (Pvt.)Ltd ., 28km Ferozepur Road Lahore

	GMP status of the manufacturer	GMP certificate garnted on 31/08/2021.
	Evidence of approval of manufacturing facility	License granted on 08/04/2006 and renewed on 08/04/2021 General tablet section approved and
	Dy. No. and date of submission & Details of fee submitted	Dy.No 7964 dated 25-03-2022 Rs.75,000/- dated 28-02-2022
	The proposed proprietary name / brand name	**Linara 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Apixaban …… 2.5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Apixaban (Anticoagulant and direct inhibitor of factor Xa.
	Reference to Finished product specifications	In-House
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Eliquis Tablet, Company: Bristol Myers Squibb,USA
	For generic drugs (me-too status)	Apixaget tablet by Getz Pharma
	Name and address of API manufacturer.	Changzhou Pharmaceuticals Factory**,** 518 Laodong East Road,Changzhou,Jianngsu Province,China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Novamed Pharmaceuticals(Pvt.) Ltd., 28km Ferozepur 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 Novamed Pharmaceuticals(Pvt.)Ltd ., 28km Ferozepur Road Lahore
Manufacturer firm	M/s Novamed Pharmaceuticals(Pvt.)Ltd ., 28km Ferozepur Road Lahore
Brand Name	Apixo Tablet 2.5 mg

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Azilsartan Medoxomil

3.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17790 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar 80mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved by US FDA
	For generic drugs (me-too status)	Not available
	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 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 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	Azilsartan Medoxomil 80mg Tablet

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
4.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17789 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….40mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 40mg tablet approved by US FDA
	For generic drugs (me-too status)	Not available

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>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</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. 33, Sundar Industrial Estate, 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:

<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore</td></tr>
<tr><td>Brand Name</td><td>Azilsartan Medoxomil 40mg Tablet</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>5.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Weather Folds Pharmaceuticals.
Plot # 69, Phase-II, Industrial Estate, Hattar</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>GMP inspection conducted on 10/12/2020
Tablet (General & General Antibiotic) section approved.</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17804 dated 14-07-2023 Rs.75,000/- dated 13-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Azzota 40mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each tablet contains:
Azilsartan Medoxomil (as Potassium) …….40mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>White to off white biconvex round shape Tablets.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Angiotensin II receptor antagonists.</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Innovator’s</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>Edarbi 40mg tablet approved b US FDA</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>N/A</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>CTX Lifesciences (P) Ltd. India</td></tr>
<tr><td></td><td colspan="2">Evaluation by PEC:</td></tr>
</table>

	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 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 WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 40MG TABLET	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
6.	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 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.
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17805 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Azzota 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. 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 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 WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: AZILTA 80MG TABLET	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

<table>
<tr><td rowspan="13">7.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Winbrains Research Laboratories.
Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>GMP inspection conducted on 10/12/2020
Tablet (General & General Antibiotic) section approved.</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17819 dated 14-07-2023 Rs.75,000/- dated 11-07-2023</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Azzilta 40mg Tablet</td></tr>
<tr><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each tablet contains:
Azilsartan Medoxomil (as Potassium) …….40mg</td></tr>
<tr><td>Pharmaceutical form of applied drug</td><td>White to off white biconvex round shape Tablets.</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Angiotensin II receptor antagonists.</td></tr>
<tr><td>Reference to Finished product specifications</td><td>Innovator’s</td></tr>
<tr><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Edarbi 40mg tablet approved b US FDA</td></tr>
<tr><td>For generic drugs (me-too status)</td><td>N/A</td></tr>
<tr><td>Name and address of API manufacturer.</td><td>CTX Lifesciences (P) Ltd. India</td></tr>
<tr><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td colspan="2">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 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:
<table>
<tr><td>Applicant firm</td><td>M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.</td></tr>
<tr><td>Brand Name</td><td>AZILTA 40MG TABLET</td></tr>
</table>
</td></tr>
<tr><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td rowspan="6">8.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Winbrains Research Laboratories.
Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>GMP inspection conducted on 10/12/2020
Tablet (General & General Antibiotic) section approved.</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17820 dated 14-07-2023 Rs.75,000/- dated 11-07-2023</td></tr>
</table>

	The proposed proprietary name / brand name	**Azzilta 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet approved b US FDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. 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 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 WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.
Brand Name	AZILTA 80MG TABLET

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Azilsartan/Chlorthalidone

9.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 17791 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar-C 40/12.5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated 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)	Not available
	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 have 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
10.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M/s Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 17792 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Azilaar-C 40/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: 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 40mg/25mg approved by US-FDA
	For generic drugs (me-too status)	Not available
	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 have 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Beclomethasone Dipropionate

11.	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	New section granted on 24/11/2021 Injectable Ampoule BF (steroid) -
	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 9423 dated 07-04-2023 Rs.75,000/- dated 21-03-2023
	The proposed proprietary name / brand name	**Becson 0.8mg/2ml Nebulization Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of Suspension Contains: Beclomethasone Dipropionate…0.8mg
	Pharmaceutical form of applied drug	Suspension for Nebulisation
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	In-house
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered in Italian Medicine Agency (AIFA), with the brand name "Clenil" by Chiesi Farmaceutici, Italy.
	For generic drugs (me-too status)	Manufacturer name: Chiesi Farmaceutici, Italy. Importer: Chiesi Pharmaceutical (Pvt.) Ltd. Brand name: Clenil, Strength: 0.8mg/2ml, Registration number: 014091
	Name and address of API manufacturer.	FARMABIOS S.p.A.Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy.
	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 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 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	Becloson Suspension for Nebulisation 0.8mg/2ml
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Bempedoic Acid

12.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 17785 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Bemzeox 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 tablets
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor
	Reference to Finished product specifications	As per innovator
	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)	Not available
	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 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 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

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
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. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 tablets
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor
	Reference to Finished product specifications	As per innovator
	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)	Not available
	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 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 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

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Bempedoic acid/Ezetimibe

14.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee	Dy.No 17786 dated 14-07-2023 Rs.75,000/- dated 14-

	submitted	07-2023
	The proposed proprietary name / brand name	**Bemzeox-E 180/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Bempedoic Acid…….180mg Ezetimibe……...10mg
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Bempedoic Acid: Lipid modifying agents, other lipid modifying agents. Adenosine triphosphate citrate lyase (ACL) inhibitor Ezetimibe: adenosine triphosphate-citrate lyase (ACL) inhibitor, Cholesterol absorption inhibitor.
	Reference to Finished product specifications	As per innovator
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nexilzet tablet approved by US FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Bempedoic Acid: 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). Ezetimibe: Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore 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 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: Bempp-z 180/10mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Budesonide

15.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Cefixime

16.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**

	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry Powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17751 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 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	Dry powder suspesnion
	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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd 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 PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore.
	Manufacturer firm	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Brand Name	Pdfim 100mg/5ml
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
17.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan

	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry Powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17749 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 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	Dry powder suspesnion
	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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd 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 PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Pdfim 100mg/5ml	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
18.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019.

		The GMP certificate specifies Capsule (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 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 & Details of fee submitted	Dy.No 17751 dated 14-07-2023 Rs.75,000/- dated 14-04-2023
	The proposed proprietary name / brand name	**Bectaxime 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 400mg capsule 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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore have already been approved by Registration Board in its 2323rd 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 PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Pdfim 400mg capsule	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
19.	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 Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	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 25514 dated 08-09-2022 Rs.75,000/- dated 24-03-2022
	The proposed proprietary name / brand name	**Cefixime 200mg/5ml DS**
	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.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	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 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 Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
Brand Name	VARICEF 200mg/5ml Dry Suspension

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
20.	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 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 & Details of fee submitted	Dy.No 22949 dated 15-08-2022 Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Fixen 100mg/5ml DS**
	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.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	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 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 Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
Brand Name	VARICEF 100mg/5ml Dry Suspension

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
21.	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 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 25618 dated 12-09-2022 Rs.75,000/- dated 04-10-2021

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Fixen 200mg/5ml Dry Suspension</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each 5ml of reconstituted suspension contains:
Cefixime (as trihydrate)……200mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Suprax suspension 200mg/5ml (USFDA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.</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 Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad 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:
<table>
<tr><td>Applicant firm</td><td>M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.</td></tr>
<tr><td>Brand Name</td><td>VARICEF 200mg/5ml Dry Suspension</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>22.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s ICU Pharmaceuticals.
Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder suspension section (Cephalosporin).</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 5105 dated 22-02-2023 Rs.75,000/- dated 02-09-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Xec-Xim 100mg/5ml Dry Suspensio</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each 5ml of reconstituted suspension contains:
Cefixime (as trihydrate)……100mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Amber colored glass bottle containing white to off</td></tr>
</table>

		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 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: 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
23.	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 Suspensio**
	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 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: CARECEF 200mg/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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
24.	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 Capsule 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 13635 dated 01-06-2023 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Xec-Xim 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each caspsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO

	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Caricef capsule of M/s Sami
	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 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: CARECEF 400mg capsule **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
25.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 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 & Details of fee submitted	Dy.No 12622 dated 24-05-2022 Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unicef 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)

<table>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.</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 Seraph Pharmaceuticals Islamabad 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:
<table>
<tr><td>Applicant firm</td><td>M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Brand Name</td><td>Saf-Xime 200mg/5ml Dry suspension</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>26.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Pine Pharmaceuticals.
Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Seraph Pharmaceuticals: GMP certificate issued on the basis of inspection conducted on 11/07/2019.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry powder suspension Cephalosporin 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 12890 dated 26-05-2022 Rs.75,000/- dated 19-05-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Pinefix 200mg/5ml Dry Suspension</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each 5ml of reconstituted suspension contains:
Cefixime (as trihydrate)……200mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Suprax suspension 200mg/5ml (USFDA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals</td></tr>
</table>

	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Saf-Xime 200mg/5ml Dry suspension	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
27.	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 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 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 & Details of fee submitted	Dy.No 12889 dated 26-05-2022 Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinefix 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.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Saf-Xime 100mg/5ml Dry suspension	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
28.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 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 & Details of fee submitted	Dy.No 12623 dated 24-05-2022 Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unicef 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.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore
	Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	Saf-Xime 100mg/5ml Dry suspension
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
29.	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 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 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 & Details of fee submitted	Dy.No 12891 dated 26-05-2022 Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinefix 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 400mg capsule by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore
	Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	Saf-Xime 400mg Capsule
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

<table>
<tr><td>30.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Unimark Pharmaceuticals Pvt Ltd.
Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Seraph Pharmaceuticals: GMP certificate issued on the basis of inspection conducted on 11/07/2019.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Capsule Cephalosporin 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 12652 dated 24-05-2022 Rs.75,000/- dated 29-03-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Unicef 400mg Capsule</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each capsule contains:
Cefixime (as trihydrate)……400mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Capsule contained in Alu Alu blister</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>JP 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>Suprax Capsule 400mg (USFDA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Tripsan 400mg capsule by Seraph Pharmaceuticals</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.</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 Seraph Pharmaceuticals Islamabad 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:
<table><tr><td>Applicant firm</td><td>M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore</td></tr><tr><td>Manufacturer firm</td><td>M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr><tr><td>Brand Name</td><td>Saf-Xime 400mg Capsule</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>31.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Jaskan Pharmaceuticals Pvt Ltd
5- Sundar Industrial Estate, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals Pvt Ltd.
Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan</td></tr>
<tr><td></td><td>Status of the applicant</td><td>☐ Manufacturer
☐ Importer</td></tr>
</table>

		☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Capsule (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 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 7367 dated 16-03-2022
	Details of fee submitted	Rs.75,000/- dated 18-01-2022
	The proposed proprietary name / brand name	**Cefixa 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefixime as Trihydrate…400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule size # 0 with blue colored body and cap having white to yellow colored powder
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	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 Cunningham Pharmaceuticals Pvt Ltd.Plot # 81, Sunder Industrial Estate, Raiwind Road 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 in 323rd meeting are as follows:	
	Applicant firm: M/s PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: PDFIM 400mg Capsule	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Cefoperazone Sodium/Sulbactam Sodium

	Name, address of Applicant / Marketing	**M/s ICU Pharmaceuticals.**

<table>
<tr><td rowspan="16">32.</td><td>Authorization Holder</td><td>Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td>GMP status of the manufacturer</td><td>Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Cephalosporin dry powder injection section.</td></tr>
<tr><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 31677 dated 03-11-2022 Rs.75,000/- dated 02-09-2022</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Cefo-Bact 2gm Injection</td></tr>
<tr><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Vial Contains:
Cefoperazone as Sodium…1000mg
Sulbactam as Sodium…1000mg</td></tr>
<tr><td>Pharmaceutical form of applied drug</td><td>Sterile white to almost white powder filled in transparent glass vials</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td>Reference to Finished product specifications</td><td>JP specs</td></tr>
<tr><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>As per SRO</td></tr>
<tr><td>For generic drugs (me-too status)</td><td>Sulperazone Intravenous Injection 2g (PMDA Japan Approved)</td></tr>
<tr><td>Name and address of API manufacturer.</td><td>Cefbac injection by Seraph Pharmaceuticals</td></tr>
<tr><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td colspan="2">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 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:
<table>
<tr><td>Applicant firm</td><td>M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td>Brand Name</td><td>Sulgen 2gm IM/IV Injection</td></tr>
</table></td></tr>
<tr><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td rowspan="3">33.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s ICU Pharmaceuticals.
Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td>GMP status of the manufacturer</td><td>Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.</td></tr>
</table>

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Cephaosporin dry powder 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 & Details of fee submitted	Dy.No 31678 dated 03-11-2022 Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Cefo-Bact 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	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	As per SRO
	For generic drugs (me-too status)	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	Name and address of API manufacturer.	Cefbac injection by Seraph Pharmaceuticals
	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 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:	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
34.	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)

Applicant firm	M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
Manufacturer firm	M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
Brand Name	Sulgen 1gm IM/IV Injection

	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 9446 dated 13-04-2022 Rs.75,000/- dated 17-03-2022
	The proposed proprietary name / brand name	**Cefsal 2gm IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…1000mg Sulbactam as Sodium…1000mg
	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	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	As per SRO
	For generic drugs (me-too status)	Sulperazone Intravenous Injection 2g (PMDA Japan Approved)
	Name and address of API manufacturer.	Cefbac injection by Seraph Pharmaceuticals
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: CEFCAR 2gm IM/IV Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
35.	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 9446 dated 13-04-2022 Rs.75,000/- dated 17-03-2022
	The proposed proprietary name / brand name	**Cefsal 1gm IV/IM 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	JP specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	As per SRO
	For generic drugs (me-too status)	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	Name and address of API manufacturer.	Cefbac injection by Seraph Pharmaceuticals
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad 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 Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan** Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: CEFCAR 1gm IM/IV Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Ceftriaxone Sodium

36.	Name, address of Applicant / Marketing Authorization Holder	**M/s Venus Pharma.** **23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies 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 & Details of fee submitted	Dy.No 17769 dated 14-07-2023 Rs.75,000/- dated 26-06-2023

	The proposed proprietary name / brand name	**Xinva 2gm IV Dry Powder For Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……2gm
	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)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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 Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 2gm IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
37.	Name, address of Applicant / Marketing Authorization Holder	**M/s Venus Pharma.** **23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies 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 & Details of fee submitted	Dy.No 17767 dated 14-07-2023 Rs.75,000/- dated 26-06-2023

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Xinva 250mg IM Dry Powder For Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Ceftriaxone (as sodium)……250mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Ceftriaxone powder for solution for injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Oxidil Injection of M/s Sami</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.</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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Brand Name</td><td>Genxone 250mg IM injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>38.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Venus Pharma.
23 km, Multan Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.
The GMP certificate specifies dry powder injection (cephalosporin) section.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) 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 17768 dated 14-07-2023 Rs.75,000/- dated 26-06-2023</td></tr>
</table>

	The proposed proprietary name / brand name	**Xinva 1gm IM Dry Powder For Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1gm
	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)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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 Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 1gm IM injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
39.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies 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 & Details of fee submitted	Dy.No 17748 dated 14-07-2023 Rs.75,000/- dated 14-04-2023

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cuxone 500mg IV Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Ceftriaxone (as sodium)……500mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Ceftriaxone powder for solution for injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Oxidil Injection of M/s Sami</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.</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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Brand Name</td><td>Genxone 5 IV injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>40.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Health Care Pharmaceuticals.
40-Km Lahore Road, Multan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.
The GMP certificate specifies dry powder injection (cephalosporin) section.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) 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 17746 dated 14-07-2023 Rs.75,000/- dated 14-04-2023</td></tr>
</table>

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cuxone 1gm IV Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Ceftriaxone (as sodium)……1gm</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Ceftriaxone powder for solution for injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Oxidil Injection of M/s Sami</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.</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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Brand Name</td><td>Genxone 1gm IV injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>41.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Health Care Pharmaceuticals.
40-Km Lahore Road, Multan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.
The GMP certificate specifies dry powder injection (cephalosporin) section.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) 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 17745 dated 14-07-2023 Rs.75,000/- dated 14-04-2023</td></tr>
</table>

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cuxone 1gm IM Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Ceftriaxone (as sodium)……1gm</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Ceftriaxone powder for solution for injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Oxidil Injection of M/s Sami</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.</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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Brand Name</td><td>Genxone 1gm IM injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>42.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Health Care Pharmaceuticals.
40-Km Lahore Road, Multan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.
The GMP certificate specifies dry powder injection (cephalosporin) section.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) 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 17747 dated 14-07-2023 Rs.75,000/- dated 14-04-2023</td></tr>
</table>

<table>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Cuxone 2gm IV Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Ceftriaxone (as sodium)……2gm</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Cephalosporin antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>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>Ceftriaxone powder for solution for injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Oxidil Injection of M/s Sami</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.</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 Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td>Brand Name</td><td>Genxone 2gm IV injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>43.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Health Care Pharmaceuticals.
40-Km Lahore Road, Multan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.
The GMP certificate specifies dry powder injection (cephalosporin) section.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) 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 17744 dated 14-07-2023 Rs.75,000/- dated 14-04-2023</td></tr>
</table>

	The proposed proprietary name / brand name	**Cuxone 500mg IM 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 & 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)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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 Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
Brand Name	Genxone 500mg IM injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
44.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies 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 & Details of fee submitted	Dy.No 17743 dated 14-07-2023 Rs.75,000/- dated 14-04-2023

	The proposed proprietary name / brand name	**Cuxone 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 & 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)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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 Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore. Manufacturer firm: M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore. Brand Name: Genxone 250mg IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
45.	Name, address of Applicant / Marketing Authorization Holder	**M/s Health Care Pharmaceuticals.** **40-Km Lahore Road, Multan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies 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 & Details of fee submitted	Dy.No 17742 dated 14-07-2023 Rs.75,000/- dated 14-04-2023

	The proposed proprietary name / brand name	**Cuxone 250mg IM 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 & 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)	Oxidil Injection of M/s Sami
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore 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 Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
Brand Name	Genxone 250mg IM injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
46.	Name, address of Applicant / Marketing Authorization Holder	**M/s Siam Pharmaceuticals.** **217, Industrial Triangle, Kahuta Road, 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 19523 dated 04-07-2022 Rs.75,000/- dated 28-06-2022
	The proposed proprietary name / brand name	**Sixone 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 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 2gm IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
47.	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 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 2gm IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
48.	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 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 12896 dated 26-05-2022 Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinecef 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1g
	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 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 1gm IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
49.	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 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 12893 dated 26-05-2022
	Details of fee submitted	Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinecef 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 250mg IV injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
50.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
51.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 12629 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unidon 250mg 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 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:	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
52.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 12626 dated 24-05-2022 Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unidon 250mg IM 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 & 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 have already been	

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 250 IV injection

	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 Siam Pharmaceuticals., Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad Manufacturer firm: M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Sixone 250mg IM injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
53.	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 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 12892 dated 26-05-2022 Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinecef 250mg IM 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 & 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 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 Siam Pharmaceuticals., Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad	

	Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	Sixone 250mg IM injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
54.	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 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 12895 dated 26-05-2022
	Details of fee submitted	Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinecef 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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
55.	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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
56.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 12629 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unidon 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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
57.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 12628 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 29-03-2022
	The proposed proprietary name / brand name	**Unidon 500mg IM 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 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 Siam Pharmaceuticals., Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad

	Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	Sixone 500mg IM injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
58.	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 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 12894 dated 26-05-2022
	Details of fee submitted	Rs.75,000/- dated 19-05-2022
	The proposed proprietary name / brand name	**Pinecef 500mg IM 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 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 Siam Pharmaceuticals., Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad

	Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	Sixone 500mg IM injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Citicoline

59.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Status of application	☐ New Drug Product (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 17603 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Wincit 1gm/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule Contains: Citicoline Sodium as Citicoline …… 1gm
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Psychostimulant and nootropic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved b AIFA of Italy
	For generic drugs (me-too status)	Citolin innjection by M/s Global Pharma Reg. No.030541
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore

	Brand Name	C-Coline 1gm/4ml Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Cholecalciferol

60.	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. 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
61.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
62.	Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	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 29090 dated 13-10-2022 Rs.75,000/- dated 19-08-2022
	The proposed proprietary name / brand name	**Univit Injection**
	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

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Colistimethate Sodium

63.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17772 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Colistat 150mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	

	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Colmate 4.5MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
64.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17771 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Colistat 68mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	Colmate 2MIU Injection		
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
65.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17770 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Colistat 34mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Brand Name	Colmate 1MIU Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
66.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17608 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 4.5 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore

	Brand Name	Colmate 4.5MIU Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
67.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17607 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 2 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Brand Name	Colmate 2MIU Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per	

	Que or as per the direction of DRAP Authority, which ever is earlier.	
68.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17606 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Colet 1 MIU Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Evaluation by PEC:	
	The applied product to be manufactured M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	Colmate 1MIU Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
69.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd.** **539-A, Sundar Industrial Estate,Raiwind,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	**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.
	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 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 17778 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 150mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
Manufacturer firm	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
Brand Name	Colizone 4.5MIU Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
70.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,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	**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.
	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 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 17777 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 68mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 2MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
71.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,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	**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.

	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 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 17776 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Choligene 34mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
72.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,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	**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.
	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 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 17724 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Cholisti 150mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 4.5MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
73.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,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	**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.
	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 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 17722 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Cholisti 68mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore. Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colizone 2MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
74.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,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	**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.
	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 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 17722 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Cholisti 34mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 34mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
75.	Name, address of Applicant / Marketing Authorization Holder	**M/s Kanel Pharma.** **Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad**
	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	**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.
	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 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 32812 dated 15-11-2022 Rs.75,000/- dated 23-05-2022
	The proposed proprietary name / brand name	**Colistime 1 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…1MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Macter International Limited. F-216, SITE, Karachi.** Manufacturer firm: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Brand Name: Colmit 1MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
76.	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 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 31676 dated 03-11-2022 Rs.75,000/- dated 14-10-2022
	The proposed proprietary name / brand name	**Hy-Colis 1 MIU Injection**
	Strength / concentration of drug of Active	Each Vial Contains: Colistimethate Sodium Eq. to 80mg of Sterile

	Pharmaceutical ingredient (API) per unit	Colistimethate Sodium…1MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R 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 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	Listim 1MIU Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
77.	Name, address of Applicant / Marketing Authorization Holder	**M/s Seraph Pharmaceuticals.** **Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad**
	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 22081 dated 03-08-2022 Rs.75,000/- dated 11-05-2022
	The proposed proprietary name / brand name	**Coliser 1 MIU IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……1 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic

<table>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</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>COLOMYCIN 1 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Colistimethate injection 1 MIU by Mukhtar Enterprises</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.</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 Biogen Life Scie nces8-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:
<table>
<tr><td>Applicant firm</td><td>M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi</td></tr>
<tr><td>Brand Name</td><td>Listim 1MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>78.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Seraph Pharmaceuticals.
Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Biogen Life Sciences.
8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder Injection section (General).</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 22080 dated 03-08-2022 Rs.75,000/- dated 11-05-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Coliser 2 MIU IV 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>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</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>COLOMYCIN 2 million International Units (IU) Injection (MHRA Approved)</td></tr>
</table>

	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises (Reg #094757)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R 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 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: Listim 2MIU Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
79.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	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.
	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 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. 17919 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Coliswim 150mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 150mg Colistimethate Base Activity
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 4.5 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	N/A

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang</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 English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colizone 4.5MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>80.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Wimits Pharmaceuticals (Pvt.) Ltd.
Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>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.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>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 general 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 17918 dated 14-07-2023 Rs.75,000/-</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Coliswim 68mg 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 Eq. to 68mg Colistimethate Base Activity</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</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>COLOMYCIN 2 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Colistimethate injection 2 MIU by Mukhtar Enterprises</td></tr>
</table>

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang</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 English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore 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:
<table>
<tr><td>Applicant firm</td><td>M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Colizone 2MIU Injection</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>81.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Wimits Pharmaceuticals (Pvt.) Ltd.
Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>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.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>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 general 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. 17917 dated 14-07-2023 Rs.75,000/-</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Coliswim 34mg 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 Eq. to 34mg Colistimethate Base Activity</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Sterile white to yellowish fine powder filled in transparent glass vials.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Antibiotic</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</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>COLOMYCIN 1 million International Units (IU) Injection (MHRA Approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Colistimethate injection 1 MIU by Mukhtar Enterprises</td></tr>
</table>

	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang
	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 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 Macter International Limited. F-216, SITE, Karachi.**
Manufacturer firm	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
Brand Name	Colmit 1MIU Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Dapagliflozin

82.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17753 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Dapag 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
83.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17813 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Dappa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17798 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Deffa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Manufacturer firm	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Brand Name	**DAPAZIN 5MG TABLET**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
85.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17793 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Daglo 5mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address：Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
86.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17823 dated 14-07-2023 Rs.75,000/
	The proposed proprietary name / brand name	**Dapego 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367

	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
87.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17715 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Dypa 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta have 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **DAPAZIN 5MG TABLET**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Dapagliflozin/Metformin

88.	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 CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s CCL Pharmaceuticals issued on the basis of inspection dated 30-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License (No. 000052) 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 & Details of fee submitted	Dy.No 17773 dated 14-07-2023 Rs.75,000/- dated 27-06-2023
	The proposed proprietary name / brand name	**Dapazin Met XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Bi-Layered Tablet Contains: Dapagliflozin Paropandediol Monohydrate Eq. to Dapagliflozin…10mg Metformin HCl…1000mg
	Pharmaceutical form of applied drug	Film coated double layer tablet
	Pharmacotherapeutic Group of (API)	Combination of oral blood glucose lowering drugs
	Reference to Finished product specifications	As per innovator's product
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Xiga-Met XR Tablet of CCL
	Name and address of API manufacturer.	Dapagliflozin: M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China. Metformin HCl: M/s Wanbury Limited., Doctor's Organic Chemical Division K Illindalaparru 534217

		Iragavaram Mandal West Godavari District Andhra Pradesh, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s CCL Pharmaceuticals (Pvt) Ltd 62-industrial Estate, Kot Lakhpat, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Manufacturer firm: M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore Brand Name: DAPAZIN MET XR 10mg/1000mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
89.	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 CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate of M/s CCL Pharmaceuticals issued on the basis of inspection dated 30-04-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of Drug Manufacturing License (No. 000052) 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 & Details of fee submitted	Dy.No 17774 dated 14-07-2023 Rs.75,000/- dated 27-06-2023
	The proposed proprietary name / brand name	**Dapazin Met XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Bi-Layered Tablet Contains: Dapagliflozin Paropandediol Monohydrate Eq. to Dapagliflozin…5mg Metformin HCl…1000mg
	Pharmaceutical form of applied drug	Film coated double layer tablet
	Pharmacotherapeutic Group of (API)	Combination of oral blood glucose lowering drugs
	Reference to Finished product specifications	As per innovator's product
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Xiga-Met XR Tablet of CCL
	Name and address of API manufacturer.	Dapagliflozin: M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China.

<table>
<tr><td></td><td></td><td>Metformin HCl: M/s Wanbury Limited., Doctor's Organic Chemical Division K Illindalaparru 534217 Iragavaram Mandal West Godavari District Andhra Pradesh, India.</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 CCL Pharmaceuticals (Pvt) Ltd 62-industrial Estate, Kot Lakhpat, Lahore 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:

<table>
<tr><td>Applicant firm</td><td>M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore</td></tr>
<tr><td>Manufacturer firm</td><td>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore</td></tr>
<tr><td>Brand Name</td><td>DAPAZIN MET XR 5mg/1000mg Tablet</td></tr>
</table>
</td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>90.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Indus Pharma (Pvt.) Ltd.
Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate of M/s CCL Pharmaceuticals issued on the basis of inspection dated 30-04-2019.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of renewal of Drug Manufacturing License (No. 000052) dated 08-06-2021 specifying Tablet (General) 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 17775 dated 14-07-2023 Rs.75,000/- dated 27-06-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Dapazin Met XR 5/500 mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each Film Coated Bi-Layered Tablet Contains:
Dapagliflozin Paropandediol Monohydrate Eq. to Dapagliflozin…5mg
Metformin HCl…500mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Film coated double layer tablet</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Combination of oral blood glucose lowering drugs</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>As per innovator's product</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>USFDA Approved</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Xiga-Met XR Tablet of CCL</td></tr>
</table>

	Name and address of API manufacturer.	Dapagliflozin: M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Flouride Industrial park, Fuxin City, Liaoning province, China. Metformin HCl: M/s Wanbury Limited., Doctor's Organic Chemical Division K Illindalaparru 534217 Iragavaram Mandal West Godavari District Andhra Pradesh, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s CCL Pharmaceuticals (Pvt) Ltd 62-industrial Estate, Kot Lakhpat, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Manufacturer firm: M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore Brand Name: DAPAZIN MET XR 5mg/500mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Drotaverine HCl

91.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Status of application	☐ New Drug Product (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 17602 dated 13-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tavar 40mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Drotaverine Hcl Eq. to Drotaverine…40mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antispasmodic, Anticholinergic
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Approved in 3 European countries (Hungary,

		Romania, Bulgaria)
	For generic drugs (me-too status)	No-spa 40mg/2ml by M/s Snofi pharma
	Name and address of API manufacturer.	M/s R.A Chem Pharma, Ltd India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Manufacturer firm: M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore Brand Name: Doviene 40mg/2ml injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Empagliflozin

92.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17717 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Emzaa 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Erli tablet of M/s Pharm Evo
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **EMPAZIN 5MG TABLET**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Empagliflozin/Metformin HCl

93.	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 Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021.
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021 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 35503 dated 07-12-2022 Rs.75,000/- dated 19-11-2022
	The proposed proprietary name / brand name	**Glifo-Met 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….12.5mg Metformin HCl……...500mg
	Pharmaceutical form of applied drug	Immediate release Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs used in diabetics (Combination of oral blood glucose lowering drugs)
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Synjardy (12.5/500mg) tablet, USFDA Approved.
	For generic drugs (me-too status)	Empagen 12.5/500 tablet by M/s Ferozsons.

	Name and address of API manufacturer.	**Empagliflozin:** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng west road, Anqing city, Anhui Province, 246000 China **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan road, Dongcheng Industrial Area, Shouguang city, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore, Multan Road, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Brand Name: Gliflo-Met 12.5/500mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
94.	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 Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021.
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021 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 35503 dated 07-12-2022 Rs.75,000/- dated 19-11-2022
	The proposed proprietary name / brand name	**Glifo-Met 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….12.5mg Metformin HCl……...1000mg
	Pharmaceutical form of applied drug	Immediate release Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs used in diabetics (Combination of oral blood glucose lowering drugs)

	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Synjardy (12.5/1000mg) tablet, USFDA Approved.
	For generic drugs (me-too status)	Empagen 12.5/1000 tablet by M/s Ferozsons.
	Name and address of API manufacturer.	**Empagliflozin:** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng west road, Anqing city, Anhui Province, 246000 China **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan road, Dongcheng Industrial Area, Shouguang city, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore, Multan Road, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Brand Name: Gliflo-Met 12.5/1000mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
95.	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 Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021.
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021 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 35501 dated 07-12-2022 Rs.75,000/- dated 19-11-2022
	The proposed proprietary name / brand name	**Glifo-Met 5/1000 mg Tablet**
	Strength / concentration of drug of Active	Each film coated tablet contains:

	Pharmaceutical ingredient (API) per unit	Empagliflozin…….5mg Metformin HCl……...1000mg
	Pharmaceutical form of applied drug	Immediate release Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs used in diabetics (Combination of oral blood glucose lowering drugs)
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Synjardy (5/1000mg) tablet, USFDA Approved.
	For generic drugs (me-too status)	Empagen 5/1000 tablet by M/s Ferozsons.
	Name and address of API manufacturer.	**Empagliflozin:** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng west road, Anqing city, Anhui Province, 246000 China **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan road, Dongcheng Industrial Area, Shouguang city, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore, Multan Road, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Manufacturer firm: M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore Brand Name: Gliflo-Met 5/1000mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
96.	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 Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	GMP status of the manufacturer	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021.
	Evidence of approval of manufacturing facility	Copy of GMP certificate No. 29/2021-DRAP(FID-2065251-174) issued on the basis of inspection conducted on 26/03/2021 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 35500 dated 07-12-2022 Rs.75,000/- dated 19-11-2022
	The proposed proprietary name / brand name	**Glifo-Met 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….5mg Metformin HCl……...500mg
	Pharmaceutical form of applied drug	Immediate release Film coated tablet
	Pharmacotherapeutic Group of (API)	Drugs used in diabetics (Combination of oral blood glucose lowering drugs)
	Reference to Finished product specifications	Innovator's
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Synjardy (5/500mg) tablet, USFDA Approved.
	For generic drugs (me-too status)	Empagen 5/500 tablet by M/s Ferozsons.
	Name and address of API manufacturer.	**Empagliflozin:** M/s Anhui Haikang Pharmaceutical Co., Ltd., No. 21 Huancheng west road, Anqing city, Anhui Province, 246000 China **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North East of Dongwaihuan road, Dongcheng Industrial Area, Shouguang city, Shandong Province, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore, Multan Road, Lahore 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 Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore
	Manufacturer firm	M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sunder Industrial Estate, Lahore
	Brand Name	Gliflo-Met 5/500mg tablet
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Esomeprazole Sodium

97.	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 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 15682 dated 21-06-2023 Rs.30,000/- dated 25-08-2022
	The proposed proprietary name / brand name	**Nexapt 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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
98.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	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 16715 dated 05-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Esolip 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
99.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	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 17754 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sar-Esom 40mg Powder for 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.	M/s Sterile India Pvt. Ltd Plot No.100, 118-G, Sector-56, Phase-IV, HSIIDC, 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 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	Epsol 40mg Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
100.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
101.	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 # 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 27897 dated 03-10-2022 Rs.75,000/- dated 26-09-2022
	The proposed proprietary name / brand name	**Esonext 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium……40mg
	Pharmaceutical form of applied drug	Almost white colored lyophilized, hygroscopic powder filled in glass vial.
	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	Nexium IV 40mg Injection of M/s AstraZeneca (USFDA approved)
	For generic drugs (me-too status)	Esomine 40mg Injection Lawari International (R# 069703)
	Name and address of API manufacturer.	M/s. 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 Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 3th17 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 # 20, Phase 4, Hattar Industrial Estate, Hattar KPK from M/s Bio-Labs (Pvt) Ltd Manufacturer firm: M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Esocare 40mg Injection • The composition shall mention "Each Lyophilized Vial contains" since manufacturer had approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
102.	Name, address of Applicant / Marketing Authorization Holder	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	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 13055 dated 28-05-2022 Rs.75,000/- dated 13-04-2022
	The proposed proprietary name / brand name	**Esorok 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium……40mg
	Pharmaceutical form of applied drug	Almost white colored lyophilized, hygroscopic powder filled in glass vial.
	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	Nexium IV 40mg Injection of M/s AstraZeneca (USFDA approved)
	For generic drugs (me-too status)	Esomine 40mg Injection Lawari International (R# 069703)
	Name and address of API manufacturer.	M/s. 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 Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 3th17 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 # 20, Phase 4, Hattar Industrial Estate, Hattar KPK from M/s Bio-Labs (Pvt) Ltd Manufacturer firm: M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Esocare 40mg Injection • The composition shall mention "Each Lyophilized Vial contains" since manufacturer had approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
103.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linear Pharma** **Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, islamabad**
	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 11100 dated 07-05-2022 Rs.75,000/- dated 30-03-2022
	The proposed proprietary name / brand name	**So-Zar 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole as sodium……40mg

<table>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Almost white colored lyophilized, hygroscopic powder filled in glass vial.</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Proton pump inhibitor</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>Innovator’s Specification</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>Nexium IV 40mg Injection of M/s AstraZeneca (USFDA approved)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Esomine 40mg Injection Lawari International (R# 069703)</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>M/s. Sterile India Pvt. Ltd. Plot No. 100, Sec-56 Phase -4, Kundli Sonipat (Haryana) India</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 Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad have already been approved by Registration Board in its 3th17 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 Cherwel Pharmaceuticals (Pvt) Ltd. plot # 20, Phase 4, Hattar Industrial Estate, Hattar KPK from M/s Bio-Labs (Pvt) Ltd</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Bio Labs Pvt Ltd.
Plot # 145, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Brand Name</td><td>Esocare 40mg Injection</td></tr>
</table>
The composition shall mention “Each Lyophilized Vial contains” since manufacturer had approval of applied formulation in “Lyophilized vial (Injectable) general section.</td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>104.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Venus Pharma.
23 km, Multan Road, Lahore</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Variant pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharmazone, 26 Km, Lahore Sharikpur Road, Sheikhupura.</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>The firm was granted New DML (000914) on the recommendations of CLB in its 273rd meeting held on 15th January, 2020</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>The firm has provided Dry powder injection section (pre-lyophilized) vial section (General) vide letter No. F. 1-1/2016-Lic of licensing division.</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 18957 dated 29-06-2022 Rs.75,000/- dated 16-02-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Eseft 40mg IV Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Esomeprazole as sodium ------- 40 mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Powder for injection/infusion (Pre-Lyophilized)</td></tr>
</table>

	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
105.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
106.	Name, address of Applicant / Marketing Authorization Holder	**M/s Biogen Pharma.** **8-Km, Chakbeli Road, Rawat, Rawalpindi, 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 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 29847 dated 21-10-2022 Rs.75,000/- dated 11-05-2022
	The proposed proprietary name / brand name	**Bioom 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
107.	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 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 27909 dated 03-10-2022 Rs.75,000/- dated 11-05-2022
	The proposed proprietary name / brand name	**Esoa 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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
108.	Name, address of Applicant / Marketing Authorization Holder	**M/s Valor Pharmaceuticals.** **124/A Industrial Triangle, Kahuta Road Islamabad**
	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 17600 dated 16-06-2022 Rs.75,000/- dated 13-05-2022
	The proposed proprietary name / brand name	**Oxilant 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
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
	Name, address of Applicant / Marketing	**M/s Well & Well Pharma Pvt Ltd.**

<table>
<tr><td rowspan="15">109.</td><td>Authorization Holder</td><td>Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Vision Pharmaceuticals.
Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>GMP status of the manufacturer</td><td>GMP certificate issued based upon inspection conducted in 26-01-2018.</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>GMP certificate issued based upon inspection conducted in 26-01-2018 declares Dry powder injection general section</td></tr>
<tr><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 35753 dated 05-12-2022 Rs.75,000/- dated 16-11-2022</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Emple 40mg Injection</td></tr>
<tr><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial of powder for solution for infusion contains Esomeprazole sodium, equivalent to 40 mg Esomeprazole.</td></tr>
<tr><td>Pharmaceutical form of applied drug</td><td>Powder for injection/infusion (Pre-Lyophilized)</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Proton Pump inhibitor</td></tr>
<tr><td>Reference to Finished product specifications</td><td>Innovator’s Specification</td></tr>
<tr><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Esomeprazole 40mg Powder for Solution for Infusion (MHRA)</td></tr>
<tr><td>For generic drugs (me-too status)</td><td>Nexium 40 mg IV injection
By M/S Getz Pharma</td></tr>
<tr><td>Name and address of API manufacturer.</td><td>M/s Vision Pharmaceuticals.
Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td colspan="2">The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad 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:
<table>
<tr><td>Applicant firm</td><td>M/s Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
<tr><td>Brand Name</td><td>Esonag 40mg IV Injection</td></tr>
</table></td></tr>
<tr><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td rowspan="2">110.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Pharma Lord (Pvt) Ltd.
12 KM, Lahore Raod, Layyah, Punjab</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Vision Pharmaceuticals.
Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</td></tr>
</table>

	GMP status of the manufacturer	GMP certificate issued based upon inspection conducted in 26-01-2018.
	Evidence of approval of manufacturing facility	GMP certificate issued based upon inspection conducted in 26-01-2018 declares Dry powder injection 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 19738 dated 06-07-2022 Rs.75,000/- dated 27-06-2022
	The proposed proprietary name / brand name	**Esolor 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder for solution for infusion contains Esomeprazole sodium, equivalent to 40 mg Esomeprazole.
	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	Esomeprazole 40mg Powder for Solution for Infusion (MHRA)
	For generic drugs (me-too status)	Nexium 40 mg IV injection By M/S Getz Pharma
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad 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 Nagarsons Pharmaceuticals (Pvt) Ltd., Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad Manufacturer firm: M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Brand Name: Esonag 40mg IV Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
111.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s 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 17915 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Aldis 40mg Powder for 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.	M/s Sterile India Pvt. Ltd Plot No.100, 118-G, Sector-56, Phase-IV, HSIIDC, 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 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: Epsol 40mg Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

<u>Esomeprazole/Naproxen</u>

112.	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 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 17698 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Ezonpp 375/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
113.	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 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 17795 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Eznop 500/20 mg DR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
114.	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 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 17794 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Esonap 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

115.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s 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 17830 dated 14-07-2023 Rs.75,000/
	The proposed proprietary name / brand name	**Esonap 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
116.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s 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 17829 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Esonap 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
117.	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 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 17822 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esonepp 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
118.	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 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 17821 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esonepp 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
119.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	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 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Zonepp 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
120.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	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 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Zonepp 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
121.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	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 17706 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esopenn DR 20/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
122.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	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 17705 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esopenn DR 20/375 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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:	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
123.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, 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 17610 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Esoncar DR 20/500 mg Table**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Esomeprazole (as magnesium trihydrate) as IR ……

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

		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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
124.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, 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 17609 dated 13-07-2023 Rs.75,000/- dated 11-07-2023

	The proposed proprietary name / brand name	**Esoncar DR 20/375 mg Table**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
125.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
126.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
127.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
128.	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 35681 dated 08-12-2022 Rs.75,000/- dated 17-10-2022
	The proposed proprietary name / brand name	**NapoEs 375/20 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 …….. 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Hydrocortisone Sodium Succinate

129.	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
	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 37072 dated 20-12-2022
	Details of fee submitted	Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Icurt 500mg 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

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
130.	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
	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 37075 dated 20-12-2022
	Details of fee submitted	Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Icurt 100mg injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 100 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 100 mg Injection** **Note: The title of the manufacturer was changed to M/s Biogen Life Sciences 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
131.	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
	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 37075 dated 20-12-2022
	Details of fee submitted	Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Icurt 250mg 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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
132.	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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
133.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Ibuprofen

134.	Name, address of Applicant / Marketing Authorization Holder	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	GMP Certificate issued on the basis of GMP inspection conducted on 11-02-2019
	Evidence of approval of manufacturing facility	GMP Certificate issued on the basis of GMP inspection conducted on 11-02-2019, 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 39365 dated 29-12-2022 Rs.75,000/- dated 12-12-2022
	The proposed proprietary name / brand name	**Calador 400mg/100ml IV Infusion**
	Strength / concentration of drug of Active	Each 100ml contains:

	Pharmaceutical ingredient (API) per unit	Ibuprofen.....400mg
	Pharmaceutical form of applied drug	Solution for IV Infusion
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's Specificatons
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Ibuprofen 400mgl100ml Solution of Infusion by B.Braun Melsungen AG-Germany approved by MHRA
	For generic drugs (me-too status)	Inbufin 400mg/100ml Infusion by Searl IV Solutions (R#094023)
	Name and address of API manufacturer.	Hubei Granules-Biocause Pharmaceutical Co., Ltd, 22 Yangwan Road, Jingmen City, Hubei Province 448000, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad **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 Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Manufacturer firm	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	Calador 400mg/100ml IV Infusion

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Imipenem Monohydrate/Cilastatin Sodium

135.	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
	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 23.12.2021
	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 & Details of fee submitted	Dy.No 17801 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Imastin 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate…500mg Cilastatin as Sodium…500mg

	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore 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 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: Nemcil 500mg/5000mg injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
136.	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
	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 23.12.2021
	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 & Details of fee submitted	Dy.No 17800 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Imastin 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).....250mg Cilastatin (as sodium).....250mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi

	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore 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 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: Nemcil 250mg/250mg injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
137.	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
	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 23.12.2021
	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 & Details of fee submitted	Dy.No 17712 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Imsetin 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate…500mg Cilastatin as Sodium…500mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore 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 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: Nemcil 500mg/5000mg injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
138.	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
	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 23.12.2021
	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 & Details of fee submitted	Dy.No 17711 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Imsetin 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……250mg Cilastatin (as sodium)……250mg
	Pharmaceutical form of applied drug	Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wallace Pharma Evolution Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore 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 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: Nemcil 250mg/250mg injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
139.	Name, address of Applicant / Marketing Authorization Holder	**M/s Harmann Pharmaceutical Laboratories Pvt Ltd.** **16 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	**Global pharmaceuticals:** 11 & 24-10-2018: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (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 22377 dated 05-08-2022 Rs.75,000/- dated 05-07-2022
	The proposed proprietary name / brand name	**Xienam 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……500mg Cilastatin (as sodium)…….500mg
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Onem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: CILSNIM 500mg Injection IV	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
140.	Name, address of Applicant / Marketing Authorization Holder	**M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	**Global pharmaceuticals:** 11 & 24-10-2018: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (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 18760 dated 28-06-2022 Rs.75,000/- dated 07-09-2021
	The proposed proprietary name / brand name	**Imicil 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……500mg Cilastatin (as sodium)…….500mg
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Onem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: CILSNIM 500mg Injection IV
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Ferric Carboxymaltose

141.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries. 17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	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 17757 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarferric 500mg/10ml 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
142.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,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	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 17708 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Haem 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
143.	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

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Isotretinoin

144.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha 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 17752 dated 14-07-2023 Rs.75,000/- dated 07-07-2023
	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
145.	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 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: The Board noted the information and decided to consider the application on its turn as per	

	Que or as per the direction of DRAP Authority, which ever is earlier.	
146.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
147.	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 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
148.	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 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 27907 dated 03-10-2022 Rs.75,000/- dated 14-10-2022
	The proposed proprietary name / brand name	**Isonide 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
149.	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 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 29757 dated 20-10-2022 Rs.75,000/- dated 08-06-2022
	The proposed proprietary name / brand name	**Tretiwan 20mg Softgel 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
150.	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 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 27910 dated 03-10-2022 Rs.75,000/- dated 08-06-2022
	The proposed proprietary name / brand name	**Tretiwan 10mg Softgel Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…10mg
	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 10 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 Sciences 8-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 10mg Capsule

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
151.	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 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 27908 dated 03-10-2022 Rs.75,000/- dated 14-10-2022
	The proposed proprietary name / brand name	**Isonide 10mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Softgel Capsule Contains: Isotretinoin…10mg
	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 10 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 10mg Capsule
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Lefamulin

152.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 17784 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Lefaa 600mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lefamulin as Acetate……..600mg
	Pharmaceutical form of applied drug	Antibacterial
	Pharmacotherapeutic Group of (API)	Immediate release film coated tablet
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Xenelta 600mg tablet, USFDA Approved.
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Kaifeng Pharmaceutical (Group) Company Limited, No. 1, Yunan street, Kaifeng Henan, Province, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore 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 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	**Lefazon tablet 600mg**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Megesterol Acetate

153.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila 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	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17808 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Jestro 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	

The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista 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 Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Brand Name	Mygest 160mg Tablet

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

154.

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 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	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
Dy. No. and date of submission & Details of fee submitted	Dy.No 17815 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
The proposed proprietary name / brand name	**Myggo 160mg Tablet**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
Reference to Finished product specifications	USP
Proposed Pack size & Unit price	As per SRO
The status in reference regulatory authorities	MHRA Approved.
For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China

Evaluation by PEC:

The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista 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 Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Brand Name	Mygest 160mg Tablet

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

<table>
<tr><td>155.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Welwrd Pharmaceuticals.
Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17696 dated 14-07-2023 Rs.75,000/- dated 13-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Majest 160mg Tablet</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each tablet contains:
Megestrol Acetate …….160mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Tablet</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Hormone related agent. (L02AB01)</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</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>MHRA Approved.</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China</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 WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista 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:
<table>
<tr><td>Applicant firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.</td></tr>
<tr><td>Brand Name</td><td>Mygest 160mg Tablet</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>156.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Welmark Pharmaceuticals.
Plot #122 Phase 5, Block B, Industrial Hattar</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Wnsfeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>GMP inspection conducted on 10/12/2020</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)</td></tr>
<tr><td></td><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17707 dated 14-07-2023 Rs.75,000/- dated 12-07-2023</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Mygeso 160mg Tablet</td></tr>
</table>

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista 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 Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Brand Name	Mygest 160mg Tablet

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
157.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	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	Tablet (steroidal hormonal) section is approved dated 18.01.2019 vide letter no. F.3-2/2006-Lic (Vol-II)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17693 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Mestrol 160mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Megestrol Acetate …….160mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Hormone related agent. (L02AB01)
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Progace 160mg tablet by M/s Medinet Pharmaceuticals, Rwp

	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bioproduct Co. Ltd. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakista 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 Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Manufacturer firm	M/s WnsFeild Pharmaceutical Plot No. 122, Block-A, Phase V, Industrial Estate Hattar KPK Pakistan.
Brand Name	Mygest 160mg Tablet

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Meropenem

158.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s 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 manufacturer	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 (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 17579 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Merop 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
159.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s 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 manufacturer	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 (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 17578dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Merop 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura
	Manufacturer firm	M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Brand Name	**RONEM 1gm Injection IV**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
160.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila 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 17811 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Nopem 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
161.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila 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 17812 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Nopem 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
162.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s 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 17825 dated 14-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Myrona 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
163.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s 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 17826 dated 14-07-2023
	Details of fee submitted	Rs.75,000/-
	The proposed proprietary name / brand name	**Myrona1gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
164.	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 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 17713 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 10-07-2023
	The proposed proprietary name / brand name	**Mopina 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
165.	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 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 17714 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 10-07-2023
	The proposed proprietary name / brand name	**Mopina 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
166.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s 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 7084 dated 10-03-2023
	Details of fee submitted	Rs.75,000/- dated 07-07-2023
	The proposed proprietary name / brand name	**Meprox 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
167.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	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 17702 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 24-02-2023

	The proposed proprietary name / brand name	**Meprox 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
168.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company Plot No. 340 Multan Industrial Estate Multan**
	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 25828 dated 13-09-2022
	Details of fee submitted	Rs.75,000/- dated 16-06-2022
	The proposed proprietary name / brand name	**Merobiz 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.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
169.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company Plot No. 340 Multan Industrial Estate Multan**
	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 25827 dated 13-09-2022
	Details of fee submitted	Rs.75,000/- dated 16-06-2022
	The proposed proprietary name / brand name	**Merobiz 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 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
170.	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 7084 dated 10-03-2023
	Details of fee submitted	Rs.75,000/- dated 24-02-2023
	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
171.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
172.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
173.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
174.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
175.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
176.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road

		Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13515 dated 31-05-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Fropen 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	**MEPEN 500 mg Injection IV**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
177.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 35351 dated 06-12-202
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Aeropen 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
178.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	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 35352 dated 06-12-202
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Aeropen 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

<table>
<tr><td></td><td></td><td>Development Zone, Hebei Province PR. China.</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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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:
<table>
<tr><td>Applicant firm</td><td>M/s Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi</td></tr>
<tr><td>Manufacturer firm</td><td>M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.</td></tr>
<tr><td>Brand Name</td><td>MEPEN 500 mg Injection IV</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>179.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Pharmedic Laboratories Pvt Ltd.
16-km, Multan Road Lahore, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td>M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.</td></tr>
<tr><td></td><td>Status of the applicant</td><td>☐ Manufacturer
☐ Importer
☒ Is involved in none of the above (contract giver)</td></tr>
<tr><td></td><td>GMP status of the manufacturer</td><td>Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.</td></tr>
<tr><td></td><td>Evidence of approval of manufacturing facility</td><td>Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)</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</td><td>Dy.No 30767 dated 31-10-2022</td></tr>
<tr><td></td><td>Details of fee submitted</td><td>Rs.75,000/- dated 05-08-2022</td></tr>
<tr><td></td><td>The proposed proprietary name / brand name</td><td>Meronac 500mg IV Injection</td></tr>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Meropenem (as trihydrate)……500mg
(blended with sodium carbonate)</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>White or almost white, hygroscopic, crystalline, powder filled in clear glass vials</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Carbapenem antibiotic</td></tr>
</table>

	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
180.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	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 30768 dated 31-10-2022
	Details of fee submitted	Rs.75,000/- dated 05-08-2022
	The proposed proprietary name / brand name	**Meronac 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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	**MEPEN 500 mg Injection IV**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
181.	Name, address of Applicant / Marketing Authorization Holder	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29095 dated 13-10-2022

	Details of fee submitted	Rs.75,000/- dated 11-08-2022
	The proposed proprietary name / brand name	**Hipem 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
182.	Name, address of Applicant / Marketing Authorization Holder	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	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 29096 dated 13-10-2022
	Details of fee submitted	Rs.75,000/- dated 11-08-2022
	The proposed proprietary name / brand name	**Hipemc1gm 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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	**MEPEN 500 mg Injection IV**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
183.	Name, address of Applicant / Marketing Authorization Holder	**M/s Harmann Pharmaceutical Laboratories Pvt Ltd.** **16 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying

		reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18579 dated 27-06-2022
	Details of fee submitted	Rs.75,000/- dated 15-06-2022
	The proposed proprietary name / brand name	**Mero-X 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
184.	Name, address of Applicant / Marketing Authorization Holder	**M/s Martin Dow Marker Limited.** **7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	GMP status of the manufacturer	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 18580 dated 27-06-2022
	Details of fee submitted	Rs.75,000/- dated 15-06-2022
	The proposed proprietary name / brand name	**Mero-X 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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	**MEPEN 500 mg Injection IV**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
185.	Name, address of Applicant / Marketing Authorization Holder	**M/s Martin Dow Marker Limited.** **7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13220 dated 30-05-2022
	Details of fee submitted	Rs.75,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Meropen 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	**MEPEN 500 mg Injection IV**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
186.	Name, address of Applicant / Marketing	**M/s Martin Dow Marker Limited.**

	Authorization Holder	**7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	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 13221 dated 30-05-2022
	Details of fee submitted	Rs.75,000/- dated 12-05-2022
	The proposed proprietary name / brand name	**Meropen 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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi
	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	**MEPEN 500 mg Injection IV**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

187.	Name, address of Applicant / Marketing Authorization Holder	**M/s Faas Pharmaceuticals (Pvt.) Ltd.** **F-748/L, S.I.T.E Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022 issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 12621 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 20-01-2022
	The proposed proprietary name / brand name	**Parem 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.	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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
188.	Name, address of Applicant / Marketing Authorization Holder	**M/s Faas Pharmaceuticals (Pvt.) Ltd.** **F-748/L, S.I.T.E Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	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 12622 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 20-01-2022
	The proposed proprietary name / brand name	**Parem 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 Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad 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 Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi Manufacturer firm: M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. Brand Name: **MEPEN 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
189.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
190.	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 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 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
191.	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 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 30452 dated 27-10-2022
	Details of fee submitted	Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Merofit 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
192.	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 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 30451 dated 27-10-2022
	Details of fee submitted	Rs.75,000/- dated 02-09-2022
	The proposed proprietary name / brand name	**Merofit 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 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 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
193.	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 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 12608 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 27-04-2022
	The proposed proprietary name / brand name	**Meron 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
194.	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 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 12609 dated 24-05-2022
	Details of fee submitted	Rs.75,000/- dated 27-04-2022
	The proposed proprietary name / brand name	**Meron 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 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 1gm Injection IV**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
195.	Name, address of Applicant / Marketing Authorization Holder	**M/s May & Baker (Pvt) Ltd.** **45-km Dina Nath, Multan 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 manufacturer	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 (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 34706 dated 30-11-2022
	Details of fee submitted	Rs.75,000/- dated 21-11-2022
	The proposed proprietary name / brand name	**Pynum 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
196.	Name, address of Applicant / Marketing Authorization Holder	**M/s May & Baker (Pvt) Ltd.** **45-km Dina Nath, Multan 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 manufacturer	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 (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 8438 dated 31-03-2022
	Details of fee submitted	Rs.75,000/- dated 22-02-2022
	The proposed proprietary name / brand name	**Pynum 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
197.	Name, address of Applicant / Marketing Authorization Holder	**M/s Safe Pharmaceuticals Pvt Ltd.** **Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	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 manufacturer	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 (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 26117 dated 15-09-2022
	Details of fee submitted	Rs.75,000/- dated 06-09-2022
	The proposed proprietary name / brand name	**Safepenem 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
198.	Name, address of Applicant / Marketing Authorization Holder	**M/s Mapel Pharmaceuticals Pvt Ltd. Plot No. 147, Sector 23, Korangi Indusrial Area, Karachi, Pakistan**
	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 manufacturer	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 (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 26118 dated 15-09-2022
	Details of fee submitted	Rs.75,000/- dated 06-09-2022
	The proposed proprietary name / brand name	**Safepenem 1G Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1gmmg (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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
199.	Name, address of Applicant / Marketing Authorization Holder	**M/s Mapel Pharmaceuticals Pvt Ltd. Plot No. 147, Sector 23, Korangi Indusrial Area, Karachi, Pakistan**
	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 manufacturer	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 (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 8437 dated 31-03-2022
	Details of fee submitted	Rs.75,000/- dated 22-02-2022
	The proposed proprietary name / brand name	**Meromap 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 500 mg Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
200.	Name, address of Applicant / Marketing Authorization Holder	**M/s Mapel Pharmaceuticals Pvt Ltd. Plot No. 147, Sector 23, Korangi Indusrial Area, Karachi, Pakistan**
	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 manufacturer	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 (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 8438 dated 31-03-2022
	Details of fee submitted	Rs.75,000/- dated 22-02-2022
	The proposed proprietary name / brand name	**Meromap 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 Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad 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 McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Manufacturer firm: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad Brand Name: **RONEM 1gm Injection IV**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
201.	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**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
202.	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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
203.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nawan Laboratories (Pvt) Ltd.** **136 sector 15 Korangi Industrial Area Karachi.**
	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 18008 dated 21-06-2022
	Details of fee submitted	Rs.75,000/- dated 23-05-2022
	The proposed proprietary name / brand name	**Merotyl 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**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
204.	Name, address of Applicant / Marketing Authorization Holder	**M/s Nawan Laboratories (Pvt) Ltd.** **136 sector 15 Korangi Industrial Area Karachi.**
	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 18009 dated 21-06-2022
	Details of fee submitted	Rs.75,000/- dated 23-05-2022
	The proposed proprietary name / brand name	**Merotyl 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 1gm Injection IV

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
205.	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-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 12518 dated 23-05-2022
	Details of fee submitted	Rs.75,000/- dated 19-04-2022
	The proposed proprietary name / brand name	**Avepenam 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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
206.	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-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 12519 dated 23-05-2022
	Details of fee submitted	Rs.75,000/- dated 05-01-2022
	The proposed proprietary name / brand name	**Avepenam 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

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
207.	Name, address of Applicant / Marketing Authorization Holder	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	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 11098 dated 07-05-2022
	Details of fee submitted	Rs.75,000/- dated 13-04-2022
	The proposed proprietary name / brand name	**Meroposh 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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
208.	Name, address of Applicant / Marketing Authorization Holder	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	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 12520 dated 23-05-2022
	Details of fee submitted	Rs.75,000/- dated 13-04-2022
	The proposed proprietary name / brand name	**Meroposh 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
209.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, islamabad**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the 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 10392 dated 23-04-2022
	Details of fee submitted	Rs.75,000/- dated 30-03-2022
	The proposed proprietary name / brand name	**Nibac 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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
210.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, islamabad**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the 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 10623 dated 23-04-2022
	Details of fee submitted	Rs.75,000/- dated 30-03-2022
	The proposed proprietary name / brand name	**Meripan 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 1gm Injection IV
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
211.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industral Estate, Hattar**
	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 10397 dated 23-04-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021
	The proposed proprietary name / brand name	**Menepor 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**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
212.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industral Estate, Hattar**
	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 10398 dated 23-04-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021
	The proposed proprietary name / brand name	**Menepor 1g 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
213.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company Plot No. 340 Multan Industrial Estate Multan**
	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 8920 dated 07-04-2022
	Details of fee submitted	Rs.75,000/- dated 05-01-2022
	The proposed proprietary name / brand name	**Meripan 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**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
214.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company Plot No. 340 Multan Industrial Estate Multan**
	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 8921 dated 07-04-2022
	Details of fee submitted	Rs.75,000/- dated 05-01-2022
	The proposed proprietary name / brand name	**Meripan 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	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Nalbuphine HCl

215.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
216.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Omeprazole

217.	Name, address of Applicant / Marketing Authorization Holder	M/s Onyx Pharmaceuticals30-A, Industrial Estate Mansehra
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020 declares availability of Capsule general setion.
	Status of application	☐ New Drug Product (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 13521 dated 31-05-2023 Rs.75,000/- dated 04-05-2023
	The proposed proprietary name / brand name	**Ozonex 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Omeprazole (as enteric coated pellets)...20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Risek capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 019364
	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 Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore 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 Sapient Pharma, 123/S, 104/S, Industrial area Kot Lakhpat, Lahore.
Manufacturer firm	M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore
Brand Name	Gosoft 20mg capsule

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Omeprazole Sodium

218.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	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 16625 dated 04-07-2023 Rs.75,000/- dated 16-03-2023
	The proposed proprietary name / brand name	**Omelip 40gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
219.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	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 17755 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sar-Omep 40mg Powder for 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
220.	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 approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
221.	Name, address of Applicant / Marketing Authorization Holder	**M/s Linear Pharma** **Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, islamabad**
	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 11101 dated 07-05-2022 Rs.75,000/- dated 30-03-2022
	The proposed proprietary name / brand name	**Ozar 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: • The composition shall mention "Each Lyophilized Vial contains" since manufacturer had approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
222.	Name, address of Applicant / Marketing Authorization Holder	**M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan**
	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 9443 dated 13-04-2022 Rs.75,000/- dated 27-10-2021
	The proposed proprietary name / brand name	**Nomizil 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

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	

		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 approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
223.	Name, address of Applicant / Marketing Authorization Holder	**M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi**
	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 8919 dated 07-04-2022 Rs.75,000/- dated 20-09-2021
	The proposed proprietary name / brand name	**Vrochi 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 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 approval of applied formulation in "Lyophilized vial (Injectable) general section.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
224.	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 1368 dated 16-01-2023 Rs.75,000/- dated 15-12-2022
	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
225.	Name, address of Applicant / Marketing Authorization Holder	**M/s Valor Pharmaceuticals.** **124/A Industrial Triangle, Kahuta Road Islamabad**
	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 17601 dated 16-06-2022 Rs.75,000/- dated 13-05-2022
	The proposed proprietary name / brand name	**Omepraval IV 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.	Rajasthan Antibiotics Ltd. A-619 & 630, Phase-I, RIICO Ind. Area Bhiwadi, Distr. Alwar (Rajasthan) India.
	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: Reflex 40mg Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
226.	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 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 14078 dated 10-06-2022 Rs.75,000/- dated 11-05-2022
	The proposed proprietary name / brand name	**O-wan 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.	Rajasthan Antibiotics Ltd. A-619 & 630, Phase-I, RIICO Ind. Area Bhiwadi, Distr. Alwar (Rajasthan) India.
	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	Reflex 40mg Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
227.	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
	GMP status of the manufacturer	GMP certificate issued based upon inspection conducted in 26-01-2018.
	Evidence of approval of manufacturing facility	GMP certificate issued based upon inspection conducted in 26-01-2018 declares Dry powder injection 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 34693 dated 30-11-2022 Rs.75,000/- dated 23-11-2022
	The proposed proprietary name / brand name	**Sante 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder for solution for infusion contains Omeprazole sodium, equivalent to 40 mg Omeprazole.
	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. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, 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 Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad
	Manufacturer firm	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name	G-Cid 40mg IV Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
228.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharma Lord (Pvt) Ltd.** **12 KM, Lahore Raod, Layyah, Punjab**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	GMP certificate issued based upon inspection conducted in 26-01-2018.
	Evidence of approval of manufacturing facility	GMP certificate issued based upon inspection conducted in 26-01-2018 declares Dry powder injection 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 19737 dated 06-07-2022 Rs.75,000/- dated 27-06-2022
	The proposed proprietary name / brand name	**Omelor 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder for solution for infusion contains Omeprazole sodium, equivalent to 40 mg Omeprazole.
	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. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, 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 Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad
	Manufacturer firm	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name	G-Cid 40mg IV Injection
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
	Name, address of Applicant / Marketing	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.**

<table>
<tr><td rowspan="15">229.</td><td>Authorization Holder</td><td>Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s English Pharmaceuticals Industries.
Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>GMP status of the manufacturer</td><td>M/s English Pharmaceuticals: Certificate of GMP Issued to English Pharmaceuticals on 16-01-2018.</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>M/s English Pharmaceuticals: The firm has provided Dry powder injection vials (General) approval.</td></tr>
<tr><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17916 dated 14-07-2023 Rs.75,000/-</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Oray 40mg Powder for Injection</td></tr>
<tr><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Omeprazole as sodium ------- 40 mg</td></tr>
<tr><td>Pharmaceutical form of applied drug</td><td>Powder for injection/infusion (Pre-Lyophilized)</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Proton Pump inhibitor</td></tr>
<tr><td>Reference to Finished product specifications</td><td>Innovator’s Specification</td></tr>
<tr><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Omeprazole 40mg Powder for Solution for Infusion (MHRA)</td></tr>
<tr><td>For generic drugs (me-too status)</td><td>Risek 40 mg IV injection
By M/S Getz Pharma</td></tr>
<tr><td>Name and address of API manufacturer.</td><td>M/s Vision Pharmaceuticals (Pvt) Ltd.
Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.</td></tr>
<tr><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td colspan="2">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:
<table>
<tr><td>Applicant firm</td><td>M/s Pharmedic laboratories., 15-16 Km, Multan Road Lahore.</td></tr>
<tr><td>Manufacturer firm</td><td>M/s English Pharmaceuticals.
Indus Link Kattar Band Road, Thokar Niaz Baig, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Nilcid 40mg Injection</td></tr>
</table></td></tr>
<tr><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td rowspan="2">230.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Well & Well Pharma Pvt Ltd.
Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s Vision Pharmaceuticals.
Plot # 22,23, Industrial Triangle, Kahuta Road,</td></tr>
</table>

		Islamabad
	GMP status of the manufacturer	GMP certificate issued based upon inspection conducted in 26-01-2018.
	Evidence of approval of manufacturing facility	GMP certificate issued based upon inspection conducted in 26-01-2018 declares Dry powder injection 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 35752 dated 05-12-2022 Rs.75,000/- dated 16-11-2022
	The proposed proprietary name / brand name	**Omrel 40mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder for solution for infusion contains Omeprazole sodium, equivalent to 40 mg Omeprazole.
	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. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, 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 Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad Manufacturer firm: M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad Brand Name: G-Cid 40mg IV Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Omeprazole/Sodium bicarbonate

231.	Name, address of Applicant / Marketing Authorization Holder	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore

	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020 declares availability of sachet general setion.
	Status of application	☐ New Drug Product (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 25242 dated 06-09-2022 Rs.75,000/- dated 23-05-2022
	The proposed proprietary name / brand name	**Shalay 40mg/1680mg 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 sachet
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Zegerid® Immediate release Powder for oral suspension of M/s Santarus is USFDA Approved
	For generic drugs (me-too status)	Mep-Insta Sachet 40mg/1680mg of M/s Bio-Mark Pharmaceuticals
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited. Regd. Office & factory: Aroor Village, Sadasivpet Mandal, Sangareddy Dist. Telangana **Sodium Bicarbonate:** M/s TATA Chemicals Europe Ltd., Mond House, Winnington Lane, Northwich Cheshire, CW84DT, United Kingdom
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore 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. Plot No 65-Quaid-e-Azam Industrial Estate Kot lakhpat,Lahore. Manufacturer firm: M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore Brand Name: Faast 40mg/1680mg Sachet for oral suspension.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
232.	Name, address of Applicant / Marketing Authorization Holder	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore

	GMP status of the manufacturer	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020
	Evidence of approval of manufacturing facility	cGMP certificate of M/s Bio-Mark issued based upon Evaluation conducted on 13-02-2020 declares availability of sachet general setion.
	Status of application	☐ New Drug Product (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 25073 dated 05-09-2022 Rs.75,000/- dated 13-06-2022
	The proposed proprietary name / brand name	**Shalay 20mg/1680mg 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 sachet
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Zegerid® Immediate release Powder for oral suspension of M/s Santarus is USFDA Approved
	For generic drugs (me-too status)	Mep-Insta Sachet 20mg/1680mg of M/s Bio-Mark Pharmaceuticals
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited. Regd. Office & factory: Aroor Village, Sadasivpet Mandal, Sangareddy Dist. Telangana **Sodium Bicarbonate:** M/s TATA Chemicals Europe Ltd., Mond House, Winnington Lane, Northwich Cheshire, CW84DT, United Kingdom

Evaluation by PEC:

The applied product to be manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore 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. Plot No 65-Quaid-e-Azam Industrial Estate Kot lakhpat,Lahore.
Manufacturer firm	M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate Lahore
Brand Name	Faast 20mg/1680mg Sachet for oral suspension.

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Ondansetron

233.	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 # 17, Special Industrial Zone, Risalpur, KPK, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	GMP certificate issued to the firm on 02-03-2021 based on inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm on 02-03-2021 based on inspection conducted on 02-03-2021 declares Tablet general section availability..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17580 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Ondex 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……8mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47, D-48, D-49, D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru, Dist: Bengaluru Rural-561203 India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistanhas 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 in 322nd meeting are as follows:	

Applicant firm	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan
Manufacturer firm	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan
Brand Name	Calsetron 8mg tablet

Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

234.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable 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	Dy.No 17756 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	

The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows:

Applicant firm	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore

	Brand Name	Stawia injection 8mg/4ml
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
235.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable 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	Dy.No 17758 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows:	

	Applicant firm	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
	Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Brand Name	Stawia injection 4mg/2ml
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
236.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sarco Chemical Industries.** **17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (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	Dy.No 17759 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Sarset 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	Oral liquid
	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.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia Syrup 4mg/5ml	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
237.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 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 17783 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……8mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia 8mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
238.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 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 17782 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……4mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 4mg tablet by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia 4mg tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
239.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable 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	Dy.No 17780 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia injection 8mg/4ml	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
240.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liuid injectable 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	Dy.No 17780 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.

	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia injection 4mg/2ml	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
241.	Name, address of Applicant / Marketing Authorization Holder	**M/s Genetics Pharmaceuticals Pvt. Ltd.** **539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Evidence of approval of manufacturing facility	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (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	Dy.No 17779 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Genset 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	Oral liquid
	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.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, 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 in 326th meeting are as follows: Applicant firm: M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan Manufacturer firm: M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore Brand Name: Stawia Syrup 4mg/5ml	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
242.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	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 17740 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Ondcare 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
243.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
244.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s 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 21517 dated 29-07-2022
	Details of fee submitted	Rs.75,000/- dated 24-06-2022
	The proposed proprietary name / brand name	**Onset Syrup 4mg/5ml**
	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 • M/s Pharmedic has already been granted approval for applied formulation by way of contract manufacturing from M/s Shrooq Pharmaceuticals (Pvt.) Ltd in 326th meeting of Registration Board.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Pantoprazole Sodium

245.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	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 16624 dated 04-07-2023 Rs.75,000/- dated 23-02-2023
	The proposed proprietary name / brand name	**Pantac 40mg IV 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
246.	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	**Gatolin 40mg IV 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Paracetamol

247.	Name, address of Applicant / Marketing Authorization Holder	**M/s Well & Well Pharma Pvt Ltd.** **Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	GMP status of the manufacturer	GMP certificate issued based upon inspection conducted in 26-01-2018.
	Evidence of approval of manufacturing facility	GMP certificate issued based upon inspection conducted in 26-01-2018 declares Liquid Injectable 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 35751 dated 05-12-2022 Rs.75,000/- dated 16-11-2022
	The proposed proprietary name / brand name	**Piractim 1gm Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Paracetamol …1000mg
	Pharmaceutical form of applied drug	Clear and colorless liquid filled in clear and colorless glass vials.
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Acetaminophen 1g/100ml Infusion by Baxter Healthcare Coporation (United states), FDA Approved.
	For generic drugs (me-too status)	Provas Infusion by Sami Pharmaceuticals (Pvt) Ltd. Reg No: 053223

	Name and address of API manufacturer.	M/s HEBEI JIHENG PHARMACEUTICAL CO., LTD. No.1 Weiwu Street Industrial Park Hengshui City, Hebei Province, 053000 China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad 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 Reliance Pharma Plot # 8, Street No. S-8, RCCI, Industrial Estate, Rawat Islamabad-Pakistan
Manufacturer firm	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	Relimol Infusion

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Piperacillin Sodium/Tazobactam Sodium

248.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s 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 manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Evidence of approval of manufacturing facility	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (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 17921 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Tazopin 4.5gm 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.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang RdDongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Fleming Pharmaceutical 23- Km Lahore- Sheikhupura 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 Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
Manufacturer firm	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
Brand Name	Fletazo Injection 4.5g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
249.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s 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 manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Evidence of approval of manufacturing facility	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (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 17920 dated 14-07-2023

	Details of fee submitted	Rs.75,000/- dated 14-06-2023
	The proposed proprietary name / brand name	**Tazopin 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.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang RdDongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Fleming Pharmaceutical 23- Km Lahore- Sheikhupura 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 Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Manufacturer firm: M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore. Brand Name: Fletazo Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
250.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fresh Pharmaceuticals.** **Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 14525 dated 09-06-2023
	Details of fee submitted	Rs.75,000/- dated 08-05-2023
	The proposed proprietary name / brand name	**Feribac 4.5gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 4.5g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
251.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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 17710 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazip 4.5gm 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 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 English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore Manufacturer firm: M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila Brand Name: ARDCIL Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
252.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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 17709 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazip 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
253.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, 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 17577 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tazocal 4.5gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
254.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caliph Pharmaceuticals Pvt Ltd.** **Plot # 17, Special Industrial Zone, Risalpur, KPK, 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 17576 dated 13-07-2023
	Details of fee submitted	Rs.75,000/- dated 22-06-2022
	The proposed proprietary name / brand name	**Tazocal 2.25gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
255.	Name, address of Applicant / Marketing Authorization Holder	**M/s World Biz Pharmaceuticals Company Plot No. 340 Multan Industrial Estate Multan**
	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 25829 dated 13-09-2022
	Details of fee submitted	Rs.75,000/- dated 16-06-2022
	The proposed proprietary name / brand name	**TazoBiz 4.5g 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
256.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar**
	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 29094 dated 13-10-2022
	Details of fee submitted	Rs.75,000/- dated 22-06-2022
	The proposed proprietary name / brand name	**Tazo-P 4.5gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
257.	Name, address of Applicant / Marketing Authorization Holder	**M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar**

	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 29732 dated 19-10-2022
	Details of fee submitted	Rs.75,000/- dated 22-06-2022
	The proposed proprietary name / brand name	**Tazo-P 2.25gm 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
	Name, address of Applicant / Marketing	**M/s Avant Pharmaceuticals.**

258.	Authorization Holder	**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 12088 dated 18-05-2022
	Details of fee submitted	Rs.75,000/- dated 21-04-2022
	The proposed proprietary name / brand name	**Tazobac 4.5gm 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 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 English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
Manufacturer firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila
Brand Name	ARDCIL Injection 4.5g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
259.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
260.	Name, address of Applicant / Marketing Authorization Holder	**M/s Islam Pharmaceuticals.** **7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 11118 dated 09-05-2022
	Details of fee submitted	Rs.75,000/- dated 20-04-2022
	The proposed proprietary name / brand name	**P-Taz 4.5gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	
	Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
261.	Name, address of Applicant / Marketing Authorization Holder	**M/s Islam Pharmaceuticals.** **7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 11117 dated 09-05-2022
	Details of fee submitted	Rs.75,000/- dated 20-04-2022
	The proposed proprietary name / brand name	**P-Taz 2.25gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 2.25g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
262.	Name, address of Applicant / Marketing Authorization Holder	**M/s Harmann Pharmaceutical Laboratories Pvt Ltd. 16 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18578 dated 27-06-2022
	Details of fee submitted	Rs.75,000/- dated 15-06-2022
	The proposed proprietary name / brand name	**Tazo-X 4.5gm 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	
	Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
263.	Name, address of Applicant / Marketing Authorization Holder	**M/s Harmann Pharmaceutical Laboratories Pvt Ltd. 16 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 18577 dated 27-06-2022
	Details of fee submitted	Rs.75,000/- dated 15-06-2022
	The proposed proprietary name / brand name	**Tazo-X 2.25gm 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 2.25g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
264.	Name, address of Applicant / Marketing Authorization Holder	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23135 dated 16-08-2022

	Details of fee submitted	Rs.75,000/- dated 07-07-2022
	The proposed proprietary name / brand name	**Synibac 4.5gm 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 4.5g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
265.	Name, address of Applicant / Marketing Authorization Holder	**M/s Barrett Hodgson Pakistan Pvt Ltd.** **F/423, SITE, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 22378 dated 05-08-2022
	Details of fee submitted	Rs.75,000/- dated 07-07-2022
	The proposed proprietary name / brand name	**Synibac 2.25gm 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 2.25g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
266.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmedic Laboratories Pvt Ltd.** **16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30778 dated 31-10-2022
	Details of fee submitted	Rs.75,000/- dated 02-08-2022
	The proposed proprietary name / brand name	**Tazolin 4.5gm 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 4.5g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
267.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharmedic Laboratories Pvt Ltd.** **16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31780 dated 04-11-2022
	Details of fee submitted	Rs.75,000/- dated 05-08-2022
	The proposed proprietary name / brand name	**Tazopep 2.25gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 2.25g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
268.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of

		GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23135 dated 16-08-2022
	Details of fee submitted	Rs.75,000/- dated 10-08-2022
	The proposed proprietary name / brand name	**Tazopep 4.5gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	
	Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
269.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 23667 dated 22-08-2022
	Details of fee submitted	Rs.75,000/- dated 10-08-2022
	The proposed proprietary name / brand name	**Tazopep 2.25gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 2.25g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
	Name, address of Applicant / Marketing	**M/s Akhai Pharmaceuticals Pvt Ltd.**

270.	Authorization Holder	**Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 35350 dated 06-12-2022
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Piptazo 4.5gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows: Applicant firm: M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat. Manufacturer firm: M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad Brand Name: PIPRABEN Injection 4.5g Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
271.	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 Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the manufacturer	**Global pharmaceuticals:** Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 04-01-2022. The certificate was issued based on the inspection dated 03-01-2022. The certificate specifies dry powder injection penicillin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 35494 dated 07-12-2022
	Details of fee submitted	Rs.75,000/- dated 22-11-2022
	The proposed proprietary name / brand name	**Piptazo 2.25gm IV 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 Nectar Lifesciences Ltd., (Unit No. 1) village saidpura Tehsil Derabassi District Sahibzada Ajit Singh Nagar Punjab India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:	

Applicant firm	M/s Benson Pharmaceuticals Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	PIPRABEN Injection 2.25g Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Racecadotril

272.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17810 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Resko 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.

	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
273.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17809 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Resko 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
274.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17803 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Racefo 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
275.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17802 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Racefo 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
276.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17828 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Riseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
277.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welwink Pharmaceuticals.** **Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17827 dated 14-07-2023 Rs.75,000/-
	The proposed proprietary name / brand name	**Riseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
278.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17818 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Raceba 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
279.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17817 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Raceba 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
280.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17721 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raseka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
281.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17718 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raseka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
282.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17700 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raceka 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
283.	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 WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17700 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Raceka 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
284.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17704 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Racode 30mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……30mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 30 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 30mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited.
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 30mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
285.	Name, address of Applicant / Marketing Authorization Holder	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hatta**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	GMP status of the manufacturer	GMP certificate based on inspection dated 27.09.2019 granted on 14.10.2019
	Evidence of approval of manufacturing facility	Sachet (General) section was approved on 12.02.2013
	Status of application	☐ New Drug Product (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 17703 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Racode 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Symed Labs Ltd. India, Unit II, Plot No 25/B, Phase III, I.D.A, Jeedimetla, Hyderabad, Telangana, India.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan. Brand Name: Raceka 10mg sachet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
286.	Name, address of Applicant / Marketing Authorization Holder	**M/s Aspin Pharma Pvt Ltd.** **Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan**
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
	GMP status of the manufacturer	GMP inspection conducted on 24/12/2021 Valid till: 17/12/2023. Sachet section (General) regularized on 21.07.2020
	Evidence of approval of manufacturing facility	Sachet section (General) regularized on 21.07.2020
	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 & Details of fee submitted	Dy.No 37584 dated 23-12-2022 Rs.75,000/- dated 05-12-2022
	The proposed proprietary name / brand name	**Roctril 10mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	Name and address of API manufacturer.	Shandong Qidu Pharmaceutical Co., Ltd. No.17, Hongda Road, Linzi District, Zibo City, Shandong, province, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan have 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 Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan Manufacturer firm: M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan Brand Name: **Raceca 10mg Granules for Oral Suspension**
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Solifenacin Succinate/Tamsulosin HCl

287.	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	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (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 12728 dated 23-05-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Maxflow-S 6/0.4 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Solifenacin Succinate(Immediate Release…….6.0mg Tamsulosin HCl (modified Release)…….0.4mg
	Pharmaceutical form of applied drug	film coated tablet.
	Pharmacotherapeutic Group of (API)	**Solifenacin Succinate**: Urologicals, Drugs for urinary frequency and incontinence **Tamsulosin HCl**: Adrenergic α_1-receptor antagonist
	Reference to Finished product specifications	As per 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)	Not available
	Name and address of API manufacturer.	**Solifenacin Succinate:** M/s Optimus Drugs (Pvt.) Limited. Survey No. 239 & 240, Dothigudan (V), Pochampally (M),

		Yadadri, BhuvanagriIndia **Tamsulosin HCl:** M/s Symed Labs (Pvt) Ltd. Survey No, 353, Domadugu (Village), Jinnaram (Mandal),Medak (Dist) ,Telangana, INDIA.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, 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 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: Sinzon-S tablet 6.0/0.4mg • M/s CCL Pharmceuticals had already applied same formulation for contract manufacturing from Ms Gloal Pharmcueticals, which had been deferred by Registration Board.	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Tapentadol

288.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17807 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Typend 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
289.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17797 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tepind 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
290.	Name, address of Applicant / Marketing	**M/s Winbrains Research Laboratories.**

	Authorization Holder	**Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17816 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Tepinda 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Manufacturer firm	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Brand Name	**Tapentawel 75mg tablet**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
291.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17716 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Tapent 75mg Tablet**
	Strength / concentration of drug of Active	Each Film Coated Tablet Contains:

	Pharmaceutical ingredient (API) per unit	Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Manufacturer firm	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
Brand Name	**Tapentawel 75mg tablet**

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
292.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17694 dated 14-07-2023
	The proposed proprietary name / brand name	**Tenpand 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India

	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
293.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet geenra section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17697 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Typint 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol as HCl……75mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	**Analgesic, opioids**
	Reference to Finished product specifications	Product Complies Innovator's Specs
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tapento tablet by M/s Sami Pharmaceuticals, Reg. No. 093064
	Name and address of API manufacturer.	M/s Precise Chemipharma Pvt Limited, C384, TTC Industrial area, MIDC, Pawne village, Nawi Mumbai, India
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Tapentawel 75mg tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per	

	Que or as per the direction of DRAP Authority, which ever is earlier.

Tenofovir alafenamide

294.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17814 dated 14-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Tenofa 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
295.	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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer

	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17799 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Tenfold 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
296.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta
	GMP status of the manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Evidence of approval of manufacturing facility	GMP certificate issued on 23.11.2021 by DRAP peshawer declares tablet general section availability
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17741 dated 14-07-2023 Rs.75,000/- dated 13-07-2023
	The proposed proprietary name / brand name	**Tenfova 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Pharmaceutical form of applied drug	Film coated tablets.

	Pharmacotherapeutic Group of (API)	Antiviral for systemic use, nucleoside and nucleotide reverse transcriptase inhibitors.
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Vemlidy Tablet 25mg by Gilead Sciences Ltd. U.S.A.., USFDA Approved.
	For generic drugs (me-too status)	Tenofomide Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109
	Name and address of API manufacturer.	Shandong Haiyo Freda Pharmaceutical Co Ltd Address: 666 Bianhai West Road Linshu West Industrial Zone, Shandong Province.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta 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 Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Manufacturer firm: M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hatta Brand Name: **Teno 25mg Tablet**	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Terbinafine HCl

297.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
298.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Ticagrelor

299.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17788 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Ticrole 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Ttablet Contains: Ticagrelor…90mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size & 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.,
	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 226407, China.
	Evaluation by PEC:	

	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have 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 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: Ticlor 90mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
300.	Name, address of Applicant / Marketing Authorization Holder	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 17787 dated 14-07-2023 Rs.75,000/- dated 14-07-2023
	The proposed proprietary name / brand name	**Ticrole 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Ttablet Contains: Ticagrelor…60mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Brilinta 60 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 60mg, PharmEvo (Pvt.) Ltd., Reg. No.093105.
	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 226407, China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, 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 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: Ticlor 90mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per	

	Que or as per the direction of DRAP Authority, which ever is earlier.

Vancomycin HCl

301.	Name, address of Applicant / Marketing Authorization Holder	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	GMP status of the manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Evidence of approval of manufacturing facility	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder 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 & Details of fee submitted	Dy.No 17605 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Myco 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….1gm
	Pharmaceutical form of applied drug	Dry Powder injection
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 1gm Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave 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 May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Manufacturer firm	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Brand Name	Myocin 1gm Dry Powder vial I.V

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

<table>
<tr><td rowspan="15">302.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Winlet Pharmaceuticals.
30-km, Lahore Sargodha Road, Lahore</td></tr>
<tr><td>Name, address of Manufacturing site.</td><td>M/s May & Baker (Pvt) Ltd.
45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td>GMP status of the manufacturer</td><td>DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.</td></tr>
<tr><td>Evidence of approval of manufacturing facility</td><td>DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022 declares Dry Powder Vial Section (General)</td></tr>
<tr><td>Status of application</td><td>☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td>Intended use of pharmaceutical product</td><td>☐ Domestic sale
☐ Export sale
☒ Domestic and Export sales</td></tr>
<tr><td>Dy. No. and date of submission & Details of fee submitted</td><td>Dy.No 17604 dated 13-07-2023 Rs.75,000/- dated 11-07-2023</td></tr>
<tr><td>The proposed proprietary name / brand name</td><td>Myco 500mg Injection</td></tr>
<tr><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each vial contains:
Vancomycin Hydrochloride equivalent to Vancomycin …….500mg
(as lyophilized powder for injection)</td></tr>
<tr><td>Pharmaceutical form of applied drug</td><td>Dry Powder injection</td></tr>
<tr><td>Pharmacotherapeutic Group of (API)</td><td>Tricyclic glycopeptide antibiotics.</td></tr>
<tr><td>Reference to Finished product specifications</td><td>As per USP Specification</td></tr>
<tr><td>Proposed Pack size & Unit price</td><td>As per SRO</td></tr>
<tr><td>The status in reference regulatory authorities</td><td>Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.</td></tr>
<tr><td>For generic drugs (me-too status)</td><td>Vanbact I.V. 500mg Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682</td></tr>
<tr><td>Name and address of API manufacturer.</td><td>M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China</td></tr>
<tr><td colspan="2">Evaluation by PEC:</td></tr>
<tr><td colspan="2">The applied product to be manufactured by M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahorehave 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:
<table>
<tr><td>Applicant firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td>Manufacturer firm</td><td>M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td></tr>
<tr><td>Brand Name</td><td>Myocin 500mg Dry Powder vial I.V</td></tr>
</table></td></tr>
<tr><td colspan="2">Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.</td></tr>
<tr><td>303.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td>M/s Surge Laboratories Pvt Ltd.
10 km, Faisalabad Road, Bikhi, District Sheikhupura</td></tr>
</table>

	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	GMP status of the manufacturer	GMP certificate issued on 06-10-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on 06-10-2020 declared availability of Lyophilized Injectable 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 13377 dated 30-05-2023 Rs.30,000/- dated 28-04-2023 & Rs.45,000/- dated 19-05-2023
	The proposed proprietary name / brand name	**Vancova 1gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….1gm (as lyophilized powder for injection)
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 1gm Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, 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 Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan Manufacturer firm: M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Brand Name: Vanco 1gm Injection	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
304.	Name, address of Applicant / Marketing Authorization Holder	**M/s Surge Laboratories Pvt Ltd.** **10 km, Faisalabad Road, Bikhi, District Sheikhupura**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan

	GMP status of the manufacturer	GMP certificate issued on 06-10-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on 06-10-2020 declared availability of Lyophilized Injectable 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 13378 dated 30-05-2023 Rs.30,000/- dated 28-04-2023 & Rs.45,000/- dated 19-05-2023
	The proposed proprietary name / brand name	**Vancova 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride USP equivalent to Vancomycin …….500mg (as lyophilized powder for injection)
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Tricyclic glycopeptide antibiotics.
	Reference to Finished product specifications	As per USP Specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Product is registered and being marketed in USA & UK by Hospira and MYLAN LABS LTD.
	For generic drugs (me-too status)	Vanbact I.V. 500mg Injection by M/s Nabiqasim Industries (Pvt.) Ltd, Reg. No. 070682
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fixing Pharmaceutical Co, Ltd Jiangyin industrial zone Fuqing Fuzhou City Fujian Province, P.R. China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, 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 Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
Manufacturer firm	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
Brand Name	Vanco 500mg Injection

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.

Vonoprazan Fumarate

305.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	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 17612 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Vonocare 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 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
306.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries.** **Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	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 17611 dated 13-07-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Vonocare 10mg 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 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
307.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
308.	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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
309.	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 37800 dated 26-12-2022 Rs.75,000/- dated 26-12-2022
	The proposed proprietary name / brand name	**Vonz 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
310.	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 37799 dated 26-12-2022 Rs.75,000/- dated 26-12-2022

	The proposed proprietary name / brand name	**Vonz 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: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
311.	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 35680 dated 08-12-2022 Rs.75,000/- dated 17-10-2022
	The proposed proprietary name / brand name	**Vox 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 20mg tablet by M/s Takeda pharmaceutical company Ltd. PMDA Japan approved
	For generic drugs (me-too status)	Vonseca 20mg tablet by M/s Tabros, Karachi ,Reg No. 112584
	Name and address of API manufacturer.	Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar 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 Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
Manufacturer firm	M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
Brand Name	Verozen 20mg Tablet

	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
312.	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 35682 dated 08-12-2022 Rs.75,000/- dated 17-10-2022
	The proposed proprietary name / brand name	**Vox 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.	Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar 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 Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar Manufacturer firm: M/s Wnsfeild Pharmaceuticals Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar Brand Name: Verozen 10mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Vonoprazan/Aspirin

313.	Name, address of Applicant / Marketing Authorization Holder	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila 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	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 17806 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Vospin 10/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer)……...…10mg

		Aspirin (as enteric coated inner core) ……..…..100mg
	Pharmaceutical form of applied drug	White to off-white color Aspirin round shape enteric coated tablet surrounded by film coated Vonoprazan tablets.
	Pharmacotherapeutic Group of (API)	Vonoprazan: Potassium-Competitive Acid Blocker Aspirin: Antithrombotic Agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Vonoprazan: Guangdong Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China Aspirin JQC (HUAYIN) Pharmaceutical Co, Ltd/ Yuquan Road, Huayin city, Shanxi province, P.R of China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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 Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan Manufacturer firm: M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan Brand Name: Venospa 10/100mg Tablet	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	
314.	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 Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar 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 17695 dated 14-07-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Vono-AS 10/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer)……...…10mg Aspirin (as enteric coated inner core) ……..…..100mg
	Pharmaceutical form of applied drug	White to off-white color Aspirin round shape enteric coated tablet surrounded by film coated Vonoprazan tablets.
	Pharmacotherapeutic Group of (API)	Vonoprazan: Potassium-Competitive Acid Blocker Aspirin: Antithrombotic Agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Vonoprazan: Guangdong Xianqiang Pharmaceutical Pvt Ltd, No. 6, industrial Avenue, Conghua, Economical Development zone, Guangzhou city, Guangdong province, China Aspirin JQC (HUAYIN) Pharmaceutical Co, Ltd/ Yuquan Road, Huayin city, Shanxi province, P.R of China
	Evaluation by PEC:	
	The applied product to be manufactured by M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, 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:	
	Decision: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, which ever is earlier.	

Applicant firm	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan
Manufacturer firm	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan
Brand Name	Venospa 10/100mg Tablet

Case no. 02 Registration applications of newly granted DML or New section

(Human)

a. **New DML**

315.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) Ltd Plot # 37- A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) Ltd Plot # 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	Firm has submitted copy of GMP certificate dated 06-04-2023 based on inspection conducted on 28-03-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2015 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 13182 dated 29-05-2023
	Details of fee submitted	PKR 30,000/- Dated 11-05-2023
	The proposed proprietary name / brand name	**Sitagmin (50/1000) film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sitagliptin (as Phosphate Monohydrate) …….. 50 mg Metformin HCl ……1000 mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Pharmaceutical form of applied drug	Light blue color oblong film coated tablet
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Janumet film coated tablet (50 /1000 mg) (USFDA Approved)
	For generic drugs (me-too status)	**Treviamet Tab 50mg/1000mg** of M/s **M/S Getz Pharma**, Karachi (Reg.No. 055443)
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate** Anhui Haikang Pharmaceutical Co., Ltd. No21, Huancheng West Road, Daguan District, Anqing, Anhui 24600, China Metformin Hydrochloride Active Fine Chemicals Limited West Muktarpur, Munshigonj, Bangaladesh
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Janumet film coated tablet (50 /1000 mg) manufactured by MSD, Firm has submitted CDP results of their product against the innovator's product Janumet film coated tablet (50 /1000 mg) 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	**Sitagliptin Phosphate Monohydrate** Anhui Haikang Pharmaceutical Co., Ltd. No21, Huancheng West Road, Daguan District, Anqing, Anhui 24600, China Postcode:246000 Metformin Hydrochloride Active Fine Chemicals Limited West Muktarpur, Munshigonj, Bangladesh
API Lot No.	Sitagliptin Phosphate Monohydrate B.No 21042602 Metformin Hydrochloride B.No MET 012104013
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.		T01	T032	T03
Batch Size		1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date		07-2022	07-2022	07-2021
Date of Initiation		28-07-2022	28-07-2022	28-07-2022
No. of Batches		03		
316.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) Ltd Plot # 37- A, Sunder Industrial Estate, Lahore.**		
	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) Ltd Plot # 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	Firm has submitted copy of GMP certificate dated 06-04-2023 based on inspection conducted on 28-03-2023.		
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2015 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 13181 dated 29-05-2023		
	Details of fee submitted	Rs.30,000/- dated 11-05-2023		
	The proposed proprietary name / brand name	**Sitagmin (50/500) film coated tablet**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sitagliptin (as Phosphate Monohydrate) …….. 50 mg Metformin HCl ……500 mg		
	Pharmacotherapeutic Group of (API)	Anti-diabetic		
	Pharmaceutical form of applied drug	Light blue color oblong film coated tablet		
	Reference to Finished product specifications	Innovator's		
	Proposed Pack size	2 x 7's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Janumet film coated tablet (50 /500 mg) (USFDA Approved)		
	For generic drugs (me-too status)	**Treviamet Tab 50mg/500mg** of M/s **M/S Getz Pharma**, Karachi (Reg.No. 055443)		
	Name and address of API manufacturer.	**Sitagliptin Phosphate Monohydrate** Anhui Haikang Pharmaceutical Co., Ltd. No21, Huancheng West Road, Daguan District, Anqing, Anhui 24600, China Metformin Hydrochloride Active Fine Chemicals Limited		

		West Muktarpur, Munshigonj, Bangaladesh
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Janumet film coated tablet (50 /500 mg) manufactured by MSD, Firm has submitted CDP results of their product against the innovator's product Janumet film coated tablet (50 /500 mg) 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	**Sitagliptin Phosphate Monohydrate** Anhui Haikang Pharmaceutical Co., Ltd. No21, Huancheng West Road, Daguan District, Anqing, Anhui 24600, China Postcode:246000 **Metformin Hydrochloride:** Active Fine Chemicals Limited West Muktarpur, Munshigonj, Bangladesh
API Lot No.	Sitagliptin Phosphate Monohydrate B.No 21042602 Metformin Hydrochloride B.No MET 012104013
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.	T01	T032	T03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2022	07-2022	07-2021
Date of Initiation	26-07-2022	26-07-2022	26-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	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. DA/6-151/2011/8568) dated 05-05-2021 issued by Ministry of health & family welfare, Directorate general of Drug Administration Oushad Bhaban, Mohakhali Dakha-1212, Bangladesh . 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 on 25-05-2021 specifying 5.0Kg of Metformin HCl. And invoice no 20220722 dated 25-06-2022 of 0.5 kg Sitagliptin Phosphate Monohydrate
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	Firm's response
1.6.5	Submit valid GMP/DML certificate of the manufacturer of Metformin HCl	Firm has submitted copy of DML no. 275 valid till 04-10-2023 issued by DGDA Bangladesh.

Decision: Registration Board approved the applications of "Sitagmin (50/500)" & "Sitagmin (50/1000)" 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.**

317.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt.) Ltd Plot # 37- A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Himark Laboratories (Pvt.) Ltd Plot # 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	Firm has submitted copy of GMP certificate dated 06-04-2023 based on inspection conducted on 28-03-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2015 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 12860 dated 24-05-2023
	Details of fee submitted	PKR 30,000/- Dated 11-05-2023
	The proposed proprietary name / brand name	**Xetvib 20 mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Paroxetine as Paroxetine HCl hemihydrate…… 20 mg
	Pharmacotherapeutic Group of (API)	Anti-depressant
	Pharmaceutical form of applied drug	White color round shaped film coated tablets
	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 b yU SFDA
	For generic drugs (me-too status)	Pronitron Tablet 20mg film coated tablet of M/s Nabiqasim Industries (Pvt.) Ltd, Karachi (Reg.No. 007990)
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	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 Seroxat 20 mg film coated tablet manufactured by GSK, Pakistan Firm has submitted CDP results of their product against the innovator's product Seroxat 20 mg film coated tablet in 3 dissolution medias along with acceptable results for f2 value
	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 Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.	5301-20-029		
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.	T01	T032	T03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2022	07-2022	07-2021
Date of Initiation	20-07-2022	20-07-2022	20-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	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. ZJ20180073) valid till 25-06-2023 issued by China Food and 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).	
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	Firm's response
3.2.S.4.2	Drug substance analytical procedure from the Drug substance manufacturer shall submitted	Submitted
3.2.S.4.4	COA of drug substance analysis for the relevant batch used in the manufacturing of drug product stability hatches shall be submitted from M/s Himark.	Firm has submitted COA of batch #5301-20-029 from M/s Himark Laboratories.
3.2.P.8.3	• Documents confirming import of drug substance with the approval of DRAP shall be submitted. • Valid GMP certificate/DML of drug substance manufacture shall be submitted since submitted GMP certificate was valid till 25-06-2023	• Firm has submitted copy of commercial invoice no. HH20200723R1 specifying 0.412Kg of Paroxetine HCl hemihydrate. Firm has also submitted DHL slip • Firm has submitted DML# 20000311 issued by Zhejiang Provincial Drug Administration valid till 12-01-2025

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.**

318.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Private Limited, 45 KM Dina Nath Multan road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker Private Limited, 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	N/A
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML dated 29-04-2022 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 11978 dated 16-05-2023
	Details of fee submitted	PKR 30,000/- Dated 05-2023
	The proposed proprietary name / brand name	**Lenzer Delayed release 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release Capsule contains: Dexlansoprazole…… 30mg
	Pharmacotherapeutic Group of (API)	PPI
	Pharmaceutical form of applied drug	Oral Capsule hard gelatin
	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	Dexilant Capsule 30mg FDA approved
	For generic drugs (me-too status)	Rodexa of M/s Pharmevo, (Reg.No. 107831)
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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 Dexilant 30mg capsule Manufacture by Takeda Pharmaceuticals. Firm has submitted CDP results of their product against the innovator's product Dexilant 30mg 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	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	DLP908		
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.	T0001	T0002	T0003
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	21-08-2022	21-08-2022	21-08-2022
Date of Initiation	15-09-2022	15-09-2022	15-09-2022
No. of Batches	03		

319.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Private Limited, 45 KM Dina Nath Multan road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker Private Limited, 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	N/A
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of DML

		dated 29-04-2022 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 11977 dated 16-05-2023
	Details of fee submitted	Rs.30,000/- dated 04-05-2023
	The proposed proprietary name / brand name	**Lenzer Delayed release 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release Capsule contains: Dexlansoprazole…… 60mg
	Pharmacotherapeutic Group of (API)	PPI
	Pharmaceutical form of applied drug	Oral Capsule hard gelatin
	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	Dexilant Capsule 60mg FDA approved
	For generic drugs (me-too status)	Rodexa of M/s Pharmevo, (Reg.No. 107382)
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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 Dexilant 60mg capsule Manufacture by Takeda Pharmaceuticals. Firm has submitted CDP results of their product against the innovator's product Dexilant 60mg 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	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	DLP908		
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.	T0001	T0002	T0003
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	24-08-2022	24-08-2022	24-08-2022
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)	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 & LT-1)-56) dated 16-04-2022 issued by Drug Regularity Authority 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).	Firm has submitted the invoice no. 60007 dated 08/08/2022 of 5 kg.
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 of stability 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.

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2.S.4.3	Submit analytical method verification studies for drug substance performed by M/s May & Baker.	Submitted.
3.2.S.4.4	Dissolution test has not been performed in drug substance analysis by M/s may & Baker.	Firm has submitted drug substance analysis COA from M/s May & Baker, wherein test for Dissolution has been included.
3.2.P.5.1	Justification shall be submitted for not including test of content uniformity in drug product specifications.	Firm had referred to the performance of test of weight variation for establishing uniformity of dosage units. Now firm has submitted revised drug product specifications including test of content uniformity.
3.2.P.5.3	Submit analytical method verification studies of drug product performed by M/s May & Baker.	Submitted.
3.2.P.8	Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
2.3.R.1	Submit clarification regarding the dispensed weight per unit capsule.	Firm has submitted justification against the potency of drug substance determined during drug substance analysis.

Decision: Registration Board approved the applications of Llenzer 30mg & 60mg capsule

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

b. New/Additional section(s)

CLB in its 288th meeting held on 18-10-2022 has approved grant of additional section of "Liquid Injectable Ampoule (General) section" for M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.

320.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022 based on inspection conducted on 11-10-2022.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10580 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Seraph WFI 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Water for injection ……. 10ml
	Pharmacotherapeutic Group of (API)	Solvent
	Pharmaceutical form of applied drug	Clear, Colorless Liquid filled in glass Ampoules.
	Reference to Finished product specifications	BP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Water for injection , MHRA UK
	For generic drugs (me-too status)	WFI 10ml Surge Laboratories
	Name and address of API manufacturer.	Seraph Pharmaceutical
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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, batch analysis and justification of specification, reference standard, container closure system 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, batch analysis and justification of specification, reference standard, container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted that water for injection in bulk is stored in SS container and is filled in ampoules within 24 hours therefore stability studies are not required to be carried out in this container closure system.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 WFI of M/s Surge Laboratories.
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	Seraph Pharmaceutical		
API Lot No.	NA		
Description of Pack (Container closure system)	One glass ampoule containing 10ml water for injection.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	18-10-2022	18-10-2022	18-10-2022
No. of Batches	03		

321.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid injectable ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10579 dated 26-04-2023
	Details of fee submitted	Rs.30,000/- dated 13-04-2023
	The proposed proprietary name / brand name	**Seraph WFI 2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Water for Injection ……. 2ml
	Pharmacotherapeutic Group of (API)	Solvent
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoules.

	Reference to Finished product specifications	BP
	Proposed Pack size	2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Water for injection , MHRA UK.
	For generic drugs (me-too status)	Water for Injection 2ml Surge Laboratories
	Name and address of API manufacturer.	Seraph Pharmaceutical
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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, batch analysis and justification of specification, reference standard, container closure system of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted that water for injection in bulk is stored in SS container and is filled in ampoules within 24 hours therefore stability studies are not required to be carried out in this container closure system.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 submitted
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA	
Manufacturer of API	Seraph Pharmaceutical
API Lot No.	N/A
Description of Pack (Container closure system)	One glass Ampoule containing 2ml water for injection
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, 6 (Months)

		Real Time: 0, 3, 6 (Months)		
Batch No.		T007	T008	T009
Batch Size		1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date		10-2022	10-2022	10-2022
Date of Initiation		18-10-2022	18-10-2022	18-10-2022
No. of Batches		03		
322.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**		
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022,based on inspection conducted on 11-10-2022.		
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission	Dy. No 11239 dated 05-05-2023		
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023		
	The proposed proprietary name / brand name	**Seraph WFI 5ml**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Water for injection ……. 5ml		
	Pharmacotherapeutic Group of (API)	Solvent		
	Pharmaceutical form of applied drug	Clear, Colorless Liquid filled in glass Ampoules.		
	Reference to Finished product specifications	BP		
	Proposed Pack size	5ml		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Water for injection , MHRA UK		
	For generic drugs (me-too status)	WFI 5ml Surge Laboratories		
	Name and address of API manufacturer.	Seraph Pharmaceutical		
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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, batch analysis and justification of specification, reference standard, container closure system 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, batch analysis and justification of specification, reference standard, container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted that water for injection in bulk is stored in SS container and is filled in ampoules within 24 hours therefore stability studies are not required to be carried out in this container closure system.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 WFI of M/s Surge Laboratories.
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Seraph Pharmaceutical		
API Lot No.	NA		
Description of Pack (Container closure system)	One glass ampoule containing 5ml water for injection.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	18-10-2022	18-10-2022	18-10-2022
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. F.3-7/2018-Addl.Dir/(QA &LT-1) dated 11-11-2022. 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).	Not applicable
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 applicable
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 #	Observation	Firm's response
3.2.P.2.2.1	Pharmaceutical equivalence report for the WFI 2 ml fill volume shall be submitted.	Submitted
3.2.P.8.3	Stability studies of 6th month time point shall be submitted.	Firm has submitted stability record for 6th month time point.

Decision: Registration Board approved the applications of "Seraph WFI 10ml ", "Seraph WFI 2ml ", & "Seraph WFI 5ml".

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

323.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022,based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10581 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Seraph NS 5ml Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Sodium Chloride…….0.9mg (0.9%)
	Pharmacotherapeutic Group of (API)	Mineral Supplement
	Pharmaceutical form of applied drug	Clear, Colorless Liquid filled in glass Ampoules.
	Reference to Finished product specifications	USP
	Proposed Pack size	5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sodium Chloride Injection BP 0.9% w/v, Hameln Pharma Ltd, UK MHRA UK
	For generic drugs (me-too status)	Celine 0.9% Injection (5ml) Surge Labortories (Reg.No. 074266)
	Name and address of API manufacturer.	M/s Salinen Austria AG, Salinen Austria AG Steinkogelstrasse 30, 4802 Ebensee, Austria.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 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 innovator's product Sodium Chloride Injection BP 0.9% w/v manufactured Hameln pharma ltd, UK

	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	Salinen Austria AG, Salinen Austria AG Steinkogelstrasse 30, 4802 Ebensee, Austria.		
API Lot No.	CRS190122		
Description of Pack (Container closure system)	One glass ampoule containing 5ml (0.9%) Sodium chloride.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	20-10-2022	20-10-2022	20-10-2022
No. of Batches	03		

324.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid injectable ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 10582 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Seraph NS 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Sodium chloride ……. 9mg (0.9%)
	Pharmacotherapeutic Group of (API)	Mineral Supplements
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoules.
	Reference to Finished product specifications	USP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Sodium chloride injection BP 0.9% W/V, Hameln Pharma Ltd, UK, MHRA UK.
	For generic drugs (me-too status)	Celine 0.9% Injection (10ml) Surge Laboratories (Reg. No. 074266)
	Name and address of API manufacturer.	Salinen Austria AG, Salinen Austria AG Steinkogelstrasse 30, 4802 Ebensee, Austria .
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 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 innovator's product Sodium chloride injection BP 0.9% W/V, Hameln Pharma Ltd, UK, MHRA UK.
	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	Salinen Austria AG, Salinen Austria AG Steinkogelstrasse 30, 4802 Ebensee, Austria .
API Lot No.	CRS190122
Description of Pack (Container closure system)	One glass Ampoule containing 10ml (0.9%) sodium chloride

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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	20-10-2022	20-10-2022	20-10-2022
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
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 cleared on 21-04-2022 specifying 24500Kg issued to Lakhani Pharma, from Lakhain pharma. Firm has also submitted Loan letter Ser/SRB/DRAB/ISB/2023-02 from M/s Lakahni 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 analytical record for product testing for stability studies.
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)	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 for the drug substance manufacturer issued by the relevant regulatory authority.	Firm has submitted copy of GMP Certificate (No. INS-481329-14173814/17029593 valid till 26-07-2024 issued by Ministry of Austria.
3.2.S.4.2	Drug substance analytical procedure shall be submitted for M/s Seraph Pharmaceuticals.	Submitted
3.2.P.8.3	Submit stability studies for the 6th month time point.	Submitted.

Decision: Registration Board approved the applications of "Seraph NS 5ml Injection" & "Seraph NS 10ml".

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
325.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying liquid Injectable ampoule 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 10575 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 19-04-2023
	The proposed proprietary name / brand name	**D-Strong Injection 7.5 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One Ampoule contains: Cholecalciferol (vitamin D3) 7.5 mg, which corresponds to 300000 I.U.
	Pharmacotherapeutic Group of (API)	Vitamin.
	Pharmaceutical form of applied drug	Liquid injection
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarenel Italfarmaco S.p.A. Xarenel® Injection is Approved in AIFA of Italy
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Fermenta Biotech Limited. Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°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	Firm has submitted Pharmaceutical equivalence studies against the Xarenel® Injection.
	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 Fermenta Biotech Limited. Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India		
API Lot No.	CLC0421283		
Description of Pack (Container closure system)	Colecalciferol is filled clear, sterilized Printed 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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	2000 Injections	2000 Injections	2000 Injections
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products.

		a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certicate No 2062043 dated issued by Food & Drugs Control Administration, Gujarat State, India valid till 17-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Clearance certificate no. E-63186525961 dated 11-02-2022 for the import of 1Kg of Cholecalciferol.
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 for the stability 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)	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
1.1	Differential fee of Rs. 45,000/- shall be submitted since applied formulation is not previously registered by DRAP.	Firm has submitted Differential fee of Rs. 45,000/-. Vide deposit slip# 765198550034.
3.2.P.1	Justification shall be submitted for proposed excess fill volume per unit ampoule.	Frim has referred to USP general chapter for the provision of excess fill volume.
3.2.P.8.3	Submit stability studies for the 6th month time point.	Submitted
2.3.R.1	Complete batch manufacturing record for the 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.**

326.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid injectable ampoule (General) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10578 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Lidox Injection 3.5 ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3.5 ml contains: Lidocaine Hydrochloride ……. 35mg
	Pharmacotherapeutic Group of (API)	Local Anesthetics
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoules.
	Reference to Finished product specifications	BP
	Proposed Pack size	3.5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Lidocain 1% Solution Tabros Pharma (045163)
	Name and address of API manufacturer.	M/s Alcon Biosciences (Pvt) Ltf. S-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°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 studies against the Lignocaine injection 3.5ml of M/s Tabros 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	M/s Alcon Biosciences (Pvt) Ltf. S-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujarat India.		
API Lot No.	U4-1021/20		
Description of Pack (Container closure system)	One glass Ampoule containing 3.5ml of Lidocain injection		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	18-10-2022	18-10-2022	18-10-2022
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certiifcate no. S-GMP20102297 of M/s Alcon Biosciences (Pvt) Ltd. A-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujrat India , issued by Food & Drugs Control Administration, valid upto 21-10-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 15-01-2021 in name of Wimits Pharma. Firm has also submitted Loan letter from M/s Wimits Pharma in name of M/s Seraph Pharmaceutical for Lignocaine 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 for the stability 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	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and

	time and accelerated)	accelerated stability chambers.
Remarks of Evaluator:		
327.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10577 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Lidox 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Lidocaine hydrochloride……20mg
	Pharmacotherapeutic Group of (API)	Local anesthetics
	Pharmaceutical form of applied drug	Clear, Colorless Liquid filled in glass Ampoules.
	Reference to Finished product specifications	BP
	Proposed Pack size	2 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Lignocaine 1% injection of M/s Surge Laboratories (026761)
	Name and address of API manufacturer.	M/s Alcon Biosciences (Pvt) Ltd. A-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 studies against the Lignocaine injection of M/s Surge Laboratories.
	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 Alcon Biosciences (Pvt) Ltd. A-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujrat India.		
API Lot No.	U4-1021/20		
Description of Pack (Container closure system)	One glass ampoule containing 2ml Lidocaine injection.		
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	10-2022	10-2022	10-2022
Date of Initiation	18-10-2022	18-10-2022	18-10-2022
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th

		meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
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 cleared on 15-01-2021 in name of Wimits Pharma. Firm has also submitted Loan letter from M/s Wimits Pharma in name of M/s Seraph Pharmaceutical for Lignocaine 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 for the stability 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)	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 issued by relevant regulatory authority of country of origin.	GMP Certiifcate no. S-GMP20102297 of M/s Alcon Biosciences (Pvt) Ltd. A-1/2104, Phase III, G.I.D.C VAPI 369 195 District Valsad, Gujrat India , issued by Food & Drugs Control Administration, valid upto 21-10-2022
3.2.P.8.3	Submit stability studies for the 6th month time point.	Submitted
2.3.R.1	Submit batch manufacturing record of stability trial batches.	Submitted

Decision: Registration Board approved the applications of "Lidox Injection 3.5 ml" & "Lidox 2ml Injection".

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

328.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022,based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 08-11-2022 specifying Liquid Injectable Ampoule (General) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 10392 dated 19-04-2023
	Details of fee submitted	PKR 30,000/- Dated 19-04-2023
	The proposed proprietary name / brand name	**RestOn Injection 8 mg/4 ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml contains: Ondansetron as HCl Dihydrate……8 mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Pharmaceutical form of applied drug	Clear, Colorless Liquid filled in glass Ampoules.
	Reference to Finished product specifications	USP
	Proposed Pack size	4 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran®, Novartis, Zofran® Injection is Approved in USFDA
	For generic drugs (me-too status)	Zofran Injection (Reg.# 020669)
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230 Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 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 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 studies against the Zofran Injection 8mg/4ml.
	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 – 394 230 Gujarat, INDIA	
API Lot No.	22ON000019	
Description of Pack (Container closure system)	One glass ampoule containing 4ml Reston injection (2mg/ml)	
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, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	T001	T002
Batch Size	2000 ampoules	2000 ampoules
Manufacturing Date	11-2022	11-2022
Date of Initiation	11-2022	11-2022
No. of Batches	02	

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
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 Clearance certificate no. E-97188603467 dated 30-04-2022 for the import of 4Kg of Ondansetron HCl in name of M/s Swiss Pharmaceutical, along with loan letter in name of M/s 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 analytical record for product testing for stability studies.
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	Firm's response
1.6.5	Submit valid GMP certificate/DML for the drug substance manufacturer issued by the relevant regulatory authority.	Firm has submitted GMP Certiifcate no. 19061470 issued by Food and Drugs Control Administration Gujrat India.
3.2.P.5.3	Concentration levels in terms of mg/ml shall be declared in the performance of accuracy parameter in analytical method verification studies.	Firm has submitted revised analytical method verification studies report with concentrations declared in terms of mg/ml for the performance of accuracy parameter.
3.2.P.6	COA of reference working standard, used for the analysis of stability batches, shale be submitted.	Submitted.
3.2.P.8.3	Stability studies data of 6th month time point 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.**

M/s Seraph had been granted DML# 000860 dated 12-06-2017 including "Dry Vial Cephalosporin section.". Firm has applied following formulations against their balance quota of priority consideration of 10 molecules per section.

329.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 12-06-2017 specifying Dry vial Cephalosporine Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13640 dated 01-06-2023
	Details of fee submitted	PKR 30,000/- Dated 01-06-2023
	The proposed proprietary name / brand name	**Cefavidime 2.0/0.5G Injection IM/IV**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftazidime…….2g Avibactam…….0.5g
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin
	Pharmaceutical form of applied drug	A White or Light Yellow Sterile free flowing powder Filled in Vials Packed in Unit Carton.
	Reference to Finished product specifications	Innovator specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avycaz 2/0.5g injection Allergan Pharma Limited FDA Approved drugs
	For generic drugs (me-too status)	Zavicefta 2g/0.5g injection Pfizer PVT Limited
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO., Ltd. No.849 Dongjia town Licheng District China 250105 Jinan,Shangdong Province.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 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 Pharmaceutical equivalence studies against Avycaz 2/0.5g injection Allergan Pharma Limited FDA Approved drugs
	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	Qilu Antibiotics Pharmaceutical CO., Ltd.		
API Lot No.	2001GJ85JB		
Description of Pack (Container closure system)	A White or Light Yellow Sterile free flowing powder Filled in Vials 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, 6 months Accelerated: 3, 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	214 Packs	214 Packs	214 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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
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 Clearance Certificate No.E-3335386526318 for the import of 2Kg of Ceftazidime+Avibactam.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	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
3.2.S.4.4	Justification shall be submitted for not performing test for "Pyridine content" by M./s Seraph pharmaceuticals.	Firm has referred to the COA of drug substance manufacturer and stated that they have relied upon the results of "Pyridine content" performed by the Drug substance manufacturer.

3.2.P.2.5	Submit compatibility study with the reconstitution diluent.	Frim has submitted compatibility studies with water for injection.
3.2.P.5.1	Justification shall be submitted for not including test of "Pyridine content" in drug product specifications as recommended by Innovator drug product.	Firm has referred to the COA of drug substance manufacturer and stated that they have relied upon the results of "Pyridine content" performed by the Drug substance manufacturer since applied formulation is formulated as ready to fill powder for injection.
3.2.P.8.3	• Submit stability data of 6th month time point. • Submit valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority.	• Firm has submitted 6th month time point study. • Firm has submitted Copy of GMP certificate (No.SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. • Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.2.R	Justify the dispensed weight per unit vial with reference to the potency of drug substance determined during drug substance analysis.	Firm has referred to the potency of drug substance determined during drug substance analysis on "as is basis" for calculation of weight per unit 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.**

330.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot # 210 Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-11-2022, based on inspection conducted on 11-10-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 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 10576 dated 26-04-2023
	Details of fee submitted	PKR 30,000/- Dated 26-04-2023
	The proposed proprietary name / brand name	**Ceffosa Injection 600mg IV/IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil (As L-rginine) …… 600mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins
	Pharmaceutical form of applied drug	White to off white powder filled in glass vial.
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 600mg Injecion, Allergan pharma Ireland, FDA Approved Drug.
	For generic drugs (me-too status)	Zinforo Injection 600mg, Pfizer Pvt Limited. (Reg.# 110515)
	Name and address of API manufacturer.	M/s Qingdao Xinnuo Pharmaceutical Chemical Co., Ltd. 50 meters North Yuanhou Neighborhood Committee Xifuzhen Street Chenyang Area Qingdao Shandong, CHINA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 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	Pharmaceutical equivalence studies have been submitted against the Innovator drug product of Zinforo 600mg injection.
	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 Qingdao Xinnuo Pharmaceutical Chemical Co., Ltd. 50 meters North Yuanhou Neighborhood Committee Xifuzhen Street Chenyang Area Qingdao Shandong, CHINA		
API Lot No.	20221002		
Description of Pack (Container closure system)	White to off white powder filled in 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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	246 Packs	246 Packs	246 Packs
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)	Our facility has been inspected by panel of inspectors for verification of stability study data for following products. a) Dexpro (Dexlansoprazole) 30 and 60mg Capsule approved in 285th meeting of Registration Board. b) Neovel 800mg Tablet approved in 288th meeting of Registration Board. c) Serbica 20mg Capsule approved in 290th meeting of Registration Board.
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 Clearance certificate no. E-3326386523852 dated 07-11-2022 for the import of 801gm of Ceftaroline fosamil with L-Arginine.
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 for the stability batches
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	Firm's response
1.6.5	Submit valid GMP certificate/DML for the drug substance manufacturer issued by the relevant regulatory authority.	Firm has submitted GMP certificate valid till 15-09-2025 issued by Center for evaluation & certification of Shandong Pharmaceutical Industry Association.
3.2.S.4	• Submitted specifications does not include test of "Acetic acid" content. • Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from M/s Seraph Pharmaceuticals. • Reports for sterility test of drug substance performed by M/s Seraph pharmaceutical shall be submitted.	• Firm has submitted analytical procedure and specifications applied by M/s Seraph pharmaceuticals including test of Acetic acid. • Firm has submitted microbial reports for the sterility testing of drug substance.
3.2.S.7.3	Stability studies of drug substance shall be submitted as per zone-IVA conditions.	Firm has submitted long term stability studies as per Zone IVA conditions form drug substance manufacturer.
3.2.P.2.5	Compatibility studies of the applied drug product with re constitution diluent shall be submitted.	Firm has submitted compatibility study with both water for injection and 0.9% NaCl as reconstitution diluent.
3.2.P.5.3	Performance of robustness parameter shall be submitted in drug product analytical method validation studies.	Submitted
3.2.P.5.4	Reports for sterility test of drug product of trial batches shall be submitted.	Microbiological reports submitted for performance for sterility tests.
3.2.P.8.3	Submit stability studies for the 6th month time point.	Submitted.

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

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

CLB in its 276th meeting held on 03rd September, 2020 has approved grant of additional section of Tablet (General) section for M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha. Now firm has applied following applications for priority consideration against new section priority.

331.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-09-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9210 dated 05-04-2023
	Details of fee submitted	PKR 30,000/- Dated 29-03-2023
	The proposed proprietary name / brand name	**PAINOXIA 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib…… 90 mg
	Pharmacotherapeutic Group of (API)	Antirheumatic
	Pharmaceutical form of applied drug	Film coated green colored round 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	Arcoxia Tablet approved by AEMPS of Spain
	For generic drugs (me-too status)	Starcox Tablet 90 mg of M/s Getz pharma, Pakistan Private Limited. (Reg.No. 105293)
	Name and address of API manufacturer.	M/**s** Kekule Pharma Limited MIA, Khazipally, Jinnaram Mandal Medak District, Telangana State. India – 502 319.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Starcox Tablet 90 mg manufactured by Getz pharma, Pakistan Limited. Firm has submitted CDP results of their product against the Starcox Tablet 90 mg of mM/s Getz 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** Kekule Pharma Limited MIA, Khazipally, Jinnaram Mandal Medak District, Telangana State. India – 502 319.		
API Lot No.	ACE06222		
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.	**PAINOXIA/90-01**	**PAINOXIA/90-02**	**PAINOXIA/90-03**
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	08-2022	08-2022	08-2022
No. of Batches	03		

332.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section 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 9209 dated 05-04-2023
	Details of fee submitted	PKR 30,000/- Dated 29-03-2023
	The proposed proprietary name / brand name	**PAINOXIA 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib…… 60 mg
	Pharmacotherapeutic Group of (API)	Antirheumatic
	Pharmaceutical form of applied drug	Film coated green colored round 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	Arcoxia Tablet approved by AEMPS of Spain
	For generic drugs (me-too status)	Starcox Tablet 60 mg of M/s Getz pharma, Pakistan Private Limited. (Reg.No. 075969)
	Name and address of API manufacturer.	M/**s** Kekule Pharma Limited MIA, Khazipally, Jinnaram Mandal Medak District, Telangana State. India – 502 319.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Starcox Tablet 60 mg manufactured by Getz pharma, Pakistan Limited. Firm has submitted CDP results of their product against the Starcox Tablet 60 mg of m/s Getz 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 Kekule Pharma Limited MIA, Khazipally, Jinnaram Mandal Medak District, Telangana State. India – 502 319.		
API Lot No.	ACE06222		
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.	**PAINOXIA-01**	**PAINOXIA-02**	**PAINOXIA-03**
Batch Size	3000Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	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)	Not available
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 cleared on 01-07-2022 in name of M/s Wimits Pharmaceuticals specifying 25Kg of Etoricoxib. The invoice is cleared by AD (I&E) DRAP, Lahore. Firm has also submitted loan letter for the Etoricoxib from M/s Wimits pharmaceuticals in name of m/s Quaper.
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 for the stability batches.
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	Firm's response
1.6.5	Submit valid GMP certificate/DML of drug substance manufacturer issued by concerned regulatory authority.	Firm has submitted copy of License no. 97906/TS/2022 valid till 06-12-2025 issued by Drugs Control Administration Government of Telangana India.
3.2.S.4.3	Analytical method verification studies of drug substance performed by M/s Quaper Pharmaceuticals shall be submitted.	Submitted
3.2.P.2.2.1	Justification shall be submitted for not performing of Pharmaceutical & CDP studies against the innovator drug product.	Due to non-availability of innovator drug product in the market we used the locally available brand of Starcox tablet for M/s Getz for comparative studies.
3.2.P.8.3	Submit raw data sheets for the dissolution test performed during stability studies.	Submitted.

Decision: Registration Board approved the applications of "PAINOXIA 90mg Tablet" & "PAINOXIA 60mg 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.**

333.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-09-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9211 dated 05-04-2023
	Details of fee submitted	PKR 30,000/- Dated 29-03-2023
	The proposed proprietary name / brand name	**QUZAN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq .to Vonoprazan……10 mg

	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker
	Pharmaceutical form of applied drug	Film coated yellow colored oblong tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vonoprazan Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vonozan Tablet 10 mg of M/s Getz pharma, Pakistan Private Limited. (Reg.No. 108570)
	Name and address of API manufacturer.	M/s Yinbin Hongguang Pharmaceutical Co., Ltd Luolong county nanxi district, Yinbin City, Sichuan Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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 Vonozan Tablet 10 mg manufactured by Getz pharma, Pakistan Limited. Firm has submitted CDP results of their product against Vonozan Tablet 10 mg by Getz pharma, Pakistan Limited 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 Yinbin Hongguang Pharmaceutical Co., Ltd Luolong county nanxi district, Yinbin City, Sichuan Province China.		
API Lot No.	MS103201-210901		
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.	**T1/22**	**T2/22**	**T3/22**
Batch Size	1500Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	10-01-2022	10-01-2022	10-01-2022
No. of Batches	03		

334.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-09-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9212 dated 05-04-2023
	Details of fee submitted	PKR 30,000/- Dated 29-03-2023
	The proposed proprietary name / brand name	**QUZAN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan Fumarate eq .to Vonoprazan……20 mg
	Pharmacotherapeutic Group of (API)	Potassium-competitive acid blocker
	Pharmaceutical form of applied drug	Film coated pink colored oblong tablet
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vonoprazan Tablet (PMDA Approved)

	For generic drugs (me-too status)	Vonozan Tablet 20 mg of M/s Getz pharma, Pakistan Private Limited. (Reg.No. 108571)
	Name and address of API manufacturer.	M/s Yinbin Hongguang Pharmaceutical Co., Ltd Luolong county nanxi district, Yinbin City, Sichuan Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	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 Vonozan Tablet 20 mg manufactured by Getz pharma, Pakistan Limited. Firm has submitted CDP results of their product against the Vonozan Tablet 20 mg manufactured by Getz pharma, Pakistan Limited 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 Yinbin Hongguang Pharmaceutical Co., Ltd Luolong county nanxi district, Yinbin City, Sichuan Province China.
API Lot No.	MS103201-210901
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.	**T1/22**	**T2/22**	**T3/22**
Batch Size	1500Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	11-01-2022	11-01-2022	11-01-2022
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)	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.	--
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[II]:

Section#	Observations	Firm's response
1.6.5	Submit valid GMP certificate/DML of drug substance manufacturer from relevant regulatory authority since submitted GMP certificate has been issued by Yibin Association of Pharmaceutical Industry.	Firm has submitted copy of GMP Certificate# SC20170003 valid till 16-03-2022 issued by CFDA.
3.2.P.5.1	Justification shall be submitted for not including test of content uniformity in the drug product specifications.	Firm has submitted revised drug product specifications including test for content uniformity.
3.2.P.8.3	Documents confirming import of drug substance shall be submitted.	Firm has submitted copy of commercial invoice attested by AD I&E DRAP, Lahore dated 08-11-2021 specifying 200g of Vonoprazan fumarate.

Decision: Registration Board approved the applications of "QUZAN 10mg Tablet" & "QUZAN 20mg 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.**

335.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**

	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-09-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14521 dated 09-06-2023
	Details of fee submitted	PKR 30,000/- Dated 05-06-2023
	The proposed proprietary name / brand name	**TERBI-Q 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as hydrochloride)…… 250 mg
	Pharmacotherapeutic Group of (API)	Antifungal for systemic use
	Pharmaceutical form of applied drug	White colored round uncoated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Tablet (TGA Australia Approved)
	For generic drugs (me-too status)	Lamisil Tablet 250 mg of M/s Novartis pharma, Pakistan Limited. (Reg.No. 013209)
	Name and address of API manufacturer.	Saptagir Laboratories Pvt. Ltd. Sy. No. Parts of 27, 46 and 50 to 56, Ananthsagar village, Chegunta mandal, Medak dist, Tilangana-502247, 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 Lamisil Tablet 250 mg manufactured by Novartis pharma, Pakistan Limited. Firm has submitted CDP results of their product against the innovator's product Lamisil Tablet 250 mg 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	Saptagir Laboratories Pvt. Ltd. Sy. No. Parts of 27, 46 and 50 to 56, Ananthsagar village, Chegunta mandal, Medak dist, Tilangana-502247, India.		
API Lot No.	TER04422		
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	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	29-11-2022	29-11-2022	29-11-2022
No. of Batches	03		

336.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.**
	Name, address of Manufacturing site.	M/s Quaper Private Limited 26-A Small Industrial Estate Lahore Road Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-08-2022 based on inspection conducted on 16-08-2022.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-09-2020 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14522 dated 09-06-2023
	Details of fee submitted	PKR 30,000/- Dated 05-06-2023
	The proposed proprietary name / brand name	**TERBI-Q 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as hydrochloride)…… 125 mg
	Pharmacotherapeutic Group of (API)	Antifungal for systemic use
	Pharmaceutical form of applied drug	White colored round uncoated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Tablet (TGA Australia Approved)
	For generic drugs (me-too status)	Lamisil Tablet 125 mg of M/s Novartis pharma, Pakistan Limited. (Reg.No. 013208)
	Name and address of API manufacturer.	Saptagir Laboratories Pvt. Ltd. Sy. No. Parts of 27, 46 and 50 to 56, Ananthsagar village, Chegunta mandal, Medak dist, Tilangana-502247, 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 Lamisil Tablet 125 mg manufactured by Novartis pharma, Pakistan Limited. Firm has submitted CDP results of their product against the innovator's product Lamisil Tablet 125 mg 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	Saptagir Laboratories Pvt. Ltd. Sy. No. Parts of 27, 46 and 50 to 56, Ananthsagar village, Chegunta mandal, Medak dist, Tilangana-502247, India.		
API Lot No.	TER04422		
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	11-2022	11-2022	11-2022
Date of Initiation	29-11-2022	29-11-2022	29-11-2022
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)	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. 54991/TS/2021) valid upto 01-03-2022 issued by Drugs Control Administration Government of Telangana 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 23-11-2022 specifying 150Kg of Terbinafine. The invoice is cleared by AD (I&E) DRAP, Lahore in name of M/s Wimits Pharmaceuticals. Firm has also submitted Loan letter form M./s Wimits Pharmaceuticals in name of M.s Quaper Pharmaceuticals
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
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:		
Decision: Registration Board approved the applications of "TERBI-Q 250mg Tablet" & "TERBI-Q 125mg 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.**		

M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
The Central Licensing Board in its 286th meeting held on 11th May, 2022 has considered and approved the grant of Drug Manufacturing License to M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore by way of Formulation vide approval letter No. F. 1-10/2012-Lic dated 7th June, 2022 with 3 sections including "Dry Powder Injection (Cephalosporin) Section".

337.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 37583 dated 23-12-2022
	Details of fee submitted	Rs.30,000/- dated 15-12-2022
	The proposed proprietary name / brand name	**Welcef 2g IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…2g
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Oxidil Injection of M/s Sami
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ceftriaxone sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, 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 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Q012008048, Q012008049, Q012008050)
	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 leader that is Oxidil injection 2g IV by M/s Sami by performing quality tests (Identification, PH, 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. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TDV001	TDV002	TDV003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	05-2022	05-2022	05-2022

Date of Initiation	19-05-22	20-05-22	21-05-22
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. SX20180229 issued by People's republic of China 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 letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	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.**			

The Central Licensing Board in its 284th meeting held on 16-12-2021 has considered and approved the grant of additional section to M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura by way of Formulation vide approval letter No. F. 1-10/2012-Lic dated 7th June, 2022 with 4 sections including "Dry Powder Injectable (Penicillin) Section".

338.	**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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy.No 5262 dated 23-02-2023
	Details of fee submitted	Rs.30,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Tazomac Injection 4.5gram**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin (as Piperacillin Sodium) ……. 4g Tazobactam (as Tazobactam Sodium) 0.5g
	Pharmaceutical form of applied drug	USP Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Antibiotics Penicillin: Broad-spectrum β-lactam Tazobactam: Beta-lactamase inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (ZOSYN 2.25g Injection)
	For generic drugs (me-too status)	Tanzo 4.5g Injection by M/s Bosch Pharmaceutical Pvt. Ltd. Karachi
	GMP status of the Finished product manufacturer	New license granted on 14/09/2021.
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: No. 849, Dongjia Town, Licheng District, 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, 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 is 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 (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 by M/s Bosch Pharma (Batch # PN220071) by performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Shandong Anxin Pharmaceutical Co. Limited. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	HF1162D3		
Description of Pack (Container closure system)	Tazomac Injection 4.5g is filled in Glass vial USP Type-II 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.	001	002	003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	28-07-2022	28-07-2022	28-07-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
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.	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
339.	**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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy.No 5261 dated 23-02-2023
	Details of fee submitted	Rs.30,000/- dated 06-01-2023
	The proposed proprietary name / brand name	**Tazomac Injection 2.25gram**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin (as Piperacillin Sodium) ……. 2g Tazobactam (as Tazobactam Sodium) 0.25g
	Pharmaceutical form of applied drug	Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Antibiotics Penicillin: Broad-spectrum β-lactam Tazobactam: Beta-lactamase inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (ZOSYN 2.25g Injection)
	For generic drugs (me-too status)	Tanzo 2.25g Injection by M/s Bosch Pharmaceutical Pvt. Ltd. Karachi Reg# 039593
	GMP status of the Finished product manufacturer	New section granted on 27-12-2021.
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: No. 849, Dongjia Town, Licheng District, 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, 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 is 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 48 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 (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 by M/s Bosch Pharma (Batch # PN220030).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Shandong Anxin Pharmaceutical Co. Limited. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	HF1162D3		
Description of Pack (Container closure system)	Tazomac Injection 2.25g is filled in Glass vial USP Type-II 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.	001	002	003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	28-07-2022	28-07-2022	28-07-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
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.	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	Firm's response
1.	**1.6.5**	Valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Copy of DML no. Lu20160009 valid till 09-11-2025 issued by CFDA
2.	**3.2.S.2.2**	Manufacturing procedure of drug substance indicate that formulated pre-mix sterile powder did not contain EDTA, how you will adjust the quantity of EDTA in the final dispensed powder per vial.	Firm has referred to the innovator drug product literature approved by US FDA stating that EDTA is only recommended for the Piperacillin/Tazobactam dry powder injection filled in plastic vial.
3.	**3.2.S.4.1**	Justify for adopting the assay limits different from that recommended in the USP monograph of Piperacillin and Tazobactam for injection.	Since we are procuring pre-mixed, ready to fill Sterile powder of APIs i.e Piperacillin and Tazobactam in (8:1) for which drug product monograph was not applied.
4.	**3.2.S.4.2**	• Evidence of availability of HPLC system equipped with Auto-sampler able to maintain temperature of 5 ± 3°, as required by USP monograph, shall be submitted. • Submitted analytical procedure for Assay test mentions the determination of "Meropenem" in calculation formula. Justification shall be submitted in this regard.	• Testing was performed with Shimadzu Shimadzu LC 20A system (Serial No. L20305566114, (Shimadzu, Tokyo, Japan). The system is equipped with a binary pump (LC-20AD), a temperature controlled auto-sampler (SIL-20ACHT), a temperature-controlled column compartment (CTO-20AC) which is equipped with thermoelectric Peltier technology, which has the ability to maintain temperature from 2oC to 50oC. Testing was carried by maintaining the temperature. • Documents of HPLC purchase, installation and calibration is submitted • Firm has submitted corrected analytical method.
5.	**3.2.S.5**	Justify of using Tazobactam pencillamine as working standard for analysis of drug substance since you have submitted the COA of working standard of Tazobactam Penicillamine, while USP recommends simple tazobactam reference standard for assay of drug substance.	Tazobactam penicillamine is used during analysis of related substance to identify the peak. Reference standard of Tazobactam penicillamine, is made by DS manufacturer i.e Shandong Anxin laboratory and it is used for the identity of peak

			and not for the calculation of impurity assay during the analysis. We used Tazobactam working standard as per USP monograph for Assay calculation. COA is submitted.
6.	**3.2.P.1**	• Justify the composition/strength (label claim) of the applied formulation i.e. 2352mg of pre-mix sterile powder of Piperacillin (as sodium) and Tazobactam (as sodium) and each vial contains a total of 2.79mEq (64mg) of sodium per gm of piperacillin and 0.5mg of EDTA in the combination product with reference to innovator product and submitted label claim.	• Actual weight of powder in a vial is to be decided after assay adjustment. Each 2.25g vial provides piperacillin sodium equivalent to 2 grams of piperacillin and Tazobactam sodium equivalent to 0.25 g of Tazobactam. Similarly, each 4.5g vial provides piperacillin sodium equivalent to 4grams of piperacillin and Tazobactam sodium equivalent to 0.5 g of Tazobactam. Mol. Weight of piperacillin sodium = 539.5 Mol. Weight of piperacillin sodium = 516.55 *Factor of Piperacillin = 1.042* Mol. Weight of Tazobactam sodium = 322.28 Mol. Weight of Tazobactam sodium = 300.29 *Factor of Tazobactam =1.073*
7.	**3.2.P.2.2.1**	• Justification shall be submitted for not performing tests of Bacterial endotoxin, sterility test, particulate matter test and uniformity of dosage unit test, as recommended by the USP monograph, during Pharmaceutical equivalence studies.	• Firm has referred to the performance of sterility testing during stability studies with acceptable results.
8.	**3.2.P.2.5**	Compatibility studies of the applied formulation with proposed re constitution diluent shall be submitted.	Submitted.
9.	**3.2.P.3.5**	Justification shall be submitted for not including all tests as per USP monograph in the finished product testing stage of process validation.	Firm has referred to the results of impurity testing performed by the drug substance manufacturer.
10.	**3.2.P.5.1**	• Submit the drug product analytical procedure document from M/s Fynk Pharmaceuticals instead of submitting the extract of USP monograph. • Evidence of availability of HPLC system equipped with Auto-sampler able to maintain temperature of 5 ± 3°, as required by USP monograph, shall be submitted. • Submitted analytical procedure for Assay test mentions the determination of "Meropenem" in	• Firm has submitted analytical procedure document form M/s Fynk Pharmaceuticals. • Testing was performed with Shimadzu Shimadzu LC 20A system (Serial No. L20305566114, (Shimadzu, Tokyo, Japan). The system is equipped with a binary pump (LC-20AD), a

		calculation formula. Justification shall be submitted in this regard. • Justify the variation in calculation formula from that proposed by USP monograph.	temperature controlled auto-sampler (SIL-20ACHT), a temperature-controlled column compartment (CTO-20AC) which is equipped with thermoelectric Peltier technology, which has the ability to maintain temperature from **2ºC to 50ºC**. Testing was carried by maintaining the temperature. • Evidence of HPLC purchase, installation and calibration is submitted
11.	**3.2.P.5.3**	• Submitted analytical method validation protocol declares that specificity test has to be performed under different conditions like heat, acid, base, oxidation to see the effects of theses on degradation, whereas no such performances are evident form the submitted analytical method verification report. • 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".	Specificity by Force degradation was not skipped because the DS manufacturer has performed the same. Since we are using ready to fill powder and no excipient are to add. However, we assure that Specificity study with force degradation will be performed on commercial batches.
12.	**3.2.P.6**	• Justify of using Tazobactam pencillamine as working standard for analysis of drug substance since you have submitted the COA of working standard of Tazobactam Penicillamine, while USP recommends simple Tazobactam reference standard for assay of drug substance.	Tazobactam penicillamine is used during analysis of related substance to identify the peak. Reference standard of Tazobactam penicillamine, is made by DS manufacturer i.e Shandong Anxin laboratory and it is used for the identity of peak and not for the calculation of impurity assay during the analysis. • We used Tazobactam working standard as per USP monograph for Assay calculation.
13.	**3.2.P.8.3**	• Clearance certificate or commercial invoice attested by AD I&E DRAP, Lahore shall be submitted as evidence of import of the drug substance. • COAs and complete raw data sheets wherein details of standard & sample solution preparation along with calculation formula applied for the performance stability studies shall be submitted for each time point. • Submitted HPLC chromatograms declare the injection volume as 20µl	• Firm has submitted License to import for 10 Kg of Piperacillin sodium/ Tazobactam sodium issued by AD I&E DRAP, Lahore dated 07-04-2022. • Submitted. • To achieve the system suitability, we use 20µl injection volume as per USP <621>, Method Verification also has

		whereas the USP monograph recommends the performance of Assay test with injection volume of 10µl.	been conducted for this variation.

Decision: Registration Board approved the applications of "Tazomac Injection 4.5gram" & "S Tazomac Injection 2.25gram".

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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 import cases

a. **New Cases (Human)**

340.	**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:** 002 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 15-08-2022 **Status:** by way of wholesaler **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	TÜM EKİP İLAÇ A.Ş; Address: İstanbul Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.55 34956 Tuzla-İSTANBUL/TURKEY
	Name, address of manufacturer(s)	TÜM EKİP İLAÇ A.Ş; Address: Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.63 34956 Tuzla-Istanbul/Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Firm has submitted original, legalized copy of CoPP certificate (No. 2020/2988) dated 13-10-2020 issued by Republic of Turkey Ministry of health and medical education. 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 13-10-2022. • Firm has submitted GMP certificate no. 06244 issued by Turkish Medicine & Medical Devices Agency for M/s	
	Details of letter of authorization / sole agency agreement • Firm has submitted copy of letter of authorization from TÜM EKİP İLAÇ A.Ş;Company. The letter shows that the manufacturer appoints M/s Gene-Tech Laboratories to register and market their products in Pakistan.	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 21170 dated 03-08-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021 & Rs.50,000/- dated 05-07-2021
	The proposed proprietary name / brand name	**Agrabloc 12.5mg/50ml Concentrate Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml Vial Contains: Tirofiban as hydrochloride monohydrate…12.5mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	B01AC17 Platelet aggregation inhibitors, except heparin
	Reference to Finished product specifications	In house
	Proposed Pack size	12.5mg/50ml, 1 vial per box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aggrastat 250mcg/ml injection approved by MHRA of UK
	For generic drugs (me-too status)	Agraban 12.5mg/50ml of M/s Pharmasol (Reg.106293)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy
	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)	The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 25ºC ± 2ºC and 60% ± 5% 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 report, control of excipients, control of drug product, specifications, analytical procedures, 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 of Caelyx injection has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	AGRABLOC 12.5 mg/50 ml IV Concentrate Solution For Infusion is packed with the following primary packaging materials: - 50 ml colorless Type I glass vial - 20 mm bromobutyl red rubber stopper - 20 mm flip-off cover AGRABLOC is supplied as 1 vial with a PIL in box containing approved text, batch number and expiration date.
	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 ± 2°C, 75 % ± 5 % R.H for 6 months. The real time stability study data is conducted at 30 ± 2°C, 75 % ± 5 % R.H for 24 months.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.3.3	Submit original valid legalized GMP certificate of drug product manufacturer and COPP of applied product issued by relevant regulatory authority of country of origin.	
1.3.5	Copy of valid DSL of the applicant shall be submitted.	
3.2.P.2.1	Submit drug-excipient compatibility studies since qualitative composition of applied formulation is different from that of the innovator drug product. Moreover Clarification shall be submitted regarding inclusion of mannitol in master formulation since innovator drug product does not contain it.	
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	
3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization.	
3.2.P.8.3	• Long term stability studies on Zone-IV conditions till claimed shelf life shall be submitted for three batches	

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

b. **Deferred cases**

341.	**Name, address of Applicant / Importer**	**M/s Biocare Pharmaceutica 807 Shdman-I, Lahore.**
	Details of Drug Sale License of importer	DSL No.: 05-352-0063-032069D Address: Biocare pharamceutica 80 shadman-I district

		Lahore. Validity: 17/04/2022 Status: License to sell drugs as Distributor
	Name and address of marketing authorization holder (abroad)	M/s Northeast Pharmaceutical Goup Shenyang No. 1 Pharmaceutical Co., Ltd., N0.8, Kunminghu street, Economic & Technological development zone, Shenyang, Liaoning
	Name, address of manufacturer(s)	M/s Northeast Pharmaceutical Group, Shenyang No. 1 Pharmaceutical Co., Ltd., No. 8, Kun Ming Hu street, Economic & Technological Development zone, Shenyang, Liaoning province, China.
	Exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certificate No. 20190072) issued by Liaoning Medical Products Administration valid till 29/07/2020. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP. • Legalized GMP certificate (No. LN20180007) valid till 25/03/2023.	
	Details of letter of authorization / sole agency agreement • Copy of sole agency agreement is submitted whereby M/s Biocare pharmaceutica is appointed as a distributor 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 30397 Dated 13/11/2020
	Details of fee submitted	Rs. 50,000/- Dated 20/08/2020 (1925409) Rs. 50,000/- dated 23/09/2020 (1925466)
	The proposed proprietary name / brand name	Fosofix Injection 4gm Alternate brand name: Fonyl Fosfix
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Fosfomycin as disodium……..4gm (equivalent to Fosfomycin disodium……5.28g)
	Pharmaceutical form of applied drug	Powder for solution for intravenous injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	In-house
	Proposed Pack size	1’s
	Proposed unit price	Rs. 1700/-
	The status in reference regulatory authorities	Fosfomycin 40mg/ml powder for solution for infusion (4gm) by M/s Infectopharm, MHRA approved.
	For generic drugs (me-too status)	Fosfomycin injection 4gm by M/s Efroze KHI, R.No.004722
	Module-II (Quality Overall Summary)	Submitted.

	Name, address of drug substance manufacturer	M/s Northeast Pharmaceutical Group Co., Ltd., 29 Shenxi Liudong road, Shenyang Economic and Technical Development zone, China. (GMP certificate No. LN20190041 valid till 15/07/2024)
	Module-III Drug Substance:	Submitted
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 36 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
	Module-III Drug Product:	Submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference product, Fosmicin-S manufactured by M/s Meiji Seka Kaisha ltd, Japan.
	Analytical method validation/verification of product	COAs: 10119030002, 10119030003, 10119030.
	Container closure system of the drug product	Injection vials made up of molded soda lime glass, rubber stopper and aluminium -plastic laminated cap
	Stability study data of drug product, shelf life and storage conditions	• 18 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

- The product in reference country in approved with a primary packaging of 100ml glass bottle while the volume of vial of the applied product is 30ml.
- The firm has submitted Original, legalized and vlaid CoPP (certificate No. 20210027) issued by Liaoning Medical Products Administration valid till 07/01/2023. The product is available for free sale in the market of exporting country. The facilities and operations conform to Chinese-GMP.
- Analytical method verification studies for API performed by drug product manufacturer are not submitted. The firm has stated that the API testing was conducted as per Chinese Pharmacopoeia therefore verification studies are not required. Moreover, the official monograph for API is present in British Pharmacopoeia.

Decision of 308th meeting:

Deferred for of following points;

- Clarification since the product in reference country in approved with a primary packaging of 50ml glass bottle while the volume of vial of the applied product is 30ml.
- Submission of analytical method validation/verification studies of drug substance performed by drug product manufacturer**.**
- Submission of real time stability study data according to the conditions of zone IV-A of 03 batches till shelf life since the submitted data is of 18 months only.

Evaluation by PEC-I:

- The firm has provided the following reference of the product which is approved with 30ml volume of the vial which is in-lined with the volume of the vial of the applied product.
  Ivozfo (Fosfomycin for injection) (2g, 4g, 8g) by M/s Verity Pharmaceuticals, Ontario, Health Canada Approved.

  IVOZFO™ (fosfomycin for injection) is supplied in clear type-I glass vials with a rubber stopper (bromobutyl rubber) and pull-off cap containing 2 g (in 30 mL vial), 4 g (in 30 mL vial) or 8 g (in 50 mL vial) of fosfomycin, respectively, in packs of 10 vials each.

  https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=97819 (accessed on 12/11/2021 at 7pm)
- As per MHRA, Water for Injections and Glucose Infusion 50 mg/ml (5 %) or Glucose Infusion 100 mg/ml (10 %) may be used as solvent for the reconstitution and dilution while according to HealthCanada, 5% dextrose solution must be used. Whereas both the authorities recommend that Sodium chloride containing solvents must not be used.
- Reconstitution: (MHRA, Ireland & Health Canada)

Shake the vial prior to the reconstitution to loosen up the powder. Reconstitute the 2 g or 4 g vials with 20ml solvent.

- Dilution (MHRA, Ireland & Health Canada)
  Transfer the reconstituted contents of **2 g vials** into an infusion container with further **30 ml** of solvent.
  Transfer the reconstituted contents of **4 g vials** into an infusion container with further **80 ml** of solvent.
- The firm has submitted analytical method validation studies for Fosfomycin including precision, accuracy, linearity and specificity. The validation studies for impurities have also been submitted.
- The firm has submitted stability data with the following details;
  24 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches
  06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
  Batches: 4190406, 4190407, 4190408
- As per the provided data, the in-use after reconstitution with 5% and 10% dextrose solution for 12 hours.
- The applied product is developed and tested according to In-House specifications while the official monograph of the product is available in J.P. The comparison of In-house and J.P specificaytions are given below.

Test	**Limits defined by J.P**	**In-house limits**
pH	6.5-8.5	6.5-8.5
Fosfomycin sodium diol (impurity A)	Test not performed	≤ 1%
Clarity of solution	Clear and colorless	Clear and colorless Should not be more pronounced than the reference suspension 1. Any color produced should not be more intense than reference solution yellow 1.
Water	≤ 4%	≤ 2%
Bacterial endotoxins	Less than 0.025EU/mg	Less than 0.033EU/mg
Visible particles	clear and free from foreign insoluble matters (foreign insoluble matter)	Absent
Particulate matter	≤ 6000/container (≥10um) ≤ 600/container (≥25um)	≤ 6000/container (≥10um) ≤ 600/container (≥25um)
Weight variation	Should meet the requirement <6.02>	±5%
Assay	90-110% **Cylinder plate method** Test Organism: Proteus Sp.	90-110% **Cup plate method** Test Organism: Micrococcus Luteus **Nephelometry test (parallel lines method)** Test Organism: Escheritia Coli

Decision of 313th meeting: The Board deliberated that the specifications limits as defined by Japanese Pharmacopoeia are more stringent and tighter than the established In-House specification as well as the method used for the testing of the applied product are also different from the method developed In-House. Therefore, the Board decided to defer the case and directed the firm to submitted all the relevant data according to the the monograph present in Japanese Pharmacopoeia.

Firm's response: According to our manufacture they recently adapted EP10.0/Innovator Standard Specification based upon International UK, Canada and Europe Fosfomycin Sodium 4 gm brands Standard. In UK, Europe and Canada they follow EP 1.0/Innovator standard instead of JPXVIL. Even in Bangladesh for Fosfomycin Sodium 4 gm they follow EP/Innovator standard. So, based upon European Pharmacopeia 10.0/Innovator standard of UK/German approved brand FOMICYT 4 GM (Infecto Pharm, Germany), Canada IVOZFO 4 GM (Verity Pharmaceuticals, Canada) & FOSFOCINE IV 4 gm Sanofi Aventis, France, our Manufacture Fosfomycir Sodium 4 gm follow EP 10.0/Innovator standard Overall our manufacturer (Northeast Pharmaceutica Group) current Fosfomycin Sodium 4 gm Sterile Powder vial follow EP10.0/Innovator

Decision: Deferred for submission of product development and stability studies data as per Japanese pharmacopeoia monograph of "Fosfomycin for injection".

342.	Name, address of Applicant / Importer	M/s The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.

		Kalalwala Stop, 20Km Lahore- Jaranwala Road, District Sheikhupura, Pakistan.
	Details of Drug Sale License of importer	License No: 05-354-0076-059245D Address: Kalalwala Stop, 20Km Lahore- Jaranwala Road, District Sheikhupura, Pakistan. Validity: 25-09-2022 Status: License to sell drugs as distributor Renewal: Firm has submitted a receipt of renewal but it does not contain any date
	Name and address of marketing authorization holder (abroad)	M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, (India).
	Name, address of manufacturer(s)	M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, (India).
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate (No. 022105) valid till 07-11-2019 issued by Food & Drugs Control Administration, Gujarat, India. 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 certificate from M/s BDR Pharmaceuticals International Pvt. Ltd
	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. 17603 dated 16-06-2022
	Details of fee submitted	PKR 75,000/- dated 13-04-2022
	The proposed proprietary name / brand name	Arbit Tablets USP 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Abiraterone acetate …… 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Other hormone antagonists and related agents
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZYTIGA 500 mg Janssen-Cilag International NV USFDA 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	BDR Life Sciences Private Limited R.S.NO.578, Near Effluent, Channel Road, Village Luna – 391 440, Ta.Padra, Dist. VADODARA, 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 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% 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 studies against the innovator product of Zytiga tablet 250mg while CDP studies have bene performed in three dissolution mediums of pH 1.2, 4.5 & 6.8 against the Zytiga 250mg tablet.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product as per USP monograph.
	Container closure system of the drug product	HDPE Container
	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% RH for 36 months.

Remarks of Evaluator:

Section#	Observation
1.1	Fee for registration has been submitted from header of DML instead of DSL. Submit valid copy of DSL.
1.3	Submit original legalized valid COPP since the submitted COPP was expired at the time of submission of registration application. Submit evidence of approval for the required manufacturing facility “Tablet (steroid)” for the applied formulation.

3.2.P.2.2.1	Submit justification for performing Pharmaceutical equivalence studies against the Zytiga 250mg tablet while the applied strength is 500mg.

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 vide their letter no. ref; SPL/BDR/3147 vide R&I dated 21-06-2023.

Section#	Observation	Firm's response
1.1	Fee for registration has been submitted from header of DML instead of DSL. Submit valid copy of DSL.	Not submitted
1.3	Submit original legalized valid COPP since the submitted COPP was expired at the time of submission of registration application. Submit evidence of approval for the required manufacturing facility "Tablet (steroid)" for the applied formulation.	Original Legalized COPP no. MFG/WHO GMP/COPP/2023/1951221591 issued by food 7 Drugs Control Administration, Gujarat, with following particulars: • Product license holder: M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, (India). • Free sale status in country of origin (India): Yes. • GMP status of the manufacturer endorsed: Yes. • Validity: 09-01-2026 Firm has also submitted copy of GMP certificate no. 1711454 (valid till 07-11-2019) issued by Food & Drugs Control Administration in name Of M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, Gujarat State (India) declaring availability of Tablet & Capsule (Cytotoxic) section.
3.2.P.2.2.1	Submit justification for performing Pharmaceutical equivalence studies against the Zytiga 250mg tablet while the applied strength is 500mg.	We BDR Pharmaceutical In. pvt. Ltd hereby justify that the Bioequivalence study with the title "A randomized open label balanced two period two sequence single dose two way crossover oral bioequivalence study of our Arbiraterone acetate 500mg tabklets of BDR Pharmaceutical international pvt. Ltd compare with Zytiga 250mg tablets of Janssen biotech inc., Horsham at a dose of 500mg (2 / 250mg) in a 36 healthy human adult male subjects under fasting conditions has started on Jan 2017 and completed on 02-02-2017 and complete don 02-02-2017. At the time of BE Study for Arbirtaerone tablet USP only Zytiga 250mg (N202379 001) HAS LISTED AS Rld IN ORANGE BOOK. Zytiga 500mg tablets has listed as RLD in Apr, 14, 2017. Therefore we selected the Zytiga 250mg as RLD against of the Arbirtaerone tablets 500mg.

Decision: Deferred for following:

- **Full fee of registration from the head of Drug Sale License.**

- **Pharmaceutical equivalence and CDP studies against the relevant strength i.e., 500mg of the Innovator drug product.**
- **Further deliberation regarding requirement of manufacturing facility for applied formulation.**

343.	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	**DSL No.:** 05-352-0065-016174D **Address:** Himmel Pharmaceuticals (Pvt) Ltd 793 D, Block C, Faisal Town, District Lahore. **Godown:** N/A **Validity:** 06/02/2022 **Status:** License to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited, Office Address: 9/B/2, Toyenbee Circular road, Motijheel, Dhaka, Bangladesh. Plant Address: Kathali, Bhaluka, Mymensingh Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited, Office Address: 9/B/2, Toyenbee Circular road, Motijheel,C/A Dhaka-1000, Bangladesh. Plant Address: Kathali, Bhaluka, Mymensingh Bangladesh.
	Exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certificate No. DA/6-110/2016/3288) issued by Directorate General of Drug Administration on 01/06/2020. The applied product is available in market of exporting country for free sale. The facilities and operations conform to WHO-GMP. • Copy of GMP certificate No. DA/6-11-/06/4950 dated 17/07/2019 on the basis of inspection conducted on 07/07/2018 (expired).	
	Details of letter of authorization / sole agency agreement • Copy of letter of authorization is submitted whereby M/s Himmel Pharmaceuticals is authorized to register and sell different products including Cobazanix capsule (20mg & 80mg).	
	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 4311 Dated 08/02/2021
	Details of fee submitted	Rs. 50,000/- Dated 10/12/2020
	The proposed proprietary name / brand name	**Cabozanix 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cobazanitinib as S-Malate……20mg
	Pharmaceutical form of applied drug	Immediate release hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In-house

	Proposed Pack size	90's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cometriq Capsule (20mg, 80mg) by Ipsen Pharma, EMA approved.
	For generic drugs (me-too status)	N/A
	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.
	Name, address of drug substance manufacturer	M/s Beijing Mesochem Technology Co., Ltd., Floor 23, Building 9, Lippo Plaza, Economic and technological Development zone Beijing (GMP certificate not provided).
	Module-III Drug Substance:	The API used belongs to BCS class II. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 24 months real time stability data at 25˚C ± 2˚C / 60% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches (150528, 150712, 150925)
	Module-III Drug Product:	Batch analysis (3590002, 3590003, 3590004) Detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	CDP against the reference product, Cometric 20mg Capsule by M/s Ipsen Pharma, France (EMA Approved) is submitted with acceptable values of f1 and f2. (Batch number C22001).
	Analytical method validation/verification of product	Data of analytical method validation is submitted including, specificity, accuracy, ruggedness, precision and linearity etc for assay of API. (validation studies of analytical method for related substance have submitted as well.
	Container closure system of the drug product	HDPE pot with srew cap, induction sealable wad containing 90 capsules along with silica gel, packed in secondary outer carton.
	Stability study data of drug product, shelf life and storage conditions	Batches: (3590002, 3590003, 3590004) Batch size: 10,000 capsules • 24 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches

		• 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches

Evaluation by PEC-I:

The drug substance manufacturer is M/s Beijing Mesochem Technology Co., Ltd., China. The submitted GMP certificate is of M/s Kaifeng Pharmaceutical (group) Co., Ltd., China. The applicant has submitted a letter form M/s Beijing Mesochem Technology Co., Ltd., China stating;

"We Beijing Mesochem Technology Co., Ltd., certiifctae that Beijing Mesochem is a manufacturer. According to cooperation agreement currently, Beijing Mesochem tehnology Co., ltd., is manufacturing at Kaifeng Pharmaceutical (group) co., Ltd.,. as per the agreement enclosed. We guarantee the site equivalence and analytical/product equivalence".

Observation	**Response**
Since the excipients used in the manufacturing of the product are different from the excipients used in manufacturing of reference product, therefore, compatibility study of the excipients with API is required to be performed. The information should be presented under relevant section in module II and module III.	The excipients used comply to current pharmacopoeial monograph (BP). These excipients are pharmaceutically inert substances and These excipients are used below "Inactive Ingredient Guide" limit of FDA. Extensive analysis of the product is done and satisfactory results of assay, dissolution and impurity profile are obtained.
Test for Genotoxic impurities in addition to impurity profiling, is included in the final specifications of the reference product while the test is not included in the specifications of the applied product, please clarify.	Not responded
As per EMA assessment report of the innovator's product, the testing specification for Drug Substance include tests for malic acid content, organic volatile impurities, genotoxic impurities, crystal form, particle size distribution and percentage purity as well while the testing specifications for Drug Substance used for the manufacturing of the applied product do not include the above-mentioned tests, please explain. Moreover, a discussion shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria with reference to above query under relevant sections in Module II and Module III.	Not responded
Pharmaceutical equivalence of the applied product is established against the innovator's product Cabometyx capsule by Ipsen Pharma France as per the submitted dossier, while Cabometyx by Ipsen Pharma, France is not actually Capsule dosage form. The mentioned brand name that is Cabometyx is film coated tablet as per the information provided on the official website of ANSM, France, please clarify.	The firm has submitted copy of clarification letter from M/s Beacon Pharmaceuticals Limited. **"**Cabometyx and Cometriq are two brand name drugs that both contain the same active ingredient of Cabozanitinib by Ipsen Pharma, France. While Cabometyx is film coated tablet and Cometriq is Capsule dosage form as per the information provided on EMc. During Bio-equivalence studies of Cabozanix 20mg Capsule, Cometriq Capsuel (B/NC21801) used as reference product".
Scientific justification for the use of 1% overage in the formulation is required.	Not responded

Previous Decision of 313th meeting: Deferred for the following;

- Submission of impurity profiling as per the innovator's product including the detail of testing of genotoxic impurities.
- Justification for not performing certain tests which include malic acid content, organic volatile impurities, genotoxic impurities, crystal form, particle size distribution and percentage purity for drug substance.
- Scientific justification for the use of 1% overage in the formulation

344.	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	**DSL No.:** 05-352-0065-016174D **Address:** Himmel Pharmaceuticals (Pvt) Ltd 793 D, Block C,

		Faisal Town, District Lahore. **Godown:** N/A **Validity:** 06/02/2022 **Status:** License to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited, Office Address: 9/B/2, Toyenbee Circular road, Motijheel, Dhaka, Bangladesh. Plant Address: Kathali, Bhaluka, Mymensingh Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited, Office Address: 9/B/2, Toyenbee Circular road, Motijheel,C/A Dhaka-1000, Bangladesh. Plant Address: Kathali, Bhaluka, Mymensingh Bangladesh.
	Exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized CoPP (certificate No. DA/6-110/2016/3289) issued by Directorate General of Drug Administration on 01/06/2020. The applied product is available in market of exporting country for free sale. The facilities and operations conform to WHO-GMP. • Copy of GMP certificate No. DA/6-11-/06/4950 dated 17/07/2019 on the basis of inspection conducted on 07/07/2018 (expired).	
	Details of letter of authorization / sole agency agreement • Copy of letter of authorization is submitted whereby M/s Himmel Pharmaceuticals is authorized to register and sell different products including Cobazanix tablet 60mg.	
	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 4306 Dated 08/02/2021
	Details of fee submitted	Rs. 50,000/- Dated 10/12/2020
	The proposed proprietary name / brand name	**Cabozanix 60mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Cobazantinib as S-Malate……20mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In-house
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cabometyx tablet (20mg, 40mg, 60mg) by M/s Ipsen Pharma EMA Approved.
	For generic drugs (me-too status)	N/A
	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.
	Name, address of drug substance manufacturer	M/s Beijing Mesochem Technology Co., Ltd., Floor 23, Building 9, Lippo Plaza, Economic and technological Development zone Beijing (GMP certificate not provided).
	Module-III Drug Substance:	The API used belongs to BCS class II. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 24 months real time stability data at 25˚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:	Batch analysis (3850002, 3850003, 3850004) Detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product is submitted. The dissolution specifications are as per USFDA dissolution method available online.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has performed Pharmaceutical Equivalence against the innovator's product, Cabometyx 60mg tablet by M/s Ipsen Pharma, France (EMA approved) (Batch number C91801). CDP against the reference product, Cabometyx 60mg tablet by M/s Ipsen Pharma, France (EMA Approved) is submitted. (Batch number C22001).
	Analytical method validation/verification of product	Data of analytical method validation is submitted including, specificity, accuracy, ruggedness, precision and linearity etc for assay of API. (validation studies of analytical method for related substance have submitted as well.
	Container closure system of the drug product	HDPE bottle with srew cap and induction sealable wad and silica gel containing 30 tablets packed in secondary outer packaging.
	Stability study data of drug product, shelf life and storage conditions	Batches: (3850002, 3850003, 3850004) Batch size: 6666 tablets • 24 months real time stability data at 30˚C ± 2˚C / 75% ± 5%RH of 03 batches • 06 month accelerated stability data 40˚C ± 2˚C / 75% ± 5%RH of 03 batches
Evaluation by PEC-I: The drug substance manufacturer is M/s Beijing Mesochem Technology Co., Ltd., China. The submitted GMP certificate is of M/s Kaifeng Pharmaceutical (group) Co., Ltd., China. The applicant has submitted a letter form		

M/s Beijing Mesochem Technology Co., Ltd., China stating;
"We Beijing Mesochem Technology Co., Ltd., certiifctae that Beijing Mesochem is a manufacturer. According to cooperation agreement currently, Beijing Mesochem tehnology Co., ltd., is manufacturing at Kaifeng Pharmaceutical (group) co., Ltd.,. as per the agreement enclosed. We guarantee the site equivalence and analytical/product equivalence".

Observation	**Response**
Since the qualitative composition of the applied product is different from the innovator/reference product, therefore, compatibility studies of the excipients with the drug substance is required. The information should be presented under relevant section in module II and module III.	The excipients used comply to current pharmacopoeial monograph (BP & USP). These excipients are pharmaceutically inert substances and These excipients are used below "Inactive Ingredient Guide" limit of FDA. Extensive analysis of the product is done and satisfactory results of assay, dissolution and impurity profile are obtained.
Justify the manufacturing process of the applied product since it is a type of direct compression method while the reference product is manufactured by wet granulation method.	"As per Beacon's manufacturing process, Direct compression method is used and the process is validated".
Test for Genotoxic impurities in addition to impurity profiling is including in the final specifications of the reference product while the test is not included in the specifications of the applied product, please clarify.	Not responded
As per EMA assessment report of the innovator's product, the testing specification for Drug Substance include tests for malic acid content, organic volatile impurities, crystal form, particle size distribution and percentage purity as well while the testing specifications for Drug Substance used for the manufacturing of the applied product do not include the above-mentioned tests, please explain. Moreover, a discussion shall be provided on the inclusion of certain tests, evolution of tests, analytical procedures and acceptance criteria with reference to above query under relevant sections in Module II and Module III.	Not responded

Decision of 313th meeting: Deferred for the following;

- Submission of impurity profiling as per the innovator's product including the detail of testing of genotoxic impurities.
- Justification for not performing certain tests which include malic acid content, organic volatile impurities, genotoxic impurities, crystal form, particle size distribution and percentage purity for drug substance.
- Submission of relevant data for drug substance as per the GUIDANCE DOCUMENT FOR SUBMISSION OF APPLICATION ON FORM 5-F FOR REGISTRATION OF PHARMACEUTICAL DRUG PRODUCTS FOR HUMAN USE available on the official website of DRUG REGULATORY AUTHORITY OF PAKISTAN.
- Clarification since the GMP certificate of M/s Kaifeng Pharmaceutical (group) Co., Ltd., China is submitted while as per submitted dossier the manufacturer of drug substance is M/s Beijing Mesochem Technology Co., Ltd., China and the relevant data related to drug substance is submitted from M/s Beijing Mesochem Technology Co., Ltd., China.

Firm's response: Firm has submitted following:

- Declaration form M/s Beijing Mesochem Technology Co., Ltd that Cabozanitinib malate is free of genotoxic impurities and organic solvents.
- Declaration form M/s Beijing Mesochem Technology Co., Ltdis a manufacturer. Acoridng to cooperation agreement currently Beijing Mesochem manufacture at Kaifeng Pharmaceutical (group) Co. ltd as per the agreement. We guarantee the site equivalence and analytical/product equivalence.
- COA of drug substance including tests of malic acid content, percentage purity and bulk density.

Decision: Registration Board approved the applications of "Cabozanix 20mg Capsule" & "Cabozanix 60mg Capsule" as per policy of inspection of manufacturer abroad.

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, 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. **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**

In compliance to the Authority decision mentioned above the following applications were considered by the board after due evaluation.

345.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mediate Pharmaceutical (PVT.) LTD. Plot No:-150-151, Sector 24, Korangi Industrial Area, Karachi Pakistan.**
	Name, address of Manufacturing site.	M/s Mediate Pharmaceutical (PVT.) LTD. Plot No:-150-151, 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	Last inspection of M/s Mediate Pharmaceuticals conducted on 10.05.2022 declaring GMP status as good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 15th -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 707 dated 09-01-2023
	Details of fee submitted	Rs.30,000/- dated 14-12-2022
	The proposed proprietary name / brand name	**Epimed DR Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release tablet contains: Divalproex sodium eq. to Valproic acid…….

		500mg Containing 538.2 mg of valproate semisodium* per tablet (equivalent to 500 mg of valproic acid). *Valproate semisodium is a stable coordination compound comprised of sodium valproate and valproic acid in a 1:1 molar relationship. It is also known as divalproex sodium (USAN).
	Pharmacotherapeutic Group of (API)	Psycholeptics, Antipsychotics, Other Antipsychotics, ATC code: N05AX.
	Pharmaceutical form of applied drug	Yellow colored enteric coated oblong shape tablet plain from both sides.
	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)	Dipodium 500mg Tablet of M/s Amarant Pharmaceutical Pvt. Ltd. (Reg.No:058621)
	Name and address of API manufacturer.	M/s Sun Pharmaceutical Industries Ltd.Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu - 603 303, 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, solubilises, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 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 innovator's product Depakote tablet 500mg manufactured by Schering –Plough Corporation. Firm has submitted CDP results of their product against the innovator's product Depakote Tablet 500mg 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 Sun Pharmaceutical Industries Ltd.Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu - 603 303, India.		
API Lot No.	DVLNF20085		
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.	MD/EM-01	MD/EM-02	MD/EM-03
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	04-2022	04-2022	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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing for stability studies
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	Firm's response
1.6.5	Submit valid GMP certificate/ DML of the drug substance manufacturer.	Firm has submitted copy of Certificate# 16478/D1/4/2021 issued by Department of Food Safety & Drugs Control Administration, Government of Tamil Nadu, valid upto 31-12-2024.
3.2.P.2.2.1	Submit comparative dissolution profile along with f2 factor calculation	Submitted
3.2.P.8.3	Submit documents confirming import of drug substance issued by DRAP I&E office.	Firm has submitted copy of loan letter from Wimits Pharmaceuticals for 2Kg of Divalproex sodium along with import documents issued by DRAP I&E Lahore.
2.3.R.1	Submit complete batch manufacturing record for 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.**

346.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Evidence of manufacturing facility	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21 declares availability of tablet general section
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 13223 dated 30-05-2022
	Details of fee submitted	Rs.30,000/- dated 01-11-2021
	The proposed proprietary name / brand name	**Dpiro 500mg CR tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release tablet contains: Divalproex sodium equivalent to Valproic acid……....500mg
	Pharmaceutical form of applied drug	Extended Release Tablet

	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Depakote ER 500mg tablet USFDA Approved.
	For generic drugs (me-too status)	Towprox CR 500mg tablet of M/s Crystolite (Reg.#087346).
	Name and address of API manufacturer.	M/s Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu – 603 303, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PDMDVLFL183, PDMDVLFL184, PDMDVLFL185)
	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 EPIVAL 500mg CR tablet by Abbott Laboratories by performing quality tests (Identification, Assay, Dissolution, Uniformity of the dosage form). CDP has been performed against the same brand that is EPIVAL 500mg CR tablet by Abbott Laboratories in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA			
Manufacturer of API	M/s Sun Pharmaceutical Industries Ltd Address: Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamilnadu – 603 303, India.		
API Lot No.	DVLNF20085		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (5×10'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.	TDA001	TDA002	TDA003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	21-12-2021	22-12-2021	23-12-2021
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.	Copy of GMP certificate No. K Dis, No: 17264/D1/4/2018 issued by Department of Safety & Drugs Control Administration Government of Tamilnadu valid untill 31/12/2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.10847/2020-DRAP Dated 06/08/2020 is submitted wherein the permission to import different APIs including Divalproex sodium USP for the purpose of test/analysis and stability studies is granted. Invoice Number: 700004927, dated 20/07/2020
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 Evaluator:

Section#	Observations	Firm's response
1.6.5	Submit valid GMP certificate/DML of the drug substance manufacturer.	Firm has submitted copy of Certificate# 16478/D1/4/2021 issued by Department of Food Safety & Drugs Control Administration, Government of Tamil Nadu, valid upto 31-12-2024.
2.3.R.1	Submit complete batch manufacturing record for stability batches.	Firm has submitted batch manufacturing record for three stability batches.

3.2.P.1	Submit clarification regarding the proposed quantity of Divalproex sodium per unit tablet against the label claim for Valproic acid.	Firm has referred to the molecular structure of Dilavproex sodium which is comprised of sodium valproate and valproic acid in a 1:1 molar relationship, hence proposed weight per unit tablet is justified with factor of molecular weight.
3.2.P.5.2	Specify which Dissolution test has been adopted from USP monograph for the drug product specifications.	Dissolution test 4 of USP monograph has been adopted.
3.2.P.8.3	Submit raw data sheets for the dissolution test for complete stability studies.	Submitted.

Decision: Approved with "Dissolution Test 4" of USP monograph of "Divalproex sodium extended release 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.**

Case no. 05 Registration applications for local manufacturing of (Human) drugs

a. **New cases**

347.	Name, address of Applicant / Marketing Authorization Holder	**M/s Cortex Pharmaceuticals. Plot # 16-A, SS-4, RCCI, Rawat, Rawalpindi, Punjab**
	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) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Shawan Pharmaceuticals:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 24-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of renewal of DML letter dated 03-09-2019 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 33300 dated 09-12-2021
	Details of fee submitted	Rs.75,000/- dated 25-11-2021
	The proposed proprietary name / brand name	**Q-Dux 1000mg 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	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	For generic drugs (me-too status)	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 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 their product against Zantum Injection of Medizan.
	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.	1078DJ81NE
Description of Pack	Glass Vials

(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.	T001	T002	T003
Batch Size	10100 vials	10100 vials	10100 vials
Manufacturing Date	06-2021	06-2021	06-2021
No. of Batches	03		

348.	Name, address of Applicant / Marketing Authorization Holder	**M/s Cortex Pharmaceuticals.** **Plot # 16-A, SS-4, RCCI, Rawat, Rawalpindi, Punjab**
	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) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Shawan Pharmaceuticals:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 24-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of Issuance of renewal of DML letter dated 03-09-2019 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 33301 dated 09-12-2021
	Details of fee submitted	Rs.75,000/- dated 25-11-2021
	The proposed proprietary name / brand name	**Q-Dux 2000mg 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	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for

		injection **Slovakia:** Sulcef 2g powder for solution for injection
	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 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 their product against Zantum Injection of Medizan.
	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.	1078DJ81NE
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.	T001	T002	T003
Batch Size	10100 vials	10100 vials	10100 vials
Manufacturing Date	06-2021	06-2021	06-2021
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. SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of License issued by AD I&E specifying import of 200Kg Cefoperazone sodium and Sulbactam sodium to M/s Shawan Pharmaceuticals dated 22-06-2022
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	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.

Evaluation by PEC:

Section#	Observations	Firm's response
3.2.P.8.3	Submit both accelerated & long term stability studies data till 6th month time point for all the stability batches.	Submitted

Decision: Registration Board approved the applications of "Q-Dux 1000mg Injection" & "Q-Dux 2000mg Injection".

- **Firm shall submit Pharmaceutical equivalence studies of each strength against the innovator/brand leader product before issuance of registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Shawan Pharmaceuticals Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi.

349.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Pvt Ltd. Lahore

	Name, address of Manufacturing site.	M/s CCL Pharma Pvt. Ltd. Plot 62 Quaid e Azam 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 8802 dated 06-04-2022
	Details of fee submitted	PKR 75,000/-: dated 16/03/2022
	The proposed proprietary name / brand name	**Trijardy XR Tablet 25mg/5mg/ 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..25mg Linagliptin……5mg Metformin HCl……1000mg
	Pharmaceutical form of applied drug	Light Brown colored, oblong biconvex shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet 25mg/5mg/1000mg by M/s Boehringer Ingelheim, USFDA Approved.
	For generic drugs (me-too status)	Not Applicable
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 30-04-2019
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru-534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Empagliflozin Batches: (20160606, 20161017, 20161219) Linagliptin Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) Metformin HCL Batches: (MS-0220601 Lot A, MS-0220601 Lot B, MS-0230601 Lot A, MS-0230601 Lot B, MS-0240601 Lot A, MS-0240601 Lot B,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Trijardy XR 25mg / 5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim international by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 25mg / 5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru- 534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-02 **Linagliptin:** L-20200920-D01-L09-01 **Metformin HCl:** MT02000221
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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.		ELMXD-T2-21	ELMXD-T3-21	ELMXD-T4-21
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		06-2021	06-2021	06-2021
Date of Initiation		06-2021	06-2021	06-2021
No. of Batches		03		
350.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Pvt Ltd. Lahore		
	Name, address of Manufacturing site.	M/s CCL Pharma Pvt. Ltd. Plot 62 Quaid e Azam 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 8801 dated 06-04-2022		
	Details of fee submitted	PKR 75,000/-: dated 16/03/2022		
	The proposed proprietary name / brand name	**Trijardy XR Tablet 12.5mg/2.5mg/ 1000mg**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..12.5mg Linagliptin……2.5mg Metformin HCl……1000mg		
	Pharmaceutical form of applied drug	Brown colored, oblong biconvex shaped film coated tablet		
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs.		
	Reference to Finished product specifications	Innovator		
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Trijardy XR Tablet 12.5mg/2.5mg/1000mg by M/s Boehringer Ingelheim, USFDA Approved.		
	For generic drugs (me-too status)	Not Applicable		
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 30-04-2019		
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru-534217, Iragavaram Mandal,		

		West Godavari District Andhra Pradesh; India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Empagliflozin Batches: (20160606, 20161017, 20161219) Linagliptin Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) Metformin HCL Batches: (MS-0220601 Lot A, MS-0220601 Lot B, MS-0230601 Lot A, MS-0230601 Lot B, MS-0240601 Lot A, MS-0240601 Lot B,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Trijardy XR 12.5mg / 2.5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim international by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 12.5mg / 2.5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API		**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning

	Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru- 534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.		
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-02 **Linagliptin:** L-20200920-D01-L09-01 **Metformin HCl:** MT02000221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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.	ELMXC-T2-21	ELMXC-T3-21	ELMXC-T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	06-2021	06-2021	06-2021
No. of Batches	03		

351.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Pvt. Ltd.Plot 62 Quaid e Azam Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s CCL Pharma Pvt. Ltd.Plot 62 Quaid e Azam 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 9047 dated 08-04-2022
	Details of fee submitted	Rs.75,000/- dated 16-03-2022
	The proposed proprietary name / brand name	**Trijardy XR Tablet 10mg/5mg/ 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..10mg Linagliptin……5mg Metformin HCl……1000mg
	Pharmaceutical form of applied drug	Light Green colored, oblong biconvex shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet 10mg/5mg/1000mg by M/s Boehringer Ingelheim, USFDA Approved.
	For generic drugs (me-too status)	Not Applicable

	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 30-04-2019
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru-534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Empagliflozin Batches: (20160606, 20161017, 20161219) Linagliptin Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) Metformin HCL Batches: (MS-0220601 Lot A, MS-0220601 Lot B, MS-0230601 Lot A, MS-0230601 Lot B, MS-0240601 Lot A, MS-0240601 Lot B,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Trijardy XR 10mg / 5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim international by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 10mg / 5mg/ 1000mg Tablet

		manufactured by M/s Boehringer Ingelheim in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru- 534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.		
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-02 **Linagliptin:** L-20200920-D01-L09-01 **Metformin HCl:** MT02000221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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.	ELMXB-T2-21	ELMXB-T3-21	ELMXB-T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	05-2021	05-2021	06-2021
Date of Initiation	05-2021	05-2021	06-2021
No. of Batches	03		
352.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Pvt. Ltd. Plot 62 Quaid e Azam Industrial Estate Lahore.	
	Name, address of Manufacturing site.	M/s CCL Pharma Pvt. Ltd. Plot 62 Quaid e Azam 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 8800 dated 06-04-2022	
	Details of fee submitted	Rs.75,000/- dated 16-03-2022	
	The proposed proprietary name / brand name	**Trijardy XR Tablet 5mg/2.5mg/ 1000mg**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..5mg Linagliptin……2.5mg Metformin HCl……1000mg	

	Pharmaceutical form of applied drug	Green colored, oblong biconvex shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy XR Tablet 5mg/2.5mg/1000mg by M/s Boehringer Ingelheim, USFDA Approved.
	For generic drugs (me-too status)	Not Applicable
	GMP status of the Finished product manufacturer	GMP inspection conducted on 21-02-2023 concludes satisfactory level of compliance.
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru-534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Empagliflozin Batches: (20160606, 20161017, 20161219) Linagliptin Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) Metformin HCl Batches: (MS-0220601 Lot A, MS-0220601 Lot B, MS-0230601 Lot A, MS-0230601 Lot B, MS-0240601 Lot A, MS-0240601 Lot B,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation

		studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Trijardy XR 5mg / 2.5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim international by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 5mg / 2.5mg/ 1000mg Tablet manufactured by M/s Boehringer Ingelheim in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Linagliptin:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd China. Fluoride industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province - 123000, China **Metformin HCl:** Wanbury Limited. Doctors Organic Chemical Division K Illindalaparru- 534217, Iragavaram Mandal, West Godavari District Andhra Pradesh; India.		
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-02 **Linagliptin:** L-20200920-D01-L09-01 **Metformin HCl:** MT02000221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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.	ELMXA-T2-21	ELMXA-T3-21	ELMXA-T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	05-2021	06-2021	06-2021
Date of Initiation	05-2021	06-2021	06-2021
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 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.	Empagliflozin: Copy of GMP certificate valid till 23/08/2023 issued by Lioning Fuxin management committee. Linagliptin: Copy of GMP certificate valid till 23/08/2023 issued by Lioning Fuxin management committee. Metformin HCl: Copy of License retention certificate

		valid till 28-07-2023 issued by Drug Control Administration, Andhra Pradesh, India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Empagliflozin: Commercial invoice no. HN21010701-J attested by AD I&E DRAP, Lahore dated 23/02/2021. • Linagliptin: Invoice No. HN201215-L attested by AD I&E DRAP, Lahore dated 15-Dec-2020 • Metformin HCl: Commercial Invoice No. 92003827 attested by AD DRAP I&E Lahore dated 05/02/2021.
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[II]:

Section#	Observations	Firm's response	Remarks
1.5.2	Submitted label claim shall elaborate the immediate release and extended release layer of the applied formulation.	Elaborated label claim is as follow: **Each film coated tablet contains;** Empagliflozin & Linagliptin as Immediate Release Metformin HCl as Extended-Release Firm has submitted fee of Rs.75,000/- for revision of label claim for each strength	
1.6.5	Copy of Valid GMP certificate./DML for M/s Fuxin Long Rui, issued by relevant regulatory authority shall be submitted.	Copy of Manufacturing License (License # LIAO 20150233) issued by Liaoning Medical Products Administration, valid upto 17-01-2027 for M/s Fuxin Long Rui has been submitted	
	Empagliflozin		
3.2.S.1.3	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility in water as "practically insoluble". Justification shall be submitted in this regard.	The phrase "practically insoluble" was a typographical error. In section S.1.3, regarding quantitative aqueous solubility, we have stated that the solubility of Empagliflozin in water is 0.5 mg/ml.	Declaration from the drug substance manufacturer shall be submitted regarding the solubility of Empagliflozin. The submitted annexure still mentions the statement of practically

			insoluble in water.
	Metformin HCl		
3.2.S.4.4	Submitted COA of Metformin HCl from M/s Wanbury declare that the product complies with BP-2014/USP-35. Clarification shall be submitted in this regard. USP and BP monograph is not harmonized hence justification shall be submitted from the drug substance manufacturer for claiming both standards simultaneously.	We adhere to the specifications mentioned in the British Pharmacopoeia (BP). The specifications for the drug substance are attached as 3.2. S.4.1. The API manufacturer has stated their compliance with both compendia. We would like to state that Wanbury Limited is EDQM certified manufacturer bearing certificate number. R1-CEP 1998-079 - Rev 10. Further we have also submitted justification of specification attached by the drug substance manufacturer Drug substance specifications are submitted Further Manufacturer is complying to USP 35 and BP 2014, and both the monograph are harmonized. Furthermore, we are complying to BP 2022 specifications.	The Assay and related substances limits of USP & BP monograph are different.
	Linagliptin		
3.2.S.1.3	• Submitted DMF declare the Polymorphic form as A, 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.	As per CDER, Linagliptin exist in two polymorphic forms- Form A and Form B. these two forms are enantiotropically related and reversible interconvert at approximately room temperature. Both forms are stable and highly soluble and both forms are equivalent with respect to equilibrium solubility and intrinsic dissolution rate, which indicates that polymorphism does not affect manufacturability or bioavailability.	Innovator literature review declares the Linagliptin as a mixture of anhydrous form A and anhydrous form B while justification is required from drug substance manufacturer for declaring the drug substance as single polymorphic form.
3.2.S.4	• Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications.	Test for Enantiomeric Purity can ensure that the content of S-enantiomer in the product which should be less than 0.15%. Further, it is evident from literature that interconversion of Linagliptin to S-Linagliptin	Innovator literature has recommended test of enantiomeric purity as stability test and identification test by Chiral HPLC. Firm has not

		does not show meaningful amounts of S-enantiomer in the drug substance. Hence, there is no need to perform Identification by chiral HPLC. Furthermore, both the API manufacturer and FPP manufacturer have already performed Identification using two different methods, namely HPLC and IR, in accordance with the recommendations outlined in ICH Q6A. However, we have requested our Drug substance manufacturer to add the test for Enantiomeric impurity in their Specifications. We have also revised our Drug substance specifications including Test for Enantiomeric Impurity	submitted any literature reference to establish the fact that performance of test for S-enantiomer (Enantiomeric purity test) is not necessary. Furthermore Registration Board in its 324th meeting has recommended performance of test Enantiomeric purity for Linagliptin.
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.	Test for Enantiomeric Purity can ensure that the content of S-enantiomer in the product which should be less than 0.15%. Further, it is evident from literature that interconversion of Linagliptin to S-Linagliptin does not show meaningful amounts of S-enantiomer in the drug substance. Hence, there is no need to perform Identification by chiral HPLC.	
3.2.S.5	Submitted COA of working standard of Linagliptin does not declare the validity date.	Valid Working standard COA of Linagliptin was already attached in 3.2. P.6. Same has been submitted.	COA of reference/working standard used for the drug substance analysis of Linagliptin by M/s CCL shall be submitted.
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. • Details of the equipment shall be submitted wherein Drug-Excipient compatibility study has been conducted with following stress conditions: • Temperature: 60°C	As per innovator patent document "PCT/EP2016/079465" the Metformin XR core is barrier coated using one or more barrier coating agents such as mixture of hydroxypropyl cellulose, HPMC or mixture of PVA, PEG. we have utilized HPMC,	Firm has submitted document for seal coating justification which is extract of a patent instead of submitting the reference from innovator drug product literature

	• Humidity: 75%RH	Talc, Purified water, and titanium dioxide for the seal coat, following the innovator's specifications. Reference is attached as **Annex-4.** We have dedicated, stability chamber for such use. Make: Memmert (X511.0138) Eqp ID: QC 018 Record of data logger is attached as Annex-5	approved by reference regulatory authorities.
3.2.P.2	• Justification shall be submitted for proposed quantity of Arginine in the formulation. • Submit the image/picture/snapshot of the innovator/reference/comparator pack against which Pharmaceutical equivalence / Comparative Dissolution Profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator/reference/comparator product. • Justification shall be submitted for not performing tests of water content, uniformity of content, microbial purity and arginine content in Pharmaceutical equivalence studies as recommended by the innovator product literature review from reference regulatory authorities.	• As per FDA Inactive Ingredient Search for Approved Drug Products, the permitted quantity for Arginine is up to 50mg, while our product has quantity up to 10mg which is within the permitted limits. • Images of innovator packs used for pharmaceutical equivalence studies are submitted. • *We hereby commit that Arginine content; Water content & content uniformity test will be part of our next Stability Study Testing Interval* as well as said test will be part of our QC Release Specifications before commercialization. • We have already performed the uniformity of content for our product. • We have tested for Average weight, content uniformity and dissolution during the study. *Further, Arginine is considered as an excipient that is why he have not tested it during pharmaceutical equivalence studies. H*owever now we have	

		added it in our specifications	
3.2.P.3.4	In contrary to the recommendations of innovator product literature, "particle size" of Empagliflozin & Linagliptin has not been identified as Critical Quality Attribute.	We have been procuring Empagliflozin and Linagliptin from our prequalified source. We have already performed Comparative dissolution profile and dissolution of our various sku's and all product complies to the specification for claimed shelf life. However, we have also requested our Drug substance manufacturer to perform the said test on next batches for compliance.	
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.	Revised Process Validation Protocol has been submitted.	
3.2.P.5.1	• Justification shall be submitted for not including tests of water content, microbial purity and arginine content in drug product specifications as recommended by the innovator product literature review from reference regulatory authorities.	We hereby commit that Arginine content; Water content & content uniformity test will be part of our next Stability Study Testing Interval as well as said test will be part of our QC Release Specifications before commercialization.	Firm has not submitted revised analytical procedure including test for Arginine & water content.
3.2.P.5.4	• Justification shall be submitted for not performing tests of water content, microbial purity and arginine content in batch analysis as recommended by innovator drug product literature		
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of working standard is submitted.	
3.2.P.8.3	• Justification shall be submitted for not including tests of water content, microbial purity and arginine content in stability studies. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	We hereby commit that Arginine content; Water content & content uniformity test will be part of our next Stability Study Testing Interval as well as said test will be part of our QC Release Specifications before commercialization.	
2.3.R	• Submitted BMR declare dispensing of Empagliflozin & Linagliptin as per 100% content of desired label claim. Justification shall be submitted that how dispensed quantity will produce 100% content of	• The justification for achieving 100% content when both APIs are included through Active coating is as follows:	Submitted process validation protocol declares use of Conventional coating pan.

	Empagliflozin & Linagliptin, when both APIs are being included by way of Active coating and how the wastage of coating solution will be compensated. • Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. • Justification shall be submitted for proceeding for the seal final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. • Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing. • Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.	• Through careful formulation and testing, the coating solution is designed to provide adequate coverage and retention of both Empagliflozin and Linagliptin during the coating process. • Further, the coating process is conducted in Automatic coating machine. • As per innovator patent document "PCT/EP2016/079465" the metformin XR core is barrier coated using one or more barrier coating agents such as mixture of hydroxypropyl cellulose, HPMC or mixture of PVA, PEG. we have utilized HPMC, Talc, Purified water, and titanium dioxide for the seal coat, following the innovator's specifications. • The coating solution undergoes testing before the coating process takes place. However, the Certificate of Analysis (COA) for the coating solutions is not included in the Trial Batch Manufacturing Record (BMR). • Our R&D Laboratory is equipped with Automatic coating machine with minimum handling capacity of 500gm and maximum capacity of 3.0Kg. Model: BGC 400	

Decision: Registration Board deferred the applications of Trijardy XR Tablet 25mg/5mg/ 1000mg, Trijardy XR Tablet 12.5mg/2.5mg/ 1000mg, Trijardy XR Tablet 10mg/5mg/ 1000mg & Trijardy XR Tablet 5mg/2.5mg/ 1000mg for following:

- **Declaration from the drug substance manufacturer shall be submitted regarding the solubility of Empagliflozin.**

- **Evidence based justification for the claim of firm that USP & BP monograph of Metformin HCl is harmonized.**
- **Justification for from the drug substance manufacturer for claiming both standards i.e., USP & BP simultaneously for Metformin HCl.**
- **Scientific justification, with reference to innovator drug product literature, for claiming Linagliptin as "Polymorphic form A" insetad of "mixture of anhydrous form A and anhydrous form B".**
- **Clarification shall be submitted regarding the isomeric form of the drug substance.**
- **Scientific Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications as recommended by the innovator drug product literature.**
- **Submitted COA of drug substance from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity" and identification test of Chiral purity. Justification shall be submitted in this regard with reference to innovator drug product literature.**
- **COA of reference/working standard used for the drug substance analysis of Linagliptin by M/s CCL shall be submitted.**
- **Scientific justification shall be submitted for the role and impact of seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation.**
- **Performance of Pharmaceutical equivalence studies against the innovator drug product including tests of water content, uniformity of content, microbial purity and arginine content.**
- **Scientific justification shall be submitted for not including tests of water content and arginine content in stability studies with reference to the innovator drug product literature.**
- **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.**
- **Evidence based justification regarding the claim of achieving 100% content as per label claim of Empagliflozin & Linagliptin, withput consuming excessive active coating solution.**

b. **Deferred cases**

353.	**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 have been 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	• Firim has submitted COA of drug substance from M/s Hebei Jiheng Pharmaceutical Co. Ltd. China for batch# COS012012049 which also includes sterility test.

	Standard", whereas 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 manufacturer 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.	
3.2.S.4.5	The said section declares that the 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.	Drug substance manufacturer complies both BP & 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	• 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.

	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 be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	• Record of digital data logger has been submitted. • GMP certificate eof the drug substance manufacturer has not been 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: Regsitration Board decided to defer the application for personal hearing of firm regarding the varied information submitted regarding the source of drug substance.

354.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta	
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, F-126, S. I. T. E., Karachi, 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 25930 dated 17/09/2021	
	Details of fee submitted	PKR 50,000/-: PKR 25,000/-:	dated 04/05/2020 dated 30/06/2021
	The proposed proprietary name / brand name	**ADVITA 20,000 IU CAPSULES**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft gel Capsule contains: Cholecalciferol…...20,000 IU	
	Pharmaceutical form of applied drug	Clear light-yellow oily liquid	
	Pharmacotherapeutic Group of (API)	Vitamin D analogs	
	Reference to Finished product specifications	USP	
	Proposed Pack size	As per SRO	

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fultium 20,0000 IU Capsule by M/s Internis Pharmaceuticals Limited, MHRA Approved.
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	Certificate No: F.14-1/DRAP/GMP/MDM-2022 issued on 03rd Feb 2022 Soft Gelatin Capsule (General) Dispensing, Mixing, Drying, Granulation, Compression, Coating, Blistering & Packaging.
	Name and address of API manufacturer.	M/s DSM Nutritional Product, France
	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 has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% RH ± 5% RH for 24 months Accelerated: 30°C ± 2°C / 65% RH ± 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, 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 Fultium 20,0000 IU Capsule by M/s Internis Pharmaceuticals Limited. Since Vitamin D3 capsules are Fat soluble in nature so the dissolution in not recommended by any Pharmacopoeia & FDA dissolution guideline.
	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 DSM Nutritional Product, France
API Lot No.	11F01901004
Description of Pack (Container closure system)	Aluminum foil with PVC/PVDC blister (2×7's)
Stability Storage Condition	Real time: 25°C ± 2°C / 60% ± 5%RH Accelerated: 30°C ± 2°C / 65% ± 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-007/20	TR-008/20	TR-009/20
Batch Size	10000 capsule	10000 capsule	10000 capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Acidex 60mg Capsule Dexlansoprazole was approved in 312th Registration Board meeting. Compliance Record of HPLC software 21CFR & audit trail reports on product testing were present
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No 18MPP077HFR02 issued by EUDRA . Period of validity is extended to 26.09.2023 in case of cholecalciferol .
	Documents for the procurement of API with approval from DRAP (in case of import).	M/s DSM Nutritional Product, France ADC Invoice No: 2831239200, 29-08-2019
	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 batches along with chromatograms, raw data sheets, COA and summary data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
	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:

Decision of 320th meeting: Deferred for following points:
Clarification of conditions of stability studies of drug substance and drug product.
Justification why comparative dissolution profile studies are not performed against the innovator drug product.

Firm's response:
Cholecalciferol is sensitive & not stable when exposed to high temperature condtion so in the light of above condition stability performed at 25oC +2oC/60% RH +5%RH. SmPc of innovator product "Fultium-D3 20,000IU capsules" clearly instructed to store the product below 25oC.
As Choleclaciferol is present in USP and its nature is fat soluble. Therefore, its dissolution is not recommended in any Pharmacopoeia as well as FDA dissolution guideline. While complete comparative analysis & Pharmaceutical equivalence with innovator has already been submitted with initial dossier.

Decision of 323rd meeting: Deferred for following:
Scientific justification for performing drug product stability studies on storage conditons different from that required by ICH/WHO guidelines for Zone IVA.
Submission of reference from pharmacopoeia/ innovator drug product literature regarding non-performance of dissolution test for applied formulation.

Firm's response:

S. No	Observation	Reply

	1.	Scientific justification for performing drug product stability studies on storage conditions different from that required by ICH/WHO guidelines for Zone IVA.	Cholecalciferol (Vitamin D3) is a sensitive vitamin & not stable when exposed to high temperature conditions so in the light of above condition stability performed at 25℃ ± 2℃ / 60% RH ± 5% RH. Leaflet (enclosed) of innovator product "Fultium 20,000 IU Capsule" clearly instructed to store the product below 25℃.
	2.	Submission of reference from pharmacopoeia/ innovator drug product literature regarding nonperformance of dissolution test for applied formulation.	Cholecalciferol (Vitamin D3) is present in USP pharmacopeia & its nature is fat soluble. Therefore, its dissolution is not recommended in any pharmacopeia as well as FDA dissolution guideline. USP Monograph of Cholecalciferol Capsule attached for reference. While complete comparative analysis and pharmaceutical equivalence with innovator has been done and already submitted with initial dossier.

Decision of 324th meeting: Deferred for submission of following:

- Justification of not performing stability studies as per Zone-IV A conditions since the MHRA Public Assessment Report of the innovator product i.e., Fultium –D3 20,000 IU capsule recommends storage condition as "Do no store above 30^0C".
- Justification on the basis of analytical record and stability studies that at what time point the product is unstable when stored at Zone IVA conditions for stability studies.

Firm's response:

- We performed long term stability studies at (25°C /60%RH) & accelerated at (40°C /75%RH) but due to appearance and degradation non-compliance at 6-month accelerated stability was observed. After that, we went for intermediate stability studies (30°C /65%RH) as per above mentioned guidelines to justify the stability of our product.
- Firm has now submitted real time stability studies data of three batches at 30°C /65%RH conditions for 24 months.

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.**

355.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, 18km mandiali stop, sheikupura road lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, 18km mandiali stop, 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. 347: 04-03-2021
	Details of fee submitted	PKR 20,000/-: 17-02-2021
	The proposed proprietary name /	**Trexime 200mg capsule**

	brand name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as trihydrate…200mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 200 mg CAPSULE by SANOFI Aventis Spain Approved
	For generic drugs (me-too status)	Cefiget 200 mg Capsule by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	15-1-2020, Overall hygienic condition of the firm is satisfactory at the time of inspection. Firm has cephalosporin capsule section.
	Name and address of API manufacturer.	M/s. Pharmagen Ltd Kot nabi Kuksh wala, 34km ferozpur road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, 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 Product):	Firm has submitted relevant information against the Module III, including, Comparative dissolution studies (reference product is cefspan capsule) Process validation protocol, Finished product analytical method validation report & stability studies data.

STABILITY STUDY DATA

Manufacturer of API	M/s. Pharmagen Ltd Kot nabi Kuksh wala, 34km ferozpur road Lahore.		
API Lot No.	00244-043-2020		
Description of Pack (Container closure system)	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.	XT1	XT2	XT3
Batch Size	5000cap	5000cap	5000cap
Manufacturing Date	02-2020	02-2020	02-2020

Date of Initiation	02-2020	02-2020	02-2020
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.	GMP certificate was issued to M/s Pharmagen Ltd based on evaluation conducted on 8-1-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice from Pharmagen Ltd specifying purchase of cephradine 25Kg is 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 record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. The firm has2 Galvano Scientific stability chambers, Model STC-SS-400-LAC with 400liter capacity
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) (VI)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers

Observation communicated	Response
Comparative dissolution profile (CDP) studies should be conducted in three BCS media (pH 1.2, 4.5 and 6.8) across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed as per requirements of section 3.2.P.2.	The firm has submitted comparative dissolution profile (CDP) in three BCS media and calculated similarity factor *f2* using CDP results.
Provide copy of Batch Manufacturing Record (BMR) of the batch XT1 of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The firm has provided copies of respective batch manufacturing record of the prepared batch.
Submit description of the primary container closure systems, including materials of construction as per section 3.2.P.7.	Description for the container closure system has been submitted.
2.3.R Regional Information is not submitted.	Regional information has been submitted.

Decision of 308th meeting: Registration Board deferred the case for further deliberation regarding finished product specifications of applied formulation/strength.

356.	Name, address of Applicant / Marketing Authorization Holder	M/s BJ Pharmaceuticals, 18km mandiali stop, sheikupura road lahore
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, 18km mandiali stop, sheikupura 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. 34827: 30-12-2020
	Details of fee submitted	PKR 20,000/-: 24-09-2020
	The proposed proprietary name / brand name	**Trexime 400mg capsule**
	Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime as trihydrate…400mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SUPRAX 400 mg CAPSULE by SANOFI Aventis , Spain Approved
	For generic drugs (me-too status)	Cefiget 400 mg Capsule by M/s GETZ Pharma
	GMP status of the Finished product manufacturer	15-1-2020, Overall hygienic condition of the firm is satisfactory at the time of inspection. Firm has cephalosporin capsule section.
	Name and address of API manufacturer.	M/s. Pharmagen Ltd Kot nabi Kuksh wala, 34km ferozpur road Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, 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 Product):	Firm has submitted relevant information against the Module III, including, Comparative dissolution studies (reference product is cefspan capsule) Process validation protocol, Finished product analytical method validation report & stability studies data.

STABILITY STUDY DATA

Manufacturer of API	M/s. Pharmagen Ltd Kot nabi Kuksh wala, 34km ferozpur road Lahore.
API Lot No.	00244-043-2020
Description of Pack (Container closure system)	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.	ZT01	ZT02	ZT03
Batch Size	5000cap	5000cap	5000cap
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	11-2019	11-2019	11-2019
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.	GMP certificate was issued to M/s Pharmagen Ltd based on evaluation conducted on 8-1-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice from Pharmagen Ltd specifying purchase of cephradine 25Kg is 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 record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets. The firm has2 Galvano Scientific stability chambers, Model STC-SS-400-LAC with 400liter capacity
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) (VI)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers

Decision of 308th meeting: Registration Board deferred the case for further deliberation regarding finished product specifications of applied formulation/strength.

Firm's reply: Firm has submitted drug product specifications as per monograph approved by Registration Board vide No. F.14-1/2022-PEC along with fee of RS. 7,500/- for each strength.

Decision: Registration Board approved the applications of "Trexime 200mg capsule" &" Trexime 400mg capsule" as per monograph approved by Registration Board vide No. F.14-1/2022-PEC

357.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 23-07-2012 which specifiesLyophilized vials (General) for M/s Bio-Labs Pharma

	Dy. No. and date of submission	Dy. No 7860 dated 10-03-2021
	Details of fee submitted	Rs.50,000/- dated 25-06-2021
	The proposed proprietary name / brand name	**UswaTig 50mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline (Lyophilized powder)……50mg
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Tigewel Injection of M/s Welwrd Pharma (Reg.# 082530)
	GMP status of the Finished product manufacturer	GMP certificate issued on 13-08-2020.
	Name and address of API manufacturer.	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd .No .1 human Yi Road, Changshou District, Chongqing 401254,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, 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.

	Stability studies	Stability study conditions: Real time: 6ºC ± 2 ºC, RH for 36 months Accelerated: 25ºC ± 2ºC/60% ± 5%RH for 6 months Batches: (Til00701V, Til00702V, Til00703V)
	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	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. BTig 50mg injection by Bosch pharmaceuticals.
	Analytical method validation/verification of product	Method verification studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd. No .1 human Yi Road, Changshou District, Chongqing 401254, P.R China.		
API Lot No.	Ti191201		
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.	L-131	L-138	L-242
Batch Size	1000 Vials	1000 Vials	700 vials
Manufacturing Date	01-2018	01-2018	08-2019
Date of Initiation	20-03-18	12-03-18	01-10-2019
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 submitted copy of GMP certificate (No. CQ20180031) issued by Chongqing food and drug administration valid upto 09-10-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Licenses to Import Drug substance Tigecycline issued by AD I&E DRAP, Islamabad dated 05-08-2019 & 02-04-2020.
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	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.

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4	mits for test of pH submitted in the drug ecifications is not as per the USP r "Tigecycline". of coloumn temperature, mobile phase ystem suitability solution mentioned in the ethod by Drug substance manufacturer is USP monograph for "Tigecycline".)A from M/s Bio-labs reflect that tests of ndotoxin & sterility have not been he Drug substance specifications and ocedures used for routine testing of the ce /Active Drug Product manufacturer is Method Verification studies including accuracy and repeatability (method formed by the Drug Product manufacturer itted. s of analysis of relevant batch(es) of Drug rformed by Drug Product manufacturer roduct development and stability studies, ertificate of Analysis (CoA) of the same Drug Substance / /Active Pharmaceutical nufacture. availability of Auto sampler in HPLC, C temperature conditions could be	• Firm has submitted revised documents submitted without justifying the deviations observed in previously submitted data. • Temperature for autosampler not reflected in analytical method. • Firm has submitted Bioburden test report from M/s Bio Lab for another batch than that submitted earlier. • Drug substance specifications and analytical procedure has been submitted from M/s Bio-Labs, but these documents are not formal and does not bear any document no., issue date or effective date. • Analytical method verification studies have been submitted from M/s Bio-Labs. • COA from API manufacturer has been submitted, which declares the product name as "Tigecycline lyophilized", whereas COA of M/s Bio-Lab declares it as "Tigecycline" only. • No Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained.
3.2. S.5	mary / secondary reference standard rce and lot number shall be provided.	COA of working standard has been submitted from M/s Fuan Pharmaceutical, China.
3.2. S.7	• The USP monograph for "Tigecycline" recommends storage condition as at refrigerated	Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein

	temperature, whereas stability studies data has been submitted as per room temperature conditions. • Specifications for pH & specific optical rotation applied in stability studies is different from that submitted in section 3.2.S.4.4.	only conditions of storage have been changed as reuired for a refrigerated item, while the analytical values for all the tests are same as presented earlier.
3.2.P.1	• Inclusion of lactose monohydrate in the composition shall be justified since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2.P.2.1	• Compatibility studies of the Drug Substance(s) with Lactose shall be provided since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2. P.5	; of fill weight/vial shall be submitted. ; does not include test of "Particulate availability of Auto sampler in HPLC, C temperature conditions could be ameter has not been performed in the hod verification studies. ant batches for which stability studies data nitted, shall be provided.	: given ; of fill weight/vial shall be submitted. availability of Auto sampler in HPLC, C temperature conditions could be ion is not proper, since it does not the base line. re not formal and does not bear any , issue date or effective date.)As does no tinclude test of particulate ommended by the USP monograph of for injection"
3.2.P.6	orking standard COA reflect date of 4-12-2019, whereas stability batches have prior to this date.	COA of working standard submitted with date of analysis as 25-12-2017, wherein the reference standard (lot# F0M325) used for its standardization was valid upto 30-09-2017.
3.2. P.8	mitted copy of Licenses to Import Drug gecycline issued by AD I&E DRAP, ted 05-08-2019 & 02-04-2020, whereas ıes have been manufactured prior to these shall be submitted whether submitted es data is of trial batches or commercial eets for stability studies, reflecting the ıdard weight, Sample dilution preparation, eference standard and Calculation formula e Assay test shall be submitted. ted stability studies data, test of particulate ot been performed, justification shall be his regard. ıg written in the stability summary sheets me points, does not relate with the relevant onths.	ed are still subsequent to the date of g of two batches. i.e. L-131 & L-138 turing date of 03-2018, whereas oice is of 08-2019. oice is for "Tigecycline lyophilized". ubmitted that provided data is of atches. ets submitted. ity study sheets have been submitted.

- As per submitted BMRs potency adjustment has not been done for the Drug substance, based upon the actual Assay results.
- As per submitted BMRs, lactose monohydrate has been used in the formulation, whereas innovator product has been formulated without use of any excipient. Justification shall be submitted in this regard.
- Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches shall be submitted shall be submitted.
- Submitted BMRs have not been filled completely.
- BMR was written with standard batch formula and now it been revised with potency adjustment as per potency of drug substance.
- Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas asper submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.
- Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage.
- Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.

Decision of 316th meeting: Deferred for following:

- **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.
- Evidence of availability of Auto sampler in HPLC, wherein 10^{o}C temperature conditions could be maintained.
- Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.
- Specifications of fill weight/vial shall be submitted.
- Peak integration is not proper, since it does not coincide with the base line.
- Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.
- Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.
- Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.
- Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage.
- Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.
- Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection"

Firm's reply:

Observation	**Firm's Reply**
• **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.	Firm has submitted analytical procedure, wherein mobile phase composition is different from that proposed by the drug substance manufcaturer.
Evidence of availability of Auto sampler in HPLC, wherein 10^{o}C temperature conditions could be maintained.	Fimr has submitted specification sof of auto sampler assembled with HPLC of Perkin Almer 200LC, wherein operating conditions for "Ambient temperature" are mentioned as 10- 30^{o}C.

Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.	The stability data has been done as per recommended storage conditions. There was typographic error in the data.
Specifications of fill weight/vial shall be submitted.	The product is in lyophilized form. For this 2 ml solution per vial was filled and then lyophilized. *It is pertinent to mention that vials are filled with 2 ml solution at an intermediate stage, whereas final dosage form of the applied product is in the powder form hence fill weight specifications are necessary to establish uniformity of dosage.*
Peak integration is not proper, since it does not coincide with the base line.	Firm has submitted chromatograms again with justification that the attenuation is increased which results in the proper coinciding of baseline.
• Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.	No reply submitted.
• Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.	The bulk and raw material of tigecycline is also available in lyophilized/sterilized form. The raw material was then formulated into solution form which is then filled and lyophilized.
• Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.	Firm has declared it as a typographic error, and has submitted revised COA of drug substance wherein Assay value has been declared as 99% on anhydrous basis, which still does not justify the dispensed amount on basis of "as is potency", since water content has been declared as 1.3%.
Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage	The solution is filled in the vials. The volume variation/checklist is attached.
• Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.	The solution is filled in glass beaker (5Ltr) whose minimum handling capacity is 500ml.
Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection".	Firm has submitted revised COAs of drug product for complete stability studies, wherein test of "Particular matter" has now been included.

Decision of 320th meeting: Deferred for following:

- Submission of commercial invoices attested by AD DRAP I&E, for the procurement of drug substance used to manufacture drug product batches. i.e. L-131 & L-138.
- Specifications for the fill weight/vial shall be submitted.
- Evidence of performance of sterility testing at the time of batch release shall be submitted.
- Scientific justification shall be submitted for using glass beaker (5Ltr) for the compounding the commercial scale batches.
- Verification of the claim of the firm regarding submitted HPLC chromatograms that "attenuation is increased which results in the proper coinciding of baseline."

Firm's response: Firm has submitted following:

- Firm has submitted copy of license to import issued by AD I&E Islamabad dated 20-12-2017 for import of 200gm of Tigecycline.
- The product is filled with a fill volume of 2ml± 0.2ml solution for lyophilisation, after lyophilisation dried cake is formed.
- Microbiological reports for the sterility testing for batch release of stability batches.
- The product is commercially manufactured with a batch size of approx. 2litre so it is manufactured in a 5litre glass beaker as per proper manufacturing procedure.
- As the attenuation or scale of the y-axis is changed the baseline is automatically changed as shown in the attached chromatograms.

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.**

358.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gray's Pharmaceuticals. Plot No. 2, street No.N-3, National Industrial Zone, Rawat Islmabad.**
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 23-07-2012 which specifiesLyophilized vials (General) for M/s Bio-Labs Pharma
	Dy. No. and date of submission	Dy. No 7458 dated 08-03-2021
	Details of fee submitted	Rs.50,000/- dated 25-02-2021
	The proposed proprietary name / brand name	**Bacticil 50mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline (Lyophilized powder) …… 50mg

	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Tigewel Injection of M/s Welwrd Pharma (Reg.# 082530)
	GMP status of the Finished product manufacturer	GMP certificate issued on 13-08-2020.
	Name and address of API manufacturer.	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd .No .1 human Yi Road, Changshou District, Chongqing 401254,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, 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.
	Stability studies	Stability study conditions: Real time: 6^{o}C ± 2 ^{o}C,RH for 36 months Accelerated: 25^{o}C ± 2^{o}C/60% ± 5%RH for 6 months Batches: (Til00701V, Til00702V, Til00703V)

	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	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. BTig 50mg injection by Bosch pharmaceuticals.
	Analytical method validation/verification of product	Method verification studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd. No .1 human Yi Road, Changshou District, Chongqing 401254, P.R China.		
API Lot No.	Ti191201		
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.	L-131	L-138	L-242
Batch Size	1000 Vials	1000 Vials	700 vials
Manufacturing Date	01-2018	01-2018	08-2019
Date of Initiation	20-03-18	12-03-18	01-10-2019
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 submitted copy of GMP certificate (No. CQ20180031) issued by Chongqing food and drug administration valid upto 09-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Licenses to Import Drug substance Tigecycline issued by AD I&E DRAP, Islamabad dated 05-08-2019 & 02-04-2020.
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw	Submitted

	data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and 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
3.2. S.4	mits for test of pH submitted in the drug ecifications is not as per the USP r "Tigecycline". of coloumn temperature, mobile phase ystem suitability solution mentioned in the ethod by Drug substance manufacturer is USP monograph for "Tigecycline".)A from M/s Bio-labs reflect that tests of ndotoxin & sterility have not been he Drug substance specifications and ocedures used for routine testing of the ce /Active Drug Product manufacturer is Method Verification studies including accuracy and repeatability (method formed by the Drug Product manufacturer itted. s of analysis of relevant batch(es) of Drug rformed by Drug Product manufacturer roduct development and stability studies, ertificate of Analysis (CoA) of the same)rug Substance / /Active Pharmaceutical nufacture. availability of Auto sampler in HPLC, C temperature conditions could be	• Firm has submitted revised documents submitted without justifying the deviations observed in previously submitted data. • Temperature for autosampler not reflected in analytical method. • Firm has submitted Bioburden test report from M/s Bio Lab for another batch than that submitted earlier. • Drug substance specifications and analytical procedure has been submitted from M/s Bio-Labs, but these documents are not formal and does not bear any document no., issue date or effective date. • Analytical method verification studies have been submitted from M/s Bio-Labs. • COA from API manufacturer has been submitted, which declares the product name as "Tigecycline lyophilized", whereas COA of M/s Bio-Lab declares it as "Tigecycline" only. • No Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained.
3.2.S.5	imary / secondary reference standard rce and lot number shall be provided.	COA of working standard has been submitted from M/s Fuan Pharmaceutical, China.
3.2. S.7	• The USP monograph for "Tigecycline" recommends storage condition as at refrigerated temperature, whereas stability studies data has been submitted as per room temperature conditions. • Specifications for pH & specific optical rotation applied in stability	Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.

	studies is different from that submitted in section 3.2.S.4.4.	
3.2.P.1	• Inclusion of lactose monohydrate in the composition shall be justified since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2.P.2.1	• Compatibility studies of the Drug Substance(s) with Lactose shall be provided since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2. P.5	• Specifications of fill weight/vial shall be submitted. • Specifications does not include test of "Particulate matter". • Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained. • Precision parameter has not been performed in the analytical method verification studies. • COAs of relevant batches for which stability studies data has been submitted, shall be provided.	• Following not given • Specifications of fill weight/vial shall be submitted. • Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained. • Peak integration is not proper, since it does not coincide with the base line. • Documents are not formal and does not bear any document no., issue date or effective date. • Submitted COAs does not include test of particulate matter as recommended by the USP monograph of "Tiogecycline for injection"
3.2.P.6	• Submitted working standard COA reflect date of analysis as 14-12-2019, whereas stability batches have been analysed prior to this date.	COA of working standard submitted with date of analysis as 25-12-2017, wherein the reference standard (lot# F0M325) used for its standardization was valid upto 30-09-2017.
3.2. P.8	• Firm has submitted copy of Licenses to Import Drug substance Tigecycline issued by AD I&E DRAP, Islamabad dated 05-08-2019 & 02-04-2020, whereas stability batches have been manufactured prior to these dates. • Clarification shall be submitted whether submitted stability studies data is of trial batches or commercial batches. • Raw data sheets for stability studies, reflecting the details of Standard weight, Sample dilution preparation, Potency of Reference standard and Calculation formula applied for the Assay test shall be submitted. • As per submitted stability studies data, test of particulate matter has not been performed, justification shall be submitted in this regard.	• Invoices shared are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019. • Submitted invoice is for "Tigecycline lyophilized". • Firm has submitted that provided data is of commercial batches. • Raw data sheets submitted. • Revised stability study sheets have been submitted.

• Dates of testing written in the stability summary sheets for different time points, does not relate with the relevant duration in months. • As per submitted BMRs potency adjustment has not been done for the Drug substance, based upon the actual Assay results. • As per submitted BMRs, lactose monohydrate has been used in the formulation, whereas innovator product has been formulated without use of any excipient. Justification shall be submitted in this regard. • Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches shall be submitted shall be submitted. • Submitted BMRs have not been filled completely.	• BMR was written with standard batch formula and now it has been revised with potency adjustment as per potency of drug substance. • Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis. • Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage. • Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.

Decision of 316th meeting: Deferred for following:

- **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.
- Evidence of availability of Auto sampler in HPLC, wherein 10^{o}C temperature conditions could be maintained.
- Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.
- Specifications of fill weight/vial shall be submitted.
- Peak integration is not proper, since it does not coincide with the base line.
- Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.
- Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.
- Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.
- Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage.
- Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.
- Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection"

Firm's reply:

Observation	Firm's Reply
• **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.	Firm has submitted analytical procedure; wherein mobile phase composition is different from that proposed by the drug substance manufacturer.
Evidence of availability of Auto sampler in HPLC, wherein 10^{o}C temperature conditions could be maintained.	Fimr has submitted specification sof of auto sampler assembled with HPLC of Perkin Almer 200LC, wherein operating conditions for "Ambient temperature" are mentioned as 10- 30^{o}C.
Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.	The stability data has been done as per recommended storage conditions. There was typographic error in the data.
Specifications of fill weight/vial shall be submitted.	The product is in lyophilized form. For this 2 ml solution per vial was filled and then lyophilized. *It is pertinent to mention that vials are filled with 2 ml solution at an intermediate stage, whereas final dosage form of the applied product is in the powder form hence fill weight specifications are necessary to establish uniformity of dosage.*
Peak integration is not proper, since it does not coincide with the base line.	Firm has submitted chromatograms again with justification that the attenuation is increased which results in the proper coinciding of baseline.
• Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.	No reply submitted.
• Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.	The bulk and raw material of tigecycline is also available in lyophilized/sterilized form. The raw material was then formulated into solution from which is then filled and lyophilized.
• Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.	Firm has declared it as a typographic error, and has submitted revised COA of drug substance wherein Assay value has been declared as 99% on anhydrous basis, which still does not justify the dispensed amount on basis of "as is potency", since water content has been declared as 1.3%.
Submitted BMRs does not reflect any test	The solution is filled in the vials. The

of filled weight per vial, sterility testing at any stage	volume variation/checklist is attached.
• Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.	The solution is filled in glass beaker (5Ltr) whose minimum handling capacity is 500ml.
Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection".	Firm has submitted revised COAs of drug product for complete stability studies, wherein test of "Particular matter" has now been included.

Decision of 320th meeting: Deferred for following:

- Submission of commercial invoices attested by AD DRAP I&E, for the procurement of drug substance used to manufacture drug product batches. i.e. L-131 & L-138.
- Specifications for the fill weight/vial shall be submitted.
- Evidence of performance of sterility testing at the time of batch release shall be submitted.
- Scientific justification shall be submitted for using glass beaker (5Ltr) for the compounding the commercial scale batches.
- Verification of the claim of the firm regarding submitted HPLC chromatograms that "attenuation is increased which results in the proper coinciding of baseline."

Firm's response: Firm has submitted following:

- Firm has submitted copy of license to import issued by AD I&E Islamabad dated 20-12-2017 for import of 200gm of Tigecycline.
- The product is filled with a fill volume of 2ml± 0.2ml solution for lyophilisation, after lyophilisation dried cake is formed.
- Microbiological reports for the sterility testing for batch release of stability batches.
- The product is commercially manufactured with a batch size of approx. 2litre so it is manufactured in a 5litre glass beaker as per proper manufacturing procedure.
- As the attenuation or scale of the y-axis is changed the baseline is automatically changed as shown in the attached chromatograms.

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.**

359.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novartana Pharmaceuticals (Pvt). Ltd 87-B Plot of Sundar Industrial Area, Raiwind Road, Lahore Pakistan.**
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 23-07-2012 which specifiesLyophilized vials (General) for M/s Bio-Labs Pharma
	Dy. No. and date of submission	Dy. No 8006 dated 11-03-2021
	Details of fee submitted	Rs.50,000/- dated 08-03-2021
	The proposed proprietary name / brand name	**Novartig 50mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline (Lyophilized powder)……50mg
	Pharmaceutical form of applied drug	Lyophilized Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Tigewel Injection of M/s Welwrd Pharma (Reg.# 082530)
	GMP status of the Finished product manufacturer	GMP certificate issued on 13-08-2020.
	Name and address of API manufacturer.	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd .No .1 human Yi Road, Changshou District, Chongqing 401254,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, 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.
	Stability studies	Stability study conditions: Real time: 6ºC ± 2 ºC,RH for 36 months Accelerated: 25ºC ± 2ºC/60% ± 5%RH for 6 months Batches: (Til00701V, Til00702V, Til00703V)
	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	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. BTig 50mg injection by Bosch pharmaceuticals.
	Analytical method validation/verification of product	Method verification studies have been submitted.

STABILITY STUDY DATA			
Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd. No .1 human Yi Road, Changshou District, Chongqing 401254, P.R China.		
API Lot No.	Ti191201		
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.	L-131	L-138	L-242
Batch Size	1000 Vials	1000 Vials	700 vials
Manufacturing Date	01-2018	01-2018	08-2019
Date of Initiation	20-03-18	12-03-18	01-10-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of	The firm has not submitted any document.

	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. CQ20180031) issued by Chongqing food and drug administration valid upto 09-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Licenses to Import Drug substance Tigecycline issued by AD I&E DRAP, Islamabad dated 05-08-2019 & 02-04-2020.
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	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.

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4	• Acceptance limits for test of pH submitted in the drug substance specifications is not as per the USP monograph for "Tigecycline". • The details of coloumn temperature, mobile phase preparation, system suitability solution mentioned in the Assay test method by Drug substance manufacturer is not as per the USP monograph for "Tigecycline". • Submitted COA from M/s Bio-labs reflect that tests of Bacterial Endotoxin & sterility have not been performed. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • 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	• Firm has submitted revised documents submitted without justifying the deviations observed in previously submitted data. • Temperature for autosampler not reflected in analytical method. • Firm has submitted Bioburden test report from M/s Bio Lab for another batch than that submitted earlier. • Drug substance specifications and analytical procedure has been submitted from M/s Bio-Labs, but these documents are not formal and does not bear any document no., issue date or effective date. • Analytical method verification studies have been submitted from M/s Bio-Labs. • COA from API manufacturer has been submitted, which declares the product name as "Tigecycline lyophilized", whereas COA of M/s Bio-Lab declares it as "Tigecycline" only. • No Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained.

	same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained.	
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	COA of working standard has been submitted from M/s Fuan Pharmaceutical, China.
3.2. S.7	• The USP monograph for "Tigecycline" recommends storage condition as at refrigerated temperature, whereas stability studies data has been submitted as per room temperature conditions. • Specifications for pH & specific optical rotation applied in stability studies is different from that submitted in section 3.2.S.4.4.	Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as reuired for a refrigerated item, while the analytical values for all the tests are same as presented earlier.
3.2.P.1	• Inclusion of lactose monohydrate in the composition shall be justified since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2.P.2.1	• Compatibility studies of the Drug Substance(s) with Lactose shall be provided since innovator product approved by US FDA & EMA is formulated without use of any excipient.	MHRA approved reference given.
3.2. P.5	• Specifications of fill weight/vial shall be submitted. • Specifications does not include test of "Particulate matter". • Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained. • Precision parameter has not been performed in the analytical method verification studies. • COAs of relevant batches for which stability studies data has been submitted, shall be provided.	: given s of fill weight/vial shall be submitted. availability of Auto sampler in HPLC, C temperature conditions could be ion is not proper, since it does not the base line. re not formal and does not bear any , issue date or effective date. Submitted COAs does no tinclude test of particulate matter as recommended by the USP monograph of "Tiogecycline for injection"
3.2.P.6	• Submitted working standard COA reflect date of analysis as 14-12-2019, whereas stability batches have been analysed prior to this date.	COA of working standard submitted with date of analysis as 25-12-2017, wherein the reference standard (lot# F0M325) used for its standardization was valid upto 30-09-2017.
3.2. P.8	• Firm has submitted copy of Licenses to Import Drug substance Tigecycline issued by AD I&E DRAP, Islamabad dated 05-08-2019 & 02-04-	ed are still subsequent to the date of g of two batches. i.e. L-131 & L-138 turing date of 03-2018, whereas oice is of 08-2019. voice is for "Tigecycline lyophilized".

	2020, whereas stability batches have been manufactured prior to these dates. • Clarification shall be submitted whether submitted stability studies data is of trial batches or commercial batches. • Raw data sheets for stability studies, reflecting the details of Standard weight, Sample dilution preparation, Potency of Reference standard and Calculation formula applied for the Assay test shall be submitted. • As per submitted stability studies data, test of particulate matter has not been performed, justification shall be submitted in this regard. • Dates of testing written in the stability summary sheets for different time points, does not relate with the relevant duration in months.	ubmitted that provided data is of atches. ets submitted. ity study sheets have been submitted.
	• As per submitted BMRs potency adjustment has not been done for the Drug substance, based upon the actual Assay results. • As per submitted BMRs, lactose monohydrate has been used in the formulation, whereas innovator product has been formulated without use of any excipient. Justification shall be submitted in this regard. • Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches shall be submitted shall be submitted. • Submitted BMRs have not been filled completely.	• BMR was written with standard batch formula and now it sbeen revised with potency adjustment as per potency of drug substance. • Revised BMR mentions the dispensed quantity of APi on the basis of 99% potency, whereas asper submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis. • Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage. Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.

Decision of 316th meeting: Deferred for following:

- **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.
- Evidence of availability of Auto sampler in HPLC, wherein 10°C temperature conditions could be maintained.
- Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.
- Specifications of fill weight/vial shall be submitted.
- Peak integration is not proper, since it does not coincide with the base line.
- Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.
- Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.

- Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.
- Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage.
- Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.
- Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection"

Firm's reply:

Observation	Firm's Reply
• **S**ubmission of formal documents for drug substance specifications & analytical procedures form M/s Bio-Labs, wherein details of document no., issue date or effective date shall have been mentioned.	Firm has submitted analytical procedure; wherein mobile phase composition is different from that proposed by the drug substance manufacturer.
Evidence of availability of Auto sampler in HPLC, wherein 10^{o}C temperature conditions could be maintained.	Firm has submitted specifications of auto sampler assembled with HPLC of Perkin Almer 200LC, wherein operating conditions for "Ambient temperature" are mentioned as 10- 30^{o}C.
Firm has submitted stability studies data of drug substance for the same batches as submitted earlier, wherein only conditions of storage have been changed as required for a refrigerated item, while the analytical values for all the tests are same as presented earlier.	The stability data has been done as per recommended storage conditions. There was typographic error in the data.
Specifications of fill weight/vial shall be submitted.	The product is in lyophilized form. For this 2 ml solution per vial was filled and then lyophilized. *It is pertinent to mention that vials are filled with 2 ml solution at an intermediate stage, whereas final dosage form of the applied product is in the powder form hence fill weight specifications are necessary to establish uniformity of dosage.*
Peak integration is not proper, since it does not coincide with the base line.	Firm has submitted chromatograms again with justification that the attenuation is increased which results in the proper coinciding of baseline.
• Submitted commercial invoices for the procurement of drug substance are still subsequent to the date of manufacturing of two batches. i.e. L-131 & L-138 with manufacturing date of 03-2018, whereas submitted invoice is of 08-2019.	No reply submitted.
• Scientific justification shall be submitted for use of Lyophilized powder of drug substance for the manufacture of finished drug product by way of lyophilization.	The bulk and raw material of tigecycline is also available in lyophilized/sterilized form. The raw material was then formulated into solution from which is then filled and lyophilized.

• Revised BMR mentions the dispensed quantity of API on the basis of 99% potency, whereas as per submitted COA of drug substance from M/s Bio-Labs, the potency of API is 98.4% on as is basis.	Firm has declared it as a typographic error, and has submitted revised COA of drug substance wherein Assay value has been declared as 99% on anhydrous basis, which still does not justify the dispensed amount on basis of "as is potency", since water content has been declared as 1.3%.
Submitted BMRs does not reflect any test of filled weight per vial, sterility testing at any stage	The solution is filled in the vials. The volume variation/checklist is attached.
• Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches have not been submitted.	The solution is filled in glass beaker (5Ltr) whose minimum handling capacity is 500ml.
Submitted COAs of drug product does not include test of particulate matter as recommended by the USP monograph of "Tigecycline for injection".	Firm has submitted revised COAs of drug product for complete stability studies, wherein test of "Particular matter" has now been included.

Decision of 320th meeting: Deferred for following:

- Submission of commercial invoices attested by AD DRAP I&E, for the procurement of drug substance used to manufacture drug product batches. i.e. L-131 & L-138.
- Specifications for the fill weight/vial shall be submitted.
- Evidence of performance of sterility testing at the time of batch release shall be submitted.
- Scientific justification shall be submitted for using glass beaker (5Ltr) for the compounding the commercial scale batches as lyophilization is performed after filling the solution in vials.
- Verification of the claim of the firm regarding submitted HPLC chromatograms that "attenuation is increased which results in the proper coinciding of baseline."

Firm's response: Firm has submitted following:

- Firm has submitted copy of license to import issued by AD I&E Islamabad dated 20-12-2017 for import of 200gm of Tigecycline.
- The product is filled with a fill volume of 2ml± 0.2ml solution for lyophilisation, after lyophilisation dried cake is formed.
- Microbiological reports for the sterility testing for batch release of stability batches.
- The product is commercially manufactured with a batch size of approx. 2litre so it is manufactured in a 5litre glass beaker as per proper manufacturing procedure.
- As the attenuation or scale of the y-axis is changed the baseline is automatically changed as shown in the attached chromatograms.

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.**		
360.	**Name and address of manufacturer / Applicant**	**M/s AGP (Private) Limited, B-23, S.I.T.E, Karachi**
	Brand Name +Dosage Form + Strength	Doxiproct Ointment
	Diary No. Date of R& I & fee	Dy.No: 335; Dated 21-010-2011, Rs.15000/- Rs.35,000/- (05-09-2013) Photocopy
	Composition	Each gram contains: Calcium Dobesilate…..40 mg Lidocaine hydrochloride…….20 mg
	Pharmacological Group	Anti haemorrhoidals
	Type of Form	Form-5 D
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack size of 15gm; Rs. 300/-
	Approval status of product in Reference Regulatory Authorities.	Doxiproct – OM Pharma, approved by Swissmedic of Switzerland.
	Me-too status	Not applicable
	GMP status	--
	Previous Remarks of the Evaluator.	• The firm has submitted 26 weeks Accelerated and 26 weeks of Intermediate Stability Study Data for 03 Batches. • Firm has performed test for Identification, Assay, Appearance, Weight of filled tubes and Microbial testing only during stability studies, whereas WHO guidelines for Stability testing of active pharmaceutical ingredients and finished pharmaceutical products recommends as under: • "Topical preparations should be evaluated for clarity, homogeneity, pH, suspendability (for lotions), consistency, viscosity, particle size distribution (for suspensions, when feasible), level of microbial contamination/sterility and weight loss (when appropriate)." Also USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests", recommends tests for "Apparent viscosity" and "Uniformity in Containers" as "Specific Tests For Topically Applied Semisolid Drug Products." • GMP certificate of supplier of Lidocaine HCl is expired. • Commercial invoice of Lidocaine has not been attested by ADC DRAP. • Commitment to follow Drug Specification Rules, 1978 has not been submitted.
	Previous Decision	The case was initially presented in 259th meeting of Registration Board wherein the case was deferred for submission of stability data as per guidelines provided in 251st RB meeting. In 272nd meeting of Registration Board the case was again presented along with stability studies data, wherein Registration Board deferred the case for following observations: i. Firm has performed test for Identification, Assay, Appearance, Weight of filled tubes and Microbial testing only during stability studies, whereas WHO guidelines for Stability testing of active pharmaceutical ingredients and finished pharmaceutical products recommends as under: "Topical preparations should be evaluated for clarity, homogeneity, pH, suspendability (for lotions), consistency, viscosity, particle size distribution (for suspensions, when feasible), level of microbial contamination/sterility and weight loss (when appropriate)." Also USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests", recommends tests for "Apparent viscosity" and "Uniformity in Containers" as "Specific Tests For Topically Applied Semisolid Drug Products." ii. GMP certificate of supplier of Lidocaine HCl is expired.

		iii. Commercial invoice of Lidocaine has not been attested by DRAP. iv. Commitment to follow Drug Specification Rules, 1978 has not been submitted.
	Evaluation of Firm's reply	Firm has replied as under: i. "We conducted the study only for the major tests because DRAP allows only limited quantity of APIs to be imported for product development. Due to small batch size we cannot perform analysis of all the required tests but tests like clarity, homogeneity and consistency have been covered in appearance of the ointment." ii. Copy of GMP certificate of supplier of Lidocaine hydrochloride i.e. M/s Gufic Life sciences Pvt. Ltd, Gujrat, India issued by FDCA Gujarat has been submitted. The certificate is valid upto 20-07-2019. iii. "Regarding the purchase of Lidocaine hydrochloride, we would like to inform you that our ordered quantity waqs very small therefore the manufacturer M/s Gufic Biosciences Ltd, India dispatched the material via DHL courier service. The material directly received by us therefore we issued to obtain the approval of ADC from local DRAP office." iv. Copy of DHL airway bill has been submitted in the name of AGP (Pvt.) ltd. for Lidocaine hydrochloride. v. Form 6 (License to import raw material for trial production, test & analysis) has been submitted. The Form 6 has been issued on 14-07-2017, whereas batch stability batches were manufactured in October 2016. vi. Commitment to follow Drug Specification Rules, 1978 has been submitted.
	Decision: Registration Board directed the firm to perform tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests". Registration Board decided to constitute following panel for onsite investigation to confirm genuineness/ authenticity of stability data, including tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests" and related documents, import of API, quality, specification, test analysis, facilities etc. • Director DTL Quetta . • Mr. Aslam Shah. • Dr. Saif ur Rehman Khattak, FGA, CDL, Karachi.	

M/s. AGP Limited, Karachi. – 02 Products

S. No.	Molecule	Brand Name of the Product
96.	Calcium Dobesilate……..40mg/g Lidocaine HCl……20mg/g	Doxiproct Ointment

Background:

Registration Board in its 273rd Meeting directed the firm to perform tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests". Registration Board decided to constitute following panel for onsite investigation to confirm genuineness/ authenticity of stability data, including tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests" and related documents, import of API, quality, specification, test analysis, facilities etc.

Composition of Panel:

- Dr. Amanullah Khan, Director Drugs Testing Laboratory, Quetta.
- Dr. Saif-ur-Rehman Khattak, Federal Government Analyst, Central Drug Laboratory, Karachi.
- Mr. Aslam Shah, Senior Manager, Pharmacy & Purchase, Indus Hospital, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire. Objective evidence was done via physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases.

Detail of investigation has been summarized as under:

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Calcium Dobesilate and Lidocaine HCl APIs?	Calcium Dobesilate (already present in firm's inventory since used in an already registered product Doxium Capsules 500mg). However, Firm produced invoice (No. SI1016000559 dated 12.08.2016) of M/s OM pharma Switzerland, and furthermore the firm on routine basis use to import Calcium Dobesilate for their product Doxium Capsules 500mg. The firm has imported 390g of Lidocaine HCl API from Gufic Bioscience Ltd., India. Firm has taken approval from DRAP.
2.	What was the rationale behind selecting the particular manufacturer of APIs?	The rationale behind selecting the API manufacturer for Calcium Dobesilate is the GMP Compliance and the experience for using the same API for their other registered product DOXIUM CAPSULE 500mg. Lidocaine HCl imported from M/s Gufic Bioscience Ltd., India which is GMP compliant manufacturer.
3.	Do you have documents confirming the import of Calcium Dobesilate and Lidocaine HCl APIs and reference standard and impurity standards?	The firm has produced documents confirming the import of APIs and their working standards. However Impurities reference standards were not available.
4.	Do you have certificate of analysis of the APIs, reference standards and impurity standards?	The firm has certificates of analysis for APIs and working standard of APIs only.
5.	Do you have any approval of APIs or GMP certificate of APIs manufacturer issued by regulatory authority of country of origin?	The firm has copy of GMP certificates of APIs manufacturer and approval by concerned regularity authority of country of origin. Calcium Dobesilate: Secretaria De Salud, Comision Federal De Proteccion Contra Reisgos Sanitarios, Mexico manufactured for OM Pharma Switzerland. Lidocaine HCl: Commissioner Food & Drugs Control Administration. Gujarat, India.
6.	Do you use APIs manufacturer method of testing?	The APIs are compendial, the firm has used APIs' Compendial method of testing as follows: Calcium Dobesilate E.P Lidocaine HCl B.P
7.	Do you have stability studies reports on APIs?	The firm has stability studies reports for both the APIs.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing of APIs has been performed by manufacturers as per SIM method and degradation products have also been quantified by the API manufacturers.
9.	Do you have method for quantifying the impurities in the APIs?	The firm has method for quantifying the impurities in the APIs.

<table>
<tr><td>10.</td><td>Do you have some remaining quantities of the APIs, their reference standard and impurities standards?</td><td>The firm has remaining quantities of the APIs & working standards of APIs only.</td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Import documents for some of the excipients are available. However, a few excipients were purchased from local markets.
Calcium Dobesilate : Import
Lidocaine HCl : Import
Polysorbatye 80 : Local Purchase
Propyl Gallate : Local Purchase
Buthylhydroxyanisole : Local Purchase
Anhydrous Citric Acid : Local Purchase
Cetyl Alcohol : Local Purchase
Polyethylene Glycol 300 : Local Purchase
Polyethylene Glycol 1500 : Import
Polyethylene Glycol 4000 : Import
Propylene Glycol : Local Purchase</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of Doxiproct Ointment?</td><td>The firm has written and authorized protocols for the development of Doxiproct Ointment.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipient compatibility studies?</td><td>The firm has not performed Drug-excipient compatibility studies as the composition of their ointment is similar to the innovator’s product Doxiproct Ointment. Manufactured by OM Pharma, Switzerland.</td></tr>
<tr><td>16.</td><td>Have you performed comparative studies?</td><td>The firm has performed comparative studies in respect of the following parameters against innovator product DOXIPROCT Ointment, OM Pharma, Switzerland:
1. Physical Appearance
2. Viscosity
3. pH
4. Assay

The product of the firm has comparable results with the product of innovator.

Furthermore, the following tests were also performed by the firm as desired by the DRAP against letter No. F.1-1/2017/PEC-DRAP (AD PEC-II).
Viscosity:
<table>
<tr><th>Batch Number</th><th>Viscosity Results (cp)</th><th>Limits</th></tr>
<tr><td>TR-135</td><td>28,500</td><td rowspan="3">26,000 – 35,000 cp at 25°C, 50rpm Spindle S-94</td></tr>
<tr><td>TR-142</td><td>29,800</td></tr>
<tr><td>TR-143</td><td>29,300</td></tr>
</table>
Uniformity in Containers:
<table>
<tr><th>Batch Number</th><th>API</th><th>Top</th><th>Middle</th><th>Bottom</th><th>Average</th></tr>
</table>
</td></tr>
</table>

		<table><tr><td rowspan="2">TR-135</td><td>Lidocaine HCl</td><td>96.22%</td><td>96.13%</td><td>97.80%</td><td>96.72%</td></tr><tr><td>Calcium Dobesilate</td><td>97.80%</td><td>97.85%</td><td>99.60%</td><td>98.42%</td></tr><tr><td rowspan="2">TR-142</td><td>Lidocaine HCl</td><td>95.97%</td><td>97.44%</td><td>96.63%</td><td>96.68%</td></tr><tr><td>Calcium Dobesilate</td><td>97.70%</td><td>99.19%</td><td>99.42%</td><td>98.44%</td></tr><tr><td rowspan="2">TR-143</td><td>Lidocaine HCl</td><td>96.48%</td><td>95.65%</td><td>96.34%</td><td>96.16%</td></tr><tr><td>Calcium Dobesilate</td><td>98.28%</td><td>97.44%</td><td>98.22%</td><td>97.98%</td></tr></table>
17.	Do you have product development (R&D) section?	The firm has dedicated product development (R&D) section for manufacturing of the product; however routine Quality Control lab has been used for analysis purpose.
18.	Do you have necessary equipment available in product development section for development of Doxiproct Ointment?	The firm has necessary equipment available in product development section for development of Doxiproct Ointment however routine Quality Control has been used for analysis purpose.
19.	Are the equipment in product development section qualified?	The equipment in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration / re-qualification program for the equipment used in Product Development section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has three technical persons comprise of one Ph.D. and two Pharm-Ds in manufacturing of New Products and three Chemists and one Pharm-D working on analytical side.
22.	Have you manufactured three stability batches for the stability studies of Doxiproct Ointment?	The firm has manufactured three stability batches for the stability studies (at 40°C/75%RH, 30°C/65%RH and 25°C/60%RH) of Doxiproct Ointment with batch number TR-135, TR-142 and TR-143. Each batch has a size of 100 tubes of 15.0g.
23.	What were the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tubes required per testing with number of testing frequencies.
24.	Do you have complete record of production of stability batches?	Batch manufacturing records for three (3) trial batches are available.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Have you developed and validated the method for testing of stability batches?	The firm has developed and validated the method for testing of stability batches of finished product.
27.	Do you have method transfer studies in case when the method of	Not applicable.

	testing being used by your firm is given by any other lab?	
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Calcium Dobesilate and Lidocaine HCl APIs and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Calcium Dobesilate and Lidocaine HCl APIs and the finished product Doxiproct Ointment.
29.	Do your method of analysis stability indicating?	The firm's method of analysis is stability indicating.
30.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR Compliant.
31.	Can you show Audit Trail reports on Calcium Dobesilate and Lidocaine HCl testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities o degradation products and stability batches?	The firm has remaining quantities of stability batches for real time stability studies; however there is no quantity of degraded products.
33.	Do you have commitment batches kept on stability testing?	The firm has three commitment batches kept on stability testing for real time stability testing up to 24 months.
34.	Do you have valid calibration status for the equipment used in Doxiproct (Calcium Dobesilate and Lidocaine HCl) Ointment production in analysis?	The firm has valid calibration status for the equipment used in Doxiproct Ointment (Calcium Dobesilate and Lidocaine HCl) production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system for stability chamber.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm has renovated their ointment/cream manufacturing area; however, this section still needs up gradation of HVAC system. Secondary change proper installation of ointment filling machine and utilities.

Conclusions:

On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Doxiproct Ointment (Calcium Dobesilate 40mg/g and Lidocaine HCl 20mg/g) is verifiable to satisfactory level. However, the facilities related to ointment manufacturing area cannot be rated as GMP compliant.

Decision of 276th meeting: Registration Board decided to defer the application for registration of "Doxiproct Ointment (Calcium Dobesilate 40mg/g and Lidocaine HCl 20mg/g)" by M/s. AGP Limited, Karachi in view of the fact that the facilities related to ointment manufacturing area cannot be rated as GMP compliant.

Firm's response: Firm has submitted GMP certificate no. 30/2021-DRAP (K) issue don basis of inspection conducted on 03-06-2021,including Semisolid (Cream/Ointment) section.

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		
361.	**Name and address of manufacturer / Applicant**	**M/s AGP (Private) Limited, B-23, S.I.T.E, Karachi**
	Brand Name +Dosage Form + Strength	Doxiproct Plus Ointment
	Diary No. Date of R& I & fee	Dy.No: 334; Dated 21-010-2011, Rs.15000/- Rs.35,000/- (02-08-2013)
	Composition	Each gram contains: Calcium Dobesilate…..40 mg Lidocaine hydrochloride…….20 mg
	Pharmacological Group	Anti haemorrhoidals
	Type of Form	Form-5 D
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 240/-
	Approval status of product in Reference Regulatory Authorities.	Doxiproct plus ointment– OM Pharma, approved by Swissmedic of Switzerland.
	Me-too status	Not applicable
	GMP status	--
	Previous Remarks of the Evaluator.	• The firm has submitted 26 weeks Accelerated and 26 weeks of Intermediate Stability Study Data for 03 Batches. • There is a significant change in Assay results of Dexamethasone in accelerated stability studies of Batch#. TR-144 i.e. initial results were 107.17% while those at 4th week were 93.12%. • There is a significant change in Assay results of Dexamethasone in accelerated stability studies of Batch#. TR-145 i.e. initial results were 107.25% while those at 6th week were 94.28%. • There is a significant change in Assay results of Dexamethasone in accelerated stability studies of Batch#. TR-146 i.e. initial results were 107.54% while those at 4th week were 94.98%. • Firm has performed test for Identification, Assay, Appearance, Weight of filled tubes and Microbial testing only during stability studies, whereas WHO guidelines for Stability testing of active pharmaceutical ingredients and finished pharmaceutical products recommends as under: • "Topical preparations should be evaluated for clarity, homogeneity, pH, suspendability (for lotions), consistency, viscosity, particle size distribution (for suspensions, when feasible), level of microbial contamination/sterility and weight loss (when appropriate)." Also USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests", recommends tests for "Apparent viscosity" and "Uniformity in Containers" as "Specific Tests For Topically Applied Semisolid Drug Products." • GMP certificate of supplier of Lidocaine HCl is expired. • Commercial invoices for Lidocaine HCl have not been attested by ADC DRAP. • Commitment to follow Drug Specification Rules, 1978 has not been submitted.
	Previous Decision	The case was initially presented in 256th meeting of Registration Board wherein the case was deferred for submission of stability data as per guidelines provided in 251st RB meeting. In 272nd meeting of Registration Board the case was again presented along with stability studies data, wherein Registration Board deferred the case for following observations: i. Firm has performed test for Identification, Assay, Appearance, Weight of filled tubes and Microbial testing only during stability studies, whereas WHO guidelines for Stability testing of active pharmaceutical ingredients

		and finished pharmaceutical products recommends as under: "Topical preparations should be evaluated for clarity, homogeneity, pH, suspendability (for lotions), consistency, viscosity, particle size distribution (for suspensions, when feasible), level of microbial contamination/sterility and weight loss (when appropriate)." Also USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests", recommends tests for "Apparent viscosity" and "Uniformity in Containers" as "Specific Tests For Topically Applied Semisolid Drug Products." ii. GMP certificate of supplier of Lidocaine HCl is expired. iii. Commercial invoice of Lidocaine has not been attested by DRAP. iv. Commitment to follow Drug Specification Rules, 1978 has not been submitted.
	Evaluation of Firm's reply	Firm has replied as under: "We conducted the study only for the major tests because DRAP allows only limited quantity of APIs to be imported for product development. Due to small batch size we cannot perform analysis of all the required tests but tests like clarity, homogeneity and consistency have been covered in appearance of the ointment." Copy of GMP certificate of supplier of Lidocaine hydrochloride i.e. M/s Gufic Life sciences Pvt. Ltd, Gujrat, India issued by FDCA Gujarat has been submitted. The certificate is valid upto 20-07-2019. "Regarding the purchase of Lidocaine hydrochloride, we would like to inform you that our ordered quantity was very small therefore the manufacturer M/s Gufic Biosciences Ltd, India dispatched the material via DHL courier service. The material directly received by us therefore we issued to obtain the approval of ADC from local DRAP office." Form 6 (License to import raw material for trial production, test & analysis) has been submitted. The Form 6 has been issued on 14-07-2017, whereas batch stability batches were manufactured in October 2016. Commitment to follow Drug Specification Rules, 1978 has been submitted.
	Decision: Registration Board directed the firm to perform tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests". Registration Board decided to constitute the following panel for onsite investigation to confirm genuineness/ authenticity of stability data, including tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests" and related documents, import of API, quality, specification, test analysis, facilities etc. • Director DTL Quetta . • Mr. Aslam Shah. • Dr. Saif ur Rehman Khattak, FGA, CDL, Karachi.	

S. No.	Molecule	Brand Name of the Product
97.	Calcium Dobesilate……..40mg/g Lidocaine HCl……20mg/g Dexamethasone Acetate……0.25mg/g	Doxiproct Plus Ointment

Background:

Registration Board in its 273rd Meeting directed the firm to perform tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests". Registration Board decided to constitute the following panel for onsite investigation to confirm genuineness / authenticity of stability data, including tests of "Apparent viscosity" and "Uniformity in Containers" as recommended in USP chapter <3> titled "Topical and Transdermal Drug Products – Product Quality Tests" and related documents, import of API, quality, specification, test analysis, facilities etc.

Composition of Panel:

- Dr. Amanullah Khan, Director Drugs Testing Laboratory, Quetta.
- Dr. Saif-ur-Rehman Khattak, Federal Government Analyst, Central Drug Laboratory, Karachi.
- Mr. Aslam Shah, Senior Manager, Pharmacy & Purchase, Indus Hospital, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire. Objective evidence was done via physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases.

Detail of investigation has been summarized as under:

Q.	Question	Observation by panel
1.	Do you have documents confirming the import of Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate APIs?	Calcium Dobesilate (already present in firm's inventory since used in an already registered product Doxium Capsules 500mg). However, Firm produced invoice (No. SI1016000559 dated 12.08.2016) of M/s OM pharma Switzerland, and furthermore the firm on routine basis use to import Calcium Dobesilate for their product Doxium Capsules 500mg. The firm has imported 390g of Lidocaine HCl API from Gufic Bioscience Ltd., India and Dexamethasone Acetate 5.0g from Zhejiang Xianju pharmaceutical Co. Firm has taken approval of both APIs from DRAP.
2.	What was the rationale behind selecting the particular manufacturer of APIs?	The rationale behind selecting the API manufacturer for Calcium Dobesilate is the GMP Compliance and the experience for using the same API for their other registered product DOXIUM CAPSULE 500mg. Lidocaine HCl imported from M/s Gufic Bioscience Ltd., India is GMP compliant and similarly the Dexamethasone Acetate imported from M/s Zhejiang Xianju pharmaceutical Co., China which is GMP compliant manufacturer.
3.	Do you have documents confirming the import of Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate APIs and reference standard and impurity standards?	The firm has produced documents confirming the import of APIs and their working standards. However Impurities reference standards were not available.
4.	Do you have certificate of analysis of the APIs, reference standards and impurity standards?	The firm has certificates of analysis for APIs and working standard of APIs only.
5.	Do you have any approval of APIs or GMP certificate of APIs manufacturer issued by regulatory authority of country of origin?	The firm has copy of GMP certificates of APIs manufacturer and approval by concerned regularity authority of country of origin. Calcium Dobesilate: Secretaria De Salud, Comision Federal De Proteccion Contra Reisgos Sanitarios, Mexico manufactured for OM Pharma Switzerland. Dexamethason Acetate: China Food and Drug Administration. Lidocaine HCl: Commissioner Food & Drugs Control Administration. Gujarat, India.
6. :	Do you use APIs manufacturer method of testing?	The APIs are compendial, the firm has used APIs' Compendial method of testing as follows: Calcium Dobesilate E.P

		Lidocaine HCl B.P Dexamethasone Acetate B.P
7.	Do you have stability studies reports on APIs?	The firm has stability studies reports for all the three APIs.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing of APIs has been performed by manufacturers as per SIM method and degradation products have also been quantified by the API manufacturers.
9.	Do you have method for quantifying the impurities in the APIs?	The firm has method for quantifying the impurities in the APIs.
10.	Do you have some remaining quantities of the APIs, their reference standard and impurities standards?	The firm has remaining quantities of the APIs & working standards of APIs only.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients.
12.	Do you have documents confirming the import of the used excipients?	Import documents for some of the excipients are available. However, a few excipients were purchased from local markets. Calcium Dobesilate : Import Lidocaine HCl : Import Dexamethasone Acetate : Import Polysorbatye 80 : Local Purchase Propyl Gallate : Local Purchase Buthylhydroxyanisole : Local Purchase Anhydrous Citric Acid : Local Purchase Cetyl Alcohol : Local Purchase Polyethylene Glycol 300 : Local Purchase Polyethylene Glycol 1500 : Import Polyethylene Glycol 4000 : Import Propylene Glycol : Local Purchase
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Doxiproct Plus Ointment?	The firm has written and authorized protocols for the development of Doxiproct Plus Ointment.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipient compatibility studies as the composition of their ointment is similar to the innovator's product Doxiproct Plus Ointment. Manufactured by OM Pharma, Switzerland.
16.	Have you performed comparative studies?	The firm has performed comparative studies in respect of the following parameters against innovator product DOXIPROCT Plus Ointment, OM Pharma, Switzerland: 1. Physical Appearance 2. Viscosity 3. pH 4. Assay The product of the firm has comparable results with the product of innovator.

<table>
<tr><td></td><td></td><td>Furthermore, the following tests were also performed by the firm as required by the DRAP against letter No. F.1-1/2017/PEC-DRAP (AD PEC-II).

Viscosity:
<table>
<tr><th>Batch Number</th><th>Viscosity Results (cp)</th><th>Limits</th></tr>
<tr><td>TR-144</td><td>32,300</td><td rowspan="3">26,000 – 35,000 cp at 25°C,
50rpm Spindle S-94</td></tr>
<tr><td>TR-145</td><td>31,100</td></tr>
<tr><td>TR-146</td><td>30,800</td></tr>
</table>

Uniformity in Containers:
<table>
<tr><th>Batch Number</th><th>API</th><th>Top</th><th>Middle</th><th>Bottom</th><th>Average</th></tr>
<tr><td rowspan="3">TR-144</td><td>Lidocaine HCl</td><td>95.55%</td><td>95.60%</td><td>95.32%</td><td>95.49%</td></tr>
<tr><td>Calcium Dobesilate</td><td>97.22%</td><td>96.51%</td><td>96.50%</td><td>96.74%</td></tr>
<tr><td>Dexamethasone</td><td>96.05%</td><td>96.01%</td><td>95.90%</td><td>95.99%</td></tr>
<tr><td rowspan="3">TR-145</td><td>Lidocaine HCl</td><td>95.69%</td><td>95.81%</td><td>95.10%</td><td>95.54%</td></tr>
<tr><td>Calcium Dobesilate</td><td>96.89%</td><td>97.07%</td><td>98.82%</td><td>97.59%</td></tr>
<tr><td>Dexamethasone</td><td>96.25%</td><td>96.34%</td><td>97.27%</td><td>96.62%</td></tr>
<tr><td rowspan="3">TR-146</td><td>Lidocaine HCl</td><td>96.91%</td><td>96.23%</td><td>96.38%</td><td>96.51%</td></tr>
<tr><td>Calcium Dobesilate</td><td>98.43%</td><td>98.34%</td><td>97.83%</td><td>98.20%</td></tr>
<tr><td>Dexamethasone</td><td>97.71%</td><td>96.68%</td><td>96.92%</td><td>97.10%</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section?</td><td>The firm has dedicated product development (R&D) section for manufacturing of the product; however routine Quality Control lab has been used for analysis purpose.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Doxiproct Plus Ointment?</td><td>The firm has necessary equipment available in product development section for development of Doxiproct Plus Ointment however routine Quality Control has been used for analysis purpose.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipment in product development section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has proper maintenance / calibration / re-qualification program for the equipment used in Product Development section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has three technical persons comprise of one Ph.D. and two Pharm-Ds in manufacturing of New Products and three Chemists and one Pharm-D working on analytical side.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Doxiproct Plus Ointment?</td><td>The firm has manufactured three stability batches for the stability studies (at 40°C/75%RH, 30°C/65%RH and 25°C/60%RH) of Doxiproct Plus Ointment with batch number TR-144, TR-145 and TR-146. Each batch has a size of 100 tubes of 10.0g.</td></tr>
</table>

23.	What were the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tubes required per testing with number of testing frequencies.
24.	Do you have complete record of production of stability batches?	Batch manufacturing records for three (3) trial batches are available.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Have you developed and validated the method for testing of stability batches?	The firm has developed and validated the method for testing of stability batches of finished product.
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?	Not applicable.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate APIs and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate APIs and the finished product Doxiproct Plus Ointment.
29.	Do your method of analysis stability indicating?	The firm's method of analysis is stability indicating.
30.	Do your HPLC software is 21CFR compliant?	HPLC software is 21CFR Compliant.
31.	Can you show Audit Trail reports on Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities o degradation products and stability batches?	The firm has remaining quantities of stability batches for real time stability studies; however there is no quantity of degraded products.
33.	Do you have commitment batches kept on stability testing?	The firm has three commitment batches kept on stability testing for real time stability testing up to 24 months.
34.	Do you have valid calibration status for the equipment used in Doxiproct Plus (Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate) Ointment	The firm has valid calibration status for the equipment used in Doxiproct Plus Ointment (Calcium Dobesilate, Lidocaine HCl and Dexamethasone Acetate) production and analysis.

	production in analysis?	
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system for stability chamber.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm has renovated their ointment / cream manufacturing section, however, this section still needs upgradation of HVAC system, creation of dispensing booth for dispensing dexamethasone. Secondary change proper installation of ointment filling machine & utilities.

Conclusions:
On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Doxiproct Plus Ointment (Calcium Dobesilate 40mg/g, Lidocaine HCl 20mg/g and Dexamethasone acetate 0.25mg/g) is verifiable to satisfactory level. However, the facilities related to ointment manufacturing area cannot be rated as GMP compliant.

Decision of 276th meeting: Registration Board decided to defer the application for registration of "Doxiproct Plus Ointment (Calcium Dobesilate 40mg/g, Lidocaine HCl 20mg/g and Dexamethasone acetate 0.25mg/g)" by M/s. AGP Limited, Karachi in view of the fact that the facilities related to ointment manufacturing area cannot be rated as GMP compliant.

Firm's response: Firm has submitted GMP certificate no. 30/2021-DRAP (K) issue don basis of inspection conducted on 03-06-2021,including Semisolid (Cream/Ointment) section.

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

362.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, 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. 671 dated 07/01/2022
	Details of fee submitted	PKR 30,000/-: dated 16/12/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 10mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)……10mg Metformin HCl (extended release)…..1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications

	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet 10mg/1000mg by Boehringer Ingelheim, USFDA, UK & Health Canada Approved.
	For generic drugs (me-too status)	Erli Plus Tablets 10mg + 1000mg by Pharmevo Reg. No. 105274
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	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 is established against the Innovator product that is Synjardy XR Tablet 10mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 10mg + 1000mg by Boehringer Ingelheim, USA in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI
Description of Pack (Container closure system)	Alu-Alu 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.	NPD-T-1614-S	NPD-T-1623-S	NPD-T-1624-S
Batch Size	2500 tablets	5000 tablets	5000 tablets
Manufacturing Date	03-08-2021	24-08-2021	24-08-2021
Date of Initiation	03-09-2021	03-09-2021	03-09-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No.

		MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.
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)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.
363.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, 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. 2526 dated 26/01/2022
	Details of fee submitted	PKR 30,000/-: dated 16/12/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 5mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)…….5mg Metformin HCl (extended release)…..1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet 5mg/1000mg by Boehringer Ingelheim, USFDA, UK & Health Canada Approved.
	For generic drugs (me-too status)	Erli Plus Tablet 5mg + 1000mg by M/s Pharmevo (Pvt.) Ltd., Reg. No. 105273
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj

		Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	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 is established against the Innovator product that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.
STABILITY STUDY DATA		
Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan	

		County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.		
API Lot No.		Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI		
Description of Pack (Container closure system)		Alu-Alu 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.		NPD-T-1656-S	NPD-T-1660-S	NPD-T-1661-S
Batch Size		5000 tablets	5000 tablets	5000 tablets
Manufacturing Date		13-09-2021	18-09-2021	18-09-2021
Date of Initiation		29-09-2021	29-09-2021	29-09-2021
No. of Batches		03		
Administrative Portion				
I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.		
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.		
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.		
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)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.		
364.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**		
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, 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. 670 dated 07/01/2022
	Details of fee submitted	PKR 30,000/-: dated 29/11/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 12.5mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)…….12.5mg Metformin HCl (extended release)…….1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Erli Plus XR Tablet 12.5/1000mg by M/s Pharmevo (Pvt.) Ltd., (Reg. No. 105275)
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch

		analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	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 IS established against the Innovator product that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.		
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu 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.	NPD-T-1626-S	NPD-T-1660-S	NPD-T-1661-S
Batch Size	5000 tablets	5000 tablets	5000 tablets

Manufacturing Date	24-08-2021	18-09-2021	18-09-2021
Date of Initiation	29-09-2021	29-09-2021	29-09-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.
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)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	The submitted stability data is till 3rd month time point, please provide stability study data till 6th month time point.	The firm has referred to the earlier submitted stability data of 6th month time point for all three strengths.
2	• Provide complete batch manufacturing record for the applied product along with the calculations for potency adjustment considering the assay value of the drug substance on As-is basis. • Provide detail of manufacturing method for the applied product.	Complete batch manufacturing record has been submitted for three batches of each strength. It is evident from the submitted batch processing record that instead of dispensing the whole API coating solution in excess to overcome the process loss, firm has used 100% excess of Empagliflozin only.

Justification of Overage:

Empator-M 25mg + 1000mg XR Tablet was developed with reference to the Innovator product, **Synjardy 25mg + 1000mg XR Tablet** of MSD, which contains extended-release core of Metformin HCl (1st API) and API coating of immediate release Empagliflozin (2nd API).

The coating process itself, is inevitable to process loss, due to which it is required to add an excess amount of raw materials in the coating solution so that the final landing quantity of API on the core tablet complies with the claimed amount.

Similar case was observed at development stage, during the coating of Empagliflozin on Metformin core, the quantity

of coating solution was gradually increased by hit n trial to comply the landing quantity of API on the tablet in accordance with the label claim.
With reference to the ***WHO Annex 3 Pharmaceutical development of multisource (generic) finished pharmaceutical products***, the excess quantity of API coating solution is justified as the excess is lost during the coating process and it was completely utilized to achieve the required quantity on the tablet after Drug loading stage.
The assay results of API Empagliflozin at release testing and throughout the stability studies, are within the label claimed amount, making it evident that the excess amount of API coating solution was lost during the coating process and was not part of the finished dosage form. The **Assay** results of the stability studies are given as reference:

Justification of dissolution profile:
Martin Dow Limited has developed following strengths of Empagliflozin + Metformin HCl XR tablets for new product registration applications,
Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 12.5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 10 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 25 mg + Metformin HCl 1000 mg XR Tablet
As per the ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products
Bracketing can be applied to studies with multiple strengths of identical or closely related formulations. Examples include but are not limited to (1) capsules of different strengths made with different fill plug sizes from the same powder blend, (2) tablets of different strengths manufactured by compressing varying amounts of the same granulation, and (3) oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colourants, flavourings).
Martin Dow has perfomed Extended-release dissolution profile at core stage before coating of Empator 12.5/1000mg XR and Empator 5/1000mg XR Tablet tablet, meanwhile establishing dissolution profile of Empator 25/1000mg XR Tablet of core stage as per the method of bracketing, and later on batches were found to have the satisfactory results with extended release dissolution profile of Metformin HCl specification at coated stage.

Decision of 326th meeting: Registration board deferred the applications of Empator-M XR Tablet 10mg + 1000mg, Empator-M XR Tablet 5mg + 1000mg & Empator-M XR Tablet 12.5mg + 1000mg for following reasons:

- Scientific justification on the basis of performance based data for using 100% excess of drug substance in the active coating of Empagliflozin.
- Submission of any performance based data to justify that 100% excessive Empagliflozin is required to overcome the process loss during active coating.
- Justification for referring the "ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products" for skipping the in-process test of dissolution of Metformin extended release core, since the cited guideline is intended to address recommendations on the application of bracketing and matrixing to stability studies.

365.	**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 MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, 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. 33103 dated 17/12/2021
	Details of fee submitted	PKR 30,000/-: dated 29/11/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 25mg+1000mg**
	Strength / concentration of drug of Active	Each film coated, extended release tablet contains:

	Pharmaceutical ingredient (API) per unit	Empagliflozin (immediate release)……..25mg Metformin HCL (extended release)…….1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR tablet by Hilton Pharma
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	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	Pharmaceutical equivalence studies have been submitted

	dissolution profile	against the innovator's product that is Synjardy XR tablet 25/1000mg mfg by Boehringer Ingelheim USA (Batch number: 3189877) by performing all the quality tests. Comparative dissolution profile is submitted agaisn the innovator's product that is Synjardy XR Tablet (25/1000mg) in 0.1N HCL, Phosphate Buffer and Acetate Buffer. F2 values are in acceptable range.
	Analytical method validation/verification of product	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI
Description of Pack (Container closure system)	Alu-Alu 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.	NPD-T-1573-S	NPD-T-1616-S	NPD-T-1617-S
Batch Size	4000 tablet	4000 tablet	4000 tablet
Manufacturing Date	07/07/2021	04/08/2021	07/07/2021
Date of Initiation	17/08/2021	17/08/2021	17/08/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance 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)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	The submitted stability data is till 3rd month time point, please provide stability study data till 6th month time point.	The firm has submitted stability summary sheets till 6 months for accelerated and long term stability studies along with the relevant documents.
2	As per submitted dossier, titration method has been used for assay estimation for Metformin HCl while according to latest edition of USP, HPLC method should be used for assay testing, please clarify.	*"The method used for assay estimation of Metformin for finished product by FPP manufacturer is HPLC as per latest edition of USP. API manufacturer has used titration method for assay estimation owing to the previous version of USP monograph".*
3	Provide complete batch manufacturing record for the applied product.	Complete batch manufacturing record is submitted.
4	As per submitted dossier, dissolution tests for Metformin core before coating has not been performed. Clarification is required for not establishing the dissolution profile for the tablet core.	*The Dissolution testing for Metformin HCl was performed at core stage before coating and results were well within specified limits. Since Metformin HCl in all strength have same label claim and same formulation, therefore dissolution profile is performed on film coated stage on risk basis. Satisfactory initial and stability results are also evident on Metformin HCl dissolution performance.* *Following core stage results are also attached herewith.* *Batch No. NPD-T-1108-T (Empagliflozin 5mg + Metformin HCl 1000 mg XR Tablet)* *Batch No. NPD-T-1107-T (Empagliflozin 12.5mg + Metformin HCl 1000 mg XR Tablet)*
5	Provide detail of manufacturing method for the applied product.	The firm has submitted complete batch manufacturing record for the applied product.

6. Scientific justification is required regarding addition of 100% overage for Empagliflozin for compensating the loss during coating.

Response:

Empagliflozin + Metformin HCl 25 + 1000 mg XR tablet is an API (Empagliflozin) coated tablet. Hence, the API is part of the coating suspension. As per label claim, 25 mg of Empagliflozin is coated on the tablet as mentioned in the Batch Production Record of Empagliflozin + Metformin HCl 25 + 1000 mg XR tablet, pp# 25 and is evident through the tablet weight that is 1479.0 mg, pp #43 95mg was coated on the tablet of 1384.0 mg thus taking it to 1479.00mg. Breakup is given below:

API Coating			
S.No.	*Raw Material*	*Quantity/tablet*	*Quantity/Batch*
1	*Empagliflozin*	*25.000 mg*	*250.000 g*
2	*Sheffcoat D white 5Y00692*	*42.000 mg*	*420.000 g*
3	*Talc*	*3.000 mg*	*30.000 g*
4	*Polysorbate 80 (Tween 80)*	*20.000 mg*	*200.000 g*

5	*Polyethylene Glycol 6000*	*5.000 mg*	*500.000 g*

Thus, no overages of the API are added which can be seen via the content increase of tablet before and after API coating mentioned above.

- *The 100% excess quantity mentioned in the BPR is for the clarity of the reviewer and the document itself.*
- *Excess quantity was added in coating material i.e., Sheffcoat D white 5Y00692, Polyethylene Glycol 6000, Talc, Polysorbate 80 (Tween 80) along with it is the **API Empagliflozin** to compensate for the process loss faced while Coating operation is being carried out, as it is an API coated tablet.*

*As it is understood that losses are observed/experienced during coating and thus extra quantities are added as a recompense. These extra quantities do not become part of the final film coated product, as is evident in the **Assay** results of **Empagliflozin** which are well within limits as per label claim.*

Decision of 322nd meeting: Registration Board deferred the case for;

- Scientific justification regarding addition of 100% overage for Empagliflozin for compensating the loss during coating.
- Clarification for not establishing the dissolution profile of the extended release core tablet before coating.

Firm's response:

Justification of Overage:

Empator-M 25mg + 1000mg XR Tablet was developed with reference to the Innovator product, **Synjardy 25mg + 1000mg XR Tablet** of MSD, which contains extended-release core of Metformin HCl (1st API) and API coating of immediate release Empagliflozin (2nd API).

The coating process itself, is inevitable to process loss, due to which it is required to add an excess amount of raw materials in the coating solution so that the final landing quantity of API on the core tablet complies with the claimed amount.

Similar case was observed at development stage, during the coating of Empagliflozin on Metformin core, the quantity of coating solution was gradually increased by hit n trial to comply the landing quantity of API on the tablet in accordance with the label claim.

With reference to the ***WHO Annex 3 Pharmaceutical development of multisource (generic) finished pharmaceutical products***, the excess quantity of API coating solution is justified as the excess is lost during the coating process and it was completely utilized to achieve the required quantity on the tablet after Drug loading stage.

The assay results of API Empagliflozin at release testing and throughout the stability studies, are within the label claimed amount, making it evident that the excess amount of API coating solution was lost during the coating process and was not part of the finished dosage form. The **Assay** results of the stability studies are given below as reference:

Batch No. NPD-T-1616-S			
Real Time			
Assay (Empagliflozin**)**	**0**	**3M**	**6M**
90.0 %-110.0 %	101.5 %	101.7 %	97.8 %
Accelerated			
90.0 %-110.0 %	101.5 %	101.9 %	98 %

Justification of dissolution profile:

Martin Dow Limited has developed following strengths of Empagliflozin + Metformin HCl XR tablets for new product registration applications,

Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet

Empagliflozin 12.5 mg + Metformin HCl 1000 mg XR Tablet

Empagliflozin 10 mg + Metformin HCl 1000 mg XR Tablet

Empagliflozin 25 mg + Metformin HCl 1000 mg XR Tablet

As per the ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products

Bracketing can be applied to studies with multiple strengths of identical or closely related formulations. Examples include but are not limited to (1) capsules of different strengths made with different fill plug sizes from the same powder blend, (2) tablets of different strengths manufactured by compressing varying amounts of the same granulation, and (3) oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colourants, flavourings).

Martin Dow has perfomed Extended-release dissolution profile at core stage before coating of Empator 12.5/1000mg

XR and Empator 5/1000mg XR Tablet tablet, meanwhile establishing dissolution profile of Empator 25/1000mg XR Tablet of core stage as per the method of bracketing, and later on batches were found to have the satisfactory results with extended release dissolution profile of Metformin HCl specification at coated stage.

Decision of 326th meeting: Registration board deferred the application for following reasons:

- Scientific justification on the basis of performance based data for using 100% excess of drug substance in the active coating of Empgaliflozin.
- Submission of any performance based data to justify that 100% excessive Empagliflozin is required to overcome the process loss during active coating.
- Justification for referring the "ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products" for skipping the in-process test of dissolution of Metformin extended release core, since the cited guideline is intended to address recommendations on the application of bracketing and matrixing to stability studies.

Firm's reply:

Sr.#	Observations
1.	• Scientific justification on the basis of performance based data for using 100% excess of drug substance in the active coating of Empagliflozin. • Submission of any performance based data to justify that 100% excessive Empagliflozin is required to overcome the process loss during active coating.

Firm's response:

- The excess quantity in the coating solution was achieved on hit and trial basis.
- Tablet coating is a process of applying a layer of polymer on rotating tablet in a coating pan which is highly susceptible to loss due to atomization, solvent evaporation, removal by exhaust system and accumulation on the surface of coating pan. So, the coating suspension/solution is generally prepared in excess to overcome these losses and achieve the desired amount of coating.
- To decide the percentage of film coating for **Empator-M XR tablet range**, various patents and coating applications were studied. As mentioned in **Aulton's Pharmaceutics – the design and manufacture of medicines Third Edition (p#502)**, coatings are up to 2-3% normally, but can deviate as per requirements.
- Keeping the above in view, a theoretical weight of each coating layer and the final coated tablet was determined to load a specific quantity of coating material and achieve the claimed amount of API-Empagliflozin on each tablet.

1st Trial batch:

The initial trial formulation was developed according to the excipients used by the Innovator and the coating suspension was prepared with 50% excess considering the losses during coating operation as described above.

Batch no.	Excess quantity (%)	Remarks
NPD-T-1135-T (B)	50% (initial)	Before achieving target theoretical weight, the coating suspension got finished. Hence, same quantity of materials was dispensed again, and suspension was prepared to complete coating.
	50% (re-dispensed)	
Total	100%	

The BPR of the above-mentioned batch is provided, which shows that during coating process the coating suspension was fully consumed, however, the theoretical weight of the tablet was not achieved. Hence, the coating suspension was dispensed again, coating was continued, and the desired theoretical weight was achieved.

2nd Trial batch:

The second trial was manufactured and, from the experience learned from 1st trial, the initial quantity of coating material was dispensed with only 75% excess to try to reduce the extra material, avoid the need for re-dispensing and achieve the desired theoretical weight in one-go.

Batch no.	Excess quantity %	Remarks
NPD-T-1135-T (D)	75% (initial)	Before achieving target weight, coating suspension was finished. Hence, same quantity of materials was dispensed again, and suspension was prepared to complete coating.
	75% (re-dispensed)	
Total	150%	

However, as mentioned in its provided BPR, the coating suspension was without reaching the desired theoretical weight. Hence, the coating suspension was dispensed again, coating was continued, and the desired theoretical weight was achieved while some of the coating suspension was left.

3rd Trial batch:

A third trial was manufactured and, from the experience learned from 1st and 2nd trials, the initial quantity of coating material was dispensed with only 85% excess to again try to reduce the extra material, avoid the need for re-dispensing and achieve the desired theoretical weight in one-go.

Batch no.	Excess quantity %	Remarks
NPD-T-1135-T (E)	85% (initial)	Before achieving target weight, coating suspension was finished. Hence, same quantity of materials was dispensed again, and suspension was prepared to complete coating.
	85% (Re-dispensed)	
Total	170%	

However, as mentioned in its provided BPR, the coating suspension was fully consumed without reaching the desired theoretical weight. Hence, the coating suspension was dispensed again, coating was continued, and the desired theoretical weight was achieved while some of the coating suspension was left.

4th Trial batch:

As per the experiences gained from previous trials, another trial batch was manufactured with 100% excess in coating suspension.

Batch no.	Excess quantity %	Remarks
NPD-T-1382-T (C)	100%	Target weight was achieved without the need of re-dispensing
NPD-T-1426-T (A)	100%	Target weight was achieved without the need of re-dispensing
NPD-T-1456-T (M)	100%	Target weight was achieved without the need of re-dispensing.

- The samples were tested with satisfactory results. The BPRs are provided. Report of satisfactory trial (1456 M) is also provided as same formulation and process controls were carried to stability batches.
- The final weight of tablets and utilization of coating suspension was monitored closely during development in order to reduce the excess as much as possible. And, in light of the development data obtained from the manufacturing and analysis of all the above-mentioned batches, the final formulation was fixed with 100% excess.
- Any excess quantity is lost during the coating process and final landing quantity of API on the tablets remains well within the specified limits and claimed amount, evident from the analytical reports, and thus, will not reach the patients. As patient safety & efficacy is MDL's prime concern.
- Moreover, from the knowledge and experience of commercial manufacturing, it can be expected that as the batch size and machine capacity will increase, the percentage of excess quantity that will be required to coat a commercial batch will reduce.

2. Justification for referring the "ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products" for skipping the in-process test of dissolution of Metformin extended release core, since the cited guideline is intended to address recommendations on the application of bracketing and matrixing to stability studies.

Firm's response:

The Dissolution Profile on Metformin HCl extended release core tablets is performed on initial trail batches. The spcecification of product is adopted on the basis of FDA Dissolution Methods Database, Center of Drug Evaluation Application No. 208658Orig1s000" Chemistry Review & USP monograph Specifiaction of Metformin HCl extended release tablet.

The methdology adopted was based on the refrences of Metformin HCl core tablet which has following stages:

First stage:

In first stage of product devleopment, Metformin HCl extended release tablet at Core Stage was developed and assesed as mentioned in table below. All tablets in the Empagliflozin + Metformin HCl XR tablet range have the exact same core of Metformin HCL 1000mg.

S.No	Product Name	Batch	Specification	Dissolution on core Performed
			Dissolution (Metformin HCl)	
01	Empagliflozin + Metformin HCl XR Tablet 5 + 1000 mg	NPD-T-1108-T	(NMT 22 - 42% in 2 hours)	✓
			(NMT 49 - 69% in 4 hours)	

			(Not less than 85% (Q=80%) in 12 hours)	
02	Empagliflozin + Metformin HCl XR Tablet 12.5 + 1000 mg	NPD-T-1107-T	(NMT 22 - 42% in 2 hours)	✓
			(NMT 49 - 69% in 4 hours)	
			(Not less than 85% (Q=80%) in 12 hours)	

As the core of Metformin HCl is exactly same in all 4 strengths of this range, and considering the satisfactory results of Dissolution testing of core tablet in 1st stage, the Comparative Dissolution Profile on the final coated tablet was performed on all strengths in comparison with the Innovator Product **"Synjardy XR Tablet"** of **Boehrenger Ingelheim** (as given in the table below) and comparable results were acheived. Satisfactory stability reslults of all strengths are well within specified limits.

S.No	Product Name	Batch	Comparitive Dissolution Profile	Innovator Batch
01	Empagliflozin + Metformin HCl XR Tablet 5 + 1000 mg	NPD-T-1656-S*	Yes	3191437
		NPD-T-1660-S	-	-
		NPD-T-1661-S	-	-
02	Empagliflozin + Metformin HCl XR Tablet 10 + 1000 mg	NPD-T-1614-S*	Yes	3188976
		NPD-T-1623-S	-	-
		NPD-T-1624-S	-	-
03	Empagliflozin + Metformin HCl XR Tablet 12.5 + 1000 mg	NPD-T-1615-S*	Yes	3188979
		NPD-T-1625-S	-	-
		NPD-T-1626-S	-	-
04	Empagliflozin + Metformin HCl XR Tablet 25 + 1000 mg	NPD-T-1573-S*	Yes	3189877
		NPD-T-1616-S	-	-
		NPD-T-1617S	-	-

*Representative stability batch

To establish the analytical target profile (ATP) of products the knowledge, experience and referance research publication play an important role in setting method specification on identified CQA (Critical Quality Attributes). All tests are bieng perfomed to assure the product quality attributes. The use of ICH Q1D is just to understand the scope of ICH Q14. Section 4. **"Knowledge and risk management in Anlytical Procedure Development and Continual Improvement"**

All future and commercial batches will be tested for dissolution and assay at core stage also as per compliance with quality guidelines.

Decision: Registration Board approved the applications of Empator-M XR Tablet 10mg + 1000mg, Empator-M XR Tablet 5mg + 1000mg, Empator-M XR Tablet 12.5mg + 1000mg & Empator-M XR Tablet 25mg+1000mg. Registrationletter will be issued upon submission of protocol for in-process testing including dissolution test to establish dissolution profile of metofmrin HCl at core stage.

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

c. **Deferred cases of Form 5.**

366.	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**

	Brand Name + Dosage Form + Strength	Fertrex N Cream 0.025%/0.5%
	Composition	Each Gm Cream Contains: Fluocinolone Acetonide 0.25mg Neomycin Sulphate 5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13558 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	029329; "BREVOXYL 4% Cream" "GSK"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision of 327th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**.**	
	Firm's response: Firm has referred to the US FDA product "Neo-Synalar cream" for the applied formulation.	
	Decision: Approved.	
367.	**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	Bitrex 4% Cream
	Composition	Each 100Gm Cream Contains: Benzoyl Peroxide….. 4g
	Diary No. Date of R& I & fee	Form-5 Dy.No 13565 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	organic compounds
	Type of Form	Form-5
	Finished product Specifications	Maxitech Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	019464; "BREVOXYL 4% Cream" "GSK"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision of 327th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**.**	
	Firm's response: Firm has referred to the Brevoxyl 4% cream approved by MHRA of UK.	
	Decision: Approved with BP specfications. 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.	
368.	**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	Fetrex Topical Solution 0.01%
	Composition	Each ml Contains: Fluocinolone Acetonide……. 0.1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13559 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator [II]:	
	Decision of 327th 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. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Firm has referred to following products: • Synalar Topical solution 0.01% approved by US FDA. • Flucinate Topical Oil 0.01% of M/s Atco (Reg.#92728)	
	Decision: Approved.	
369.	**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	D-Light 50000 soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Vitamin D3 50000IU
	Diary No. Date of R& I & fee	Form-5 Dy.No 13570 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Altavita D3 50000 iu soft capsules HPRA
	Me-too status (with strength and dosage form)	097598; "HUESO-D 50000IU SOFT GELATIN CAPSULE" "VALOR/AL-HAMEED"
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator [II]:	
	• **Decision of 327th meeting:** Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
	Firm's response: Firm has copy of letter no. F.2-12/2012-Lic dated 25-11-2016 for issuance of DML including Soft gelatin capsule section.	
	Decision: Approved.	
370.	**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	Clospo 25mg Soft Gelatin Capsule
	Composition	Each Soft Gelatin Capsule Contains: Cyclosporin …… 25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13568 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sandimmune® Soft Gelatin Capsule USFDA Approved.
	Me-too status (with strength and dosage form)	Sandimum soft Gelatin Capsules NOVARTIS
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator [II]:	

	Decision of 327th meeting: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
	Firm's response: Firm has copy of letter no. F.2-12/2012-Lic dated 25-11-2016 for issuance of DML including Soft gelatin capsule section.	
	Decision: Approved.	
371.	**Name and address of manufacturer / Applicant**	**M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan"**
	Brand Name +Dosage Form + Strength	Colimate Lyophilized 200,0000 IU Injection
	Composition	"Each Vial Contains: Colistimethate Sodium…200,0000 IU"
	Diary No. Date of R& I & fee	Dy. No 2686 dated 21-01-2019, Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	New Section (Letter Issuance date: 11th April, 2017) Lyophilized Vials Injectable (general)
	Remarks of the Evaluator[II]	
	Previous Decision of 289th meeting: Deferred for submission of stability studies both accelerated & real time for six months as per guidelines approved & reviewed by registration board in its 251st & 278th meeting respectively.	
	Firm's response: Firm has submitted request for withdrawal of Form 5-D application of Colimate 2MIU applied on Form 5.	
	Decision: Registration Board accede with the request of the firm and declared the application as disposed of.	

Agenda of Evaluator PEC-III

Case No. 01 Registration applications of CTD cases

a. Cases of Export Facilitation

M/s Welmark Pharmaceuticals
Depauty Director PRV/EFD vide its letter dated 2nd June 2023 informed that in pursuance of decision of 133rd meeting of the Authority wherein it was decided that for each 100,000 USD worth of export during a fiscal year one molecule will be considered on priority basis. In compliance to this, M/s Welmark Pharmaceuticals, Hattar has achieved the benchmark of more than 100,000 USD during the financial year 2022-2023. Accordingly, the firm has requested for priority consideration of the following molecule

371.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals, Plot No. 122, Block B, Phase V, Industrial Estate Hattar District Haripur.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals Plot No. 69/2, Block B, Industrial Estate, Hattar, Haripur.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate

		of M/s Weather Folds Pharmaceuticals, Hattar issued on the basis of inspection dated 12-10-2022. The firm has submitted copy of GMP certificate of M/s Welmark Pharmaceuticals, Hattar issued on the basis of inspection dated 11-11-2021.
	Evidence of approval of manufacturing facility	The firm has submitted copy of GMP certificate of M/s Weather Folds Pharmaceuticals, Hattar issued on the basis of inspection dated 12-10-2022. The certificate specifies 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. 13763: 02-06-2023
	Details of fee submitted	PKR 75,000/-: 01-06-2023
	The proposed proprietary name / brand name	**CEFZECT 2.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Ceftazidime (as pentahydrate)……2000mg Avibactam (as sodium salt)……500mg
	Pharmaceutical form of applied drug	White to off white color sterile powder for injection filled in glass vials.
	Pharmacotherapeutic Group of (API)	Cephlosporin
	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	**(USFDA** Approved)
	For generic drugs (me-too status)	Zavicefta Injection by Pfizer (Reg No. 106848)
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai Guangdong 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 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Zavicefta Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai Guangdong China.		
API Lot No.	202112001		
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, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	200 vials	200 vials	200 vials
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	16-08-2022	16-08-2022	16-08-2022
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)	Firm has referred to their previous PSI inspection conducted for the product SACUVAL Tablet conducted on 01-09-2020 which was considered by Registration Board in its 296th 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. GD20180909) issued by CFDA China. The certificate is valid till 05-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Goods Declaration (GD) dated 16-05-2022 which mention 2Kg

		ceftazidime avibactam Batch No. 202112001.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports
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 communicated	Response by the firm
1.	Specify the details of applicant firm in section 1.3.1, since you have mentioned M/s weather folds pharmaceuticals as applicant, while the fee challan specifies that the applicant is M/s Welmark Pharmaceuticals.	Written mistakenly revised and correct resubmitted
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."	Copies of the drug substance specifications and analytical procedures used for routine testing of Drug substance /Active Pharmaceutical Ingredient by both Drug substance and Drug Product manufacturer is submitted.
3.	The specifications of API submitted in section 3.2.S.4.1 specifies that acceptance criteria for ceftazidime is NMT 68.5%, while the acceptance criteria for ceftazidime mentioned in API of batch 202112001 is 68.5% - 75%. Clarify how the specifications are different.	In S part data taken from DMF while received COA along with API shows limits range.
4.	Submit verification studies of the drug substance performed by drug product manufacturer, since you have only submitted a singke table for the results without any protocols and detailed results of each test of verification studies.	Verification studies of the drug substance performed by drug product manufacturer is submitted.
5.	The COA of API manufacturer specifies that the acceptance criteria for ceftazidime is 68.5% - 75% and avibactam is 17.1% to 18.9%, while your own COA for the same batch specifies that the acceptance criteria for ceftazidime and avibactam is 90% - 110%. Clarify how the drug product manufacturer can have different acceptance criteria.	We consider API as finish product that's why we give limits of finish product.
6.	Submit COA of reference standard actually used in the analysis of drug substance and drug product.	Submitted by the firm.
7.	Submit stability study data of drug substance till claimed shelf life, since you have only submitted stability data for 6 months.	Firm has submitted stability study data of drg substance till 24 months
8.	Specify the diluent along with its exact quantity which will be supplied with this product.	Water for injection
9.	Submit image/picture/snapshot claearly indicating batch number and expiry date of the reference product against which pharmaceutical equivalence studies have been conducted, since the submitted pictures do not show these details.	Submitted by the firm
10.	Submit microbiological properties in section	Submitted by the firm

	3.2.P.2.5 as per ICH requirement, since the submitted description doe not provide the required information.	
11.	Submit compatibility studies of the apllied product with the recommended diluent in section 3.2.P.2.6.	Already performed by innovators
12.	Justify why sodium content test is not included in the drug product specifications.	No sodium content test performed by innovator and API Manufacturer.
13.	Submit complete method of analysis of the drug product, since the submitted method is incomplete and not properly printed.	Submitted by the firm
14.	Submit complete report of validation studies of the drug product, since you have only submitted a singke table for the results without any protocols and detailed results of each test of verification studies.	Submitted by the firm
15.	Your batch size is 200 vials and your own calculation specifies that total vials required to carry out all physical and chemical tests during stability studies are 216 vials and that you have 360 injections as retained samples. Clarification is required in this regard.	Mistakenly written revised and correct data sheet resubmitted.
16.	Submit stability study data in section 3.2.P.8.3 as per the 6 points checklist as mentioned in the CTD guidance document, since you have randomly submitted the data without following the recommendations of guidance document.	Submitted by the firm
17.	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 293rd meeting, which includes the following documents: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing o Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm
18.	You have manufactured three batches while the BMR indicates that the filling of all the three batches was carried out on 16-08-2022 at the same time during 2.00 to 3.00 PM. Clarification is required how three batches can be filled at a time.	Capacity of vial filling machine 1000 per hour same container filled continuously.

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.**

b. New cases of local manufacturing

372.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 13-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-10-2019 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12903: 25-05-2023
	Details of fee submitted	PKR 75,000/-: 13-03-2023
	The proposed proprietary name / brand name	**ROXAGET Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……20mg
	Pharmaceutical form of applied drug	Blue colored oblong shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	12's
	Proposed unit price	7000/-
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 / 75 ± 5% RH 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China		
API Lot No.	RST20210704		
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.	635DS01	635DS02	
Batch Size	5000 Tablet	5000 Tablet	
Manufacturing Date	07-2022	07-2022	
Date of Initiation	25-08-2022	25-08-2022	
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)	Firm has referred to their last product specific inspection conducted for "Emclide 10mg & 25mg Tablet", which was conducted on 2nd December, 2021, and was presented in 316th meeting of Registration Board. The 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.
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 Form 6, License to import drugs for clinical trials, examination, test of analysis dated 06-04-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Submit real time stability study data of drug substance till claimed shelf life, since the submitted data is till 18 months.	
3.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

373.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 13-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of

		DML dated 30-10-2019 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12902: 25-05-2023
	Details of fee submitted	PKR 75,000/-: 13-03-2023
	The proposed proprietary name / brand name	**ROXAGET Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……50mg
	Pharmaceutical form of applied drug	Blue colored oblong shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	12's
	Proposed unit price	7000/-
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 / 75 ± 5% RH 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China		
API Lot No.	RST20210704		
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.	636DS01	636DS02	
Batch Size	5000 Tablet	5000 Tablet	
Manufacturing Date	07-2022	07-2022	
Date of Initiation	25-08-2022	25-08-2022	
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)	Firm has referred to their last product specific inspection conducted for "Emclide 10mg & 25mg Tablet", which was conducted on 2nd December, 2021, and was presented in 316th meeting of Registration Board. The 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.
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 Form 6, License to import drugs for clinical trials, examination, test of analysis dated 06-04-2022.

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

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Submit real time stability study data of drug substance till claimed shelf life, since the submitted data is till 18 months.	
3.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

374.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt) Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 13-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-10-2019 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12901: 25-05-2023
	Details of fee submitted	PKR 75,000/-: 13-03-2023
	The proposed proprietary name / brand name	**ROXAGET Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……100mg
	Pharmaceutical form of applied drug	Blue colored oblong shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations

	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	12's
	Proposed unit price	7000/-
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 / 75 ± 5% RH 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd in 3

		dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Daixi Street, Luoyang Town, Wujin District, Changzhou Jiangsu China		
API Lot No.	RST20210704		
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.	634DS01	634DS02	634DS03
Batch Size	1100 Tablet	5000 Tablet	1100 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	25-08-2022	25-08-2022	25-08-2022
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)	Firm has referred to their last product specific inspection conducted for "Emclide 10mg & 25mg Tablet", which was conducted on 2nd December, 2021, and was presented in 316th meeting of Registration Board. The 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.
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 Form 6, License to import drugs for clinical trials, examination, test of analysis dated 06-04-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	

2.	Submit real time stability study data of drug substance till claimed shelf life, since the submitted data is till 18 months.	
3.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

375.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2257: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……20mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	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	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
API Lot No.	AFPH007658
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.	RLD-001	RLD-002	RLD-003
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	03-06-2022	03-06-2022	03-06-2022
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)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

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Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is	

	observed in 0.1N HCl and 4.5 buffer.	
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
6.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

376.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2258: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……50mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	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	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
API Lot No.	AFPH007658
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.	RDM-001	RDM-002	RDM-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	06-06-2022	06-06-2022	06-06-2022
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)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

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Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	Justify the results of CDP studies in which the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is	

	observed in 0.1N HCl and 4.5 buffer.	
4.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	
5.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
6.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

377.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 14-10-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2259: 24-01-2023
	Details of fee submitted	PKR 75,000/-: 16-01-2023
	The proposed proprietary name / brand name	**ROXATA Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……100mg
	Pharmaceutical form of applied drug	Red colored oval shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	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	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
API Lot No.	AFPH007658
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.	RDH-001	RDH-002	RDH-003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	08-06-2022	08-06-2022	08-06-2022
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)	Firm has referred to their last product specific inspection conducted for "Empazon 10mg & 25mg Tablet", which was conducted on 1st June, 2021, and was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR Compliant. • Firm has demonstrated Audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh dated 18-02-2022. The certificate was valid till 1 year. Firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 24-02-2022. The invoice specifies 1kg Roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

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Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this product.	
2.	Specify the concentration of each solution used in the verification studies of the analytical method of drug substance.	
3.	The pharmaceutical equivalence studies have been performed for 50mg strength of applied product. Clarification is required in this regard.	
4.	Justify the results of CDP studies in which	

	the drug product shows more than 85% release in 0.1N HCl and 4.5pH buffer in 30 minutes, since the innovator's product review reveals that very less drug release is observed in 0.1N HCl and 4.5 buffer.	
5.	Provide image / snapshot of the pack of the reference product against which pharmaceutical equivalence and CDP studies were conducted.	
6.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
7.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

378.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-08-2019. Firm has submitted copy of inspection report dated 11-08-2020 which concludes that overall cGMP compliance of the firm was satisfactory.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 24-09-2012 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14301: 13-07-2022
	Details of fee submitted	PKR 75,000/-: 09-05-2022
	The proposed proprietary name / brand name	**ROXASTAT Tablet 20mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……20mg
	Pharmaceutical form of applied drug	Yellow colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated

		with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data 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 Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China		
API Lot No.	RST20181202		
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.	TF-01	TF-02	TF-03
Batch Size	700 Tablet	700 Tablet	700 Tablet
Manufacturing Date	07-2020	09-2020	09-2020
Date of Initiation	06-08-2020	14-09-2020	14-09-2020
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)	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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 License to import drugs for clinical trials examination, test of analysis dated 30-06-2020 for 0.5Kg roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this 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.	The analytical method of the drug substance specifies that the concentration of standard and sample solution is 0.04mg/ml, while in verification studies the accuracy test is performed at a concentration range of 0.16mg/ml to 0.24mg/ml. Justify how this verification studies are applicable to the analytical method.	
4.	The concentration of the sample solution used in precision studies is different from that concentration of standard and sample solution in assay method. Clarify how you have developed the protocols for verification studies.	
5.	Justify the accelerated stability studies of the drug substance performed till 12 months.	
6.	Provide master formulation as per the CTD guidance document in section 3.2.P.1	
7.	Justify the performance of CDP studies in which time points for 0.1N HCl and 4.5pH buffer is not taken as per WHO guidelines, since you have stopped the study samples before 85% drug release or before plateau is achieved.	
8.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
9.	Provide results of validation studies of the analytical method of drug product along with complete protocols as per ICH guidelines. Provide tabulated results for each test along with concentration of each solution and number of replicates used to study the average.	
10.	Submit valid GMP certificate / DML of the drug substance manufacturer, since the submitted GMP certificate is issued by Linhai Food and Drug Association which is not the relevant regulatory authority.	
11.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	
12.	As per submitted Form 6, license to import, 0.5Kg of roxadustat was allowed for import while as per your COA of raw material the quantity of the raw material received and tested was 2.7gm. Clarification is required in this regard.	
13.	Provide BMR for the three stability batches.	

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

shortcomings and evaluation by PE&R Division.		
379.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-08-2019. Firm has submitted copy of inspection report dated 11-08-2020 which concludes that overall cGMP compliance of the firm was satisfactory.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 24-09-2012 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14302: 13-07-2022
	Details of fee submitted	PKR 75,000/-: 09-05-2022
	The proposed proprietary name / brand name	**ROXASTAT Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……50mg
	Pharmaceutical form of applied drug	Peach colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data 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 Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China		
API Lot No.	RST20181202		
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.	TF-01	TF-02	TF-03
Batch Size	700 Tablet	700 Tablet	700 Tablet

Manufacturing Date	09-2020	10-2020	10-2020
Date of Initiation	22-10-2020	22-10-2020	22-10-2020
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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 License to import drugs for clinical trials examination, test of analysis dated 30-06-2020 for 0.5Kg roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this 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.	The analytical method of the drug substance specifies that the concentration of standard and sample solution is 0.04mg/ml, while in verification studies the accuracy test is performed at a concentration range of 0.16mg/ml to 0.24mg/ml. Justify how this verification studies are applicable to the analytical method.	
4.	The concentration of the sample solution used in precision studies is different from that concentration of standard and sample solution in assay method. Clarify how you have developed the protocols for verification	

	studies.	
5.	Justify the accelerated stability studies of the drug substance performed till 12 months.	
6.	Provide master formulation as per the CTD guidance document in section 3.2.P.1	
7.	Justify how drug release at a later point is less than the drug release at earlier time point i.e. the average drug release after 30 mins in 0.1N HCl was 19.91% while the drug release in same medium after 45 minutes become 15.29%.	
8.	Justify the performance of CDP studies in which time points for 0.1N HCl and 4.5pH buffer is not taken as per WHO guidelines, since you have stopped the study samples before 85% drug release or before plateau is achieved.	
9.	Provide scientific rationale for selection of dissolution parameters and acceptance criteria.	
10.	Provide results of validation studies of the analytical method of drug product along with complete protocols as per ICH guidelines. Provide tabulated results for each test along with concentration of each solution and number of replicates used to study the average.	
11.	Submit valid GMP certificate / DML of the drug substance manufacturer, since the submitted GMP certificate is issued by Linhai Food and Drug Association which is not the relevant regulatory authority.	
12.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	
13.	As per submitted Form 6, license to import, 0.5Kg of roxadustat was allowed for import while as per your COA of raw material the quantity of the raw material received and tested was 2.7gm. Clarification is required in this regard.	
14.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

380.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate

		issued on the basis of inspection dated 28-08-2019. Firm has submitted copy of inspection report dated 11-08-2020 which concludes that overall cGMP compliance of the firm was satisfactory.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 24-09-2012 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14303: 13-07-2022
	Details of fee submitted	PKR 75,000/-: 09-05-2022
	The proposed proprietary name / brand name	**ROXASTAT Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……100mg
	Pharmaceutical form of applied drug	Peach colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data 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 Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Hongyuan Pharmaceutical Co., Ltd. Chem & API's Industrial Zone, Linhai, Zhejiang, P.R. China		
API Lot No.	RST20181202		
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.	TF-01	TF-02	TF-03
Batch Size	700 Tablet	700 Tablet	700 Tablet
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	22-10-2020	22-10-2020	22-10-2020
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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 License to import drugs for clinical trials examination, test of analysis dated 30-06-2020 for 0.5Kg roxadustat.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the exact polymorphic form of the drug substance used in the development of this 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.	The analytical method of the drug substance specifies that the concentration of standard and sample solution is 0.04mg/ml, while in verification studies the accuracy test is performed at a concentration range of 0.16mg/ml to 0.24mg/ml. Justify how this verification studies are applicable to the analytical method.	
4.	The concentration of the sample solution used in precision studies is different from that concentration of standard and sample solution in assay method. Clarify how you have developed the protocols for verification studies.	
5.	Justify the accelerated stability studies of the drug substance performed till 12 months.	
6.	Provide master formulation as per the CTD guidance document in section 3.2.P.1	
7.	Justify the performance of CDP studies in which time points for 0.1N HCl and 4.5pH buffer is not taken as per WHO guidelines, since you have stopped the study samples before 85% drug release or before plateau is achieved.	
8.	Provide scientific rationale for selection of dissolution parameters and acceptance	

	criteria.	
9.	Provide results of validation studies of the analytical method of drug product along with complete protocols as per ICH guidelines. Provide tabulated results for each test along with concentration of each solution and number of replicates used to study the average.	
10.	Submit valid GMP certificate / DML of the drug substance manufacturer, since the submitted GMP certificate is issued by Linhai Food and Drug Association which is not the relevant regulatory authority.	
11.	Submit evidence of import of drug substance since you have only submitted Form 6, License to import which does not confirm that the drug substance has been imported or not.	
12.	As per submitted Form 6, license to import, 0.5Kg of roxadustat was allowed for import while as per your COA of raw material the quantity of the raw material received and tested was 2.7gm. Clarification is required in this regard.	
13.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

381.	**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 CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 30-04-2019. Firm has also submitted a letter from additional director DRAP Lahore dated 07-07-2022 that firm has applied for GMP inspection and application is under process. The Firm's last GMP status in compliant / Good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-06-2021 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5493: 27-02-2023
	Details of fee submitted	PKR 75,000/-: 03-02-2023
	The proposed proprietary name / brand name	**ROXA Tablet 20mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……20mg
	Pharmaceutical form of applied drug	Pink colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 20mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam Distri 532409, Andhra Pradesh, India.		
API Lot No.	AFPH002059		
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.	ROXA-T2-22	ROXA-T3-22	ROXA-T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	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)	Firm has referred to their previous PSI inspection conducted for the product Dexlan DR Capsule 30 and 60mg conducted on 26-08-2019 which was considered by Registration Board in its 294th meeting. The Board approved the case and following things were noted in the inspection report: • HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. • The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through record, chromatograms and logbooks.
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 Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 13-07-2022 specifying import of 1.3Kg Roxadustat (Form A).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA,	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.

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

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have used Form A polymorphic form of the drug substance, provide scientific evidence that the same polymorphic form is also used by the innovator's product.	
2.	Submit complete accelerated stability studies of the drug substance, since the submitted studies are only till 2 months.	
3.	Provide details about the manufacturer of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.	
4.	The CDP studies at 6.8pH phosphate buffer shows that more than 85% drug is released at 10 minutes' time point, while in dissolution studies where the dissolution medium is same i.e. 6.8pH phosphate buffer, the acceptance criteria is NLT 75%(Q) in 30 minutes. Provide scientific justification how your dissolution method is discriminatory in nature.	
5.	Specify the exact date of initiation of stability studies for each batch instead of mentioning the month.	
6.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

382.	**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 CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 30-04-2019. Firm has also submitted a letter from additional director DRAP Lahore dated 07-07-2022 that firm has applied for GMP inspection and application is under process. The Firm's last GMP status in compliant / Good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-06-2021 which specifies Tablet section (General).

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5494: 27-02-2023
	Details of fee submitted	PKR 75,000/-: 03-02-2023
	The proposed proprietary name / brand name	**ROXA Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……50mg
	Pharmaceutical form of applied drug	Pink colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 50mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam Distri 532409, Andhra Pradesh, India.		
API Lot No.	AFPH002059		
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.	ROXB-T2-22	ROXB-T3-22	ROXB-T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	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)	Firm has referred to their previous PSI inspection conducted for the product Dexlan DR Capsule 30 and 60mg conducted on 26-08-2019 which was considered by Registration Board in its 294th meeting. The Board approved the case and following things were noted in the inspection report: • HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. • The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through record, chromatograms and logbooks.

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 Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 13-07-2022 specifying import of 1.3Kg Roxadustat (Form A).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have used Form A polymorphic form of the drug substance, provide scientific evidence that the same polymorphic form is also used by the innovator's product.	
2.	Submit complete accelerated stability studies of the drug substance, since the submitted studies are only till 2 months.	
3.	Provide details about the manufacturer of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.	
4.	The CDP studies at 6.8pH phosphate buffer shows that more than 85% drug is released at 10 minutes' time point, while in dissolution studies where the dissolution medium is same i.e. 6.8pH phosphate buffer, the acceptance criteria is NLT 75%(Q) in 30 minutes. Provide scientific justification how your dissolution method is discriminatory in nature.	
5.	Specify the exact date of initiation of stability studies for each batch instead of mentioning the month.	
6.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

383.	**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 CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate

		issued on the basis of inspection dated 30-04-2019. Firm has also submitted a letter from additional director DRAP Lahore dated 07-07-2022 that firm has applied for GMP inspection and application is under process. The Firm's last GMP status in compliant / Good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-06-2021 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5495: 27-02-2023
	Details of fee submitted	PKR 75,000/-: 03-02-2023
	The proposed proprietary name / brand name	**ROXA Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Roxadustat……100mg
	Pharmaceutical form of applied drug	Pink colored round biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Clinical Indication	Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Evrenzo Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam District 532409, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed 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	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd. Firm has submitted results of CDP for their product against Evrenzo tablet 100mg manufactured by M/s Astellas Pharma Ltd in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dr. Reddy's Laboratories Limited Chemical Technical operations Unit-VI, APIIC Industrial Estate, Pydibhimavaram village, Ranasthalam Mandal, Srikakulam Distri 532409, Andhra Pradesh, India.		
API Lot No.	AFPH002059		
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.	ROXC-T2-22	ROXC-T3-22	ROXC-T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	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)	Firm has referred to their previous PSI inspection conducted for the product Dexlan DR Capsule 30 and 60mg conducted on 26-08-2019 which was considered by Registration Board in its 294th

		meeting. The Board approved the case and following things were noted in the inspection report: • HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. • The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through record, chromatograms and logbooks.
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 Drugs Control Administration Government of Andhra Pradesh India dated 20-06-2022. The certificate is valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 13-07-2022 specifying import of 1.3Kg Roxadustat (Form A).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	You have used Form A polymorphic form of the drug substance, provide scientific evidence that the same polymorphic form is also used by the innovator's product.	
2.	Submit complete accelerated stability studies of the drug substance, since the submitted studies are only till 2 months.	
3.	Provide details about the manufacturer of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.	
4.	The CDP studies at 6.8pH phosphate buffer shows that more than 85% drug is released at 10 minutes' time point, while in dissolution studies where the dissolution medium is same i.e. 6.8pH phosphate buffer, the acceptance criteria is NLT 75%(Q) in 30 minutes. Provide scientific justification how your dissolution method is discriminatory in nature.	
5.	Specify the exact date of initiation of stability studies for each batch instead of mentioning the month.	
6.	Provide BMR for the three stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

384.	**Name, address of Applicant / Marketing**	**M/s CCL Pharmaceuticals (Pvt) Ltd. 62-**

	Authorization Holder	**Industrial Estate, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 30-04-2019. Firm has also submitted a letter from additional director DRAP Lahore dated 07-07-2022 that firm has applied for GMP inspection and application is under process. The Firm's last GMP status in compliant / Good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-06-2021 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1858: 19-01-2023
	Details of fee submitted	PKR 75,000/-: 30-12-2022
	The proposed proprietary name / brand name	**LASMIN Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Lasmiditan hemisuccinate eq to lasmiditan……50mg
	Pharmaceutical form of applied drug	Light brown-colored round biconvex film coated tablets
	Pharmacotherapeutic Group of (API)	Selective serotonin (5HT1) agonists
	Clinical Indication	REYVOW® is indicated for the acute treatment of migraine with or without aura in adults. **Limitations of Use** REYVOW is not indicated for the preventive treatment of migraine.
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Reyvow Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Enantiotech Corporation Limited. No. 6, Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong 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 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 Reyvow tablet 50mg manufactured by M/s Lilly USA LLC. Firm has submitted results of CDP for their product against Reyvow tablet 50mg manufactured by M/s Lilly USA LLC in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Enantiotech Corporation Limited. No. 6, Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong Province China.
API Lot No.	LAS09-220302
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.	LASA-T2-22	LASA-T3-22	LASA-T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	07-2022	07-2022	07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their previous PSI inspection conducted for the product Dexlan DR Capsule 30 and 60mg conducted on 26-08-2019 which was considered by Registration Board in its 294th meeting. The Board approved the case and following things were noted in the inspection report: • HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. • The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through record, chromatograms and logbooks.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 23-06-2022 specifying import of 1.3Kg Lasmiditan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place **lasmiditan in schedule V of the Controlled Substances Act** (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

Sr. No	Shortcomings / Observations	Response by the firm
1.	Specify the exact polymorphic form of drug substance used in the development of applied product.	
2.	The quality review depicts that particle size distribution of the drug substance was controlled by innovator's product. Justify how you have developed your product without controlling the particle size.	
3.	Justify how drug release at a later point is less	

	than the drug release at earlier time point i.e. the average drug release after 20 mins in 0.1N HCl was 100.2% while the drug release in same medium after 30 minutes become 99.7%, similarly average drug release in 6.8pH buffer after 15 minutes was 100.1% while it declined to 99.4% after 20 minutes and 98.8% after 30 minutes.	
4.	Justify the acceptance criteria if disintegration test i.e. NMT 30 minutes while more than 80% drug is dissolved within 15 minutes.	
5.	The quality review of the innovator's product depicts that disintegration test was used by the innovator's product since it has more discriminatory power as compared to the dissolution test. While you have used dissolution test and kept a wide acceptance criteria of disintegration test to compromise its discriminatory power. Clarify how your specifications can be considered equivalent to that of the innovator's product and how batch to batch consistency in drug release be ensured.	
6.	Submit valid GMP certificate / DML of the manufacturer of drug substance, issued by relevant regulatory authority of the country of origin since the submitted GMP certificate is issued by Guangdong pharmaceutical industry association which is not a concerned regulatory authority.	
7.	Specify the exact date of initiation of stability studies for each batch instead of mentioning the month.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division. Moreover, the Board also decided that the case shall be forwarded to Controlled Drug Division for their comments on the scheduling of the drug by USFDA.

385.	**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 CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate issued on the basis of inspection dated 30-04-2019. Firm has also submitted a letter from additional director DRAP Lahore dated 07-07-2022 that firm has applied for GMP inspection and application is under process. The Firm's last GMP status in compliant / Good.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 08-06-2021 which specifies Tablet section (General).

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1859: 19-01-2023
	Details of fee submitted	PKR 75,000/-: 30-12-2022
	The proposed proprietary name / brand name	**LASMIN Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Lasmiditan hemisuccinate eq to lasmiditan……100mg
	Pharmaceutical form of applied drug	Light brown-colored biconvex tablets
	Pharmacotherapeutic Group of (API)	Selective serotonin (5HT1) agonists
	Clinical Indication	REYVOW® is indicated for the acute treatment of migraine with or without aura in adults. **Limitations of Use** REYVOW is not indicated for the preventive treatment of migraine.
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Reyvow Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Not Applicable
	Name and address of API manufacturer.	Enantiotech Corporation Limited. No. 6, Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong 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 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 Reyvow tablet 50mg manufactured by M/s Lilly USA LLC. Firm has submitted results of CDP for their product against Reyvow tablet 50mg manufactured by M/s Lilly USA LLC in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Enantiotech Corporation Limited. No. 6, Zhongjing Road, Zhongshan Torch Hi-Tech Industrial Development Zone, Zhongshan City, Guangdong Province China.		
API Lot No.	LAS09-220302		
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.	LASB-T2-22	LASB-T3-22	LASB-T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	07-2022	07-2022	07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their previous PSI inspection conducted for the product Dexlan DR Capsule 30 and 60mg conducted on 26-08-2019 which was considered by Registration Board in its 294th meeting. The Board approved the case and following things were noted in the inspection report: • HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. • The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through

		record, chromatograms and logbooks.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 23-06-2022 specifying import of 1.3Kg Lasmiditan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place **lasmiditan in schedule V of the Controlled Substances Act** (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

Sr. No	Shortcomings / Observations	Response by the firm
1.	Specify the exact polymorphic form of drug substance used in the development of applied product.	
2.	The quality review depicts that particle size distribution of the drug substance was controlled by innovator's product. Justify how you have developed your product without controlling the particle size.	
3.	Justify how drug release at a later point is less than the drug release at earlier time point i.e. the average drug release after 20 mins in 0.1N HCl was 100.1% while the drug release in same medium after 30 minutes become 99.8%, similarly average drug release in 0.01N HCl after 15 minutes was 100.4% while it declined to 99.9% after 20 minutes and 98.8% after 30 minutes.	
4.	Justify the acceptance criteria if disintegration test i.e. NMT 30 minutes while more than 80% drug is dissolved within 15 minutes.	
5.	The quality review of the innovator's product depicts that disintegration test was used by the innovator's product since it has more discriminatory power as compared to the dissolution test. While you have used dissolution test and kept a wide acceptance criteria of disintegration test to compromise its discriminatory power. Clarify how your	

	specifications can be considered equivalent to that of the innovator's product and how batch to batch consistency in drug release be ensured.	
6.	Submit valid GMP certificate / DML of the manufacturer of drug substance, issued by relevant regulatory authority of the country of origin since the submitted GMP certificate is issued by Guangdong pharmaceutical industry association which is not a concerned regulatory authority.	
7.	Specify the exact date of initiation of stability studies for each batch instead of mentioning the month.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division. Moreover, the Board also decided that the case shall be forwarded to controlled drug division for their comments on the scheduling of the drug by USFDA.

386.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate of issued on the basis of inspection dated 08-08-2022.
	Evidence of approval of manufacturing facility	The firm has submitted copy of letter of renewal of DML dated 06-03-2019 specifying Cream / Ointment Section (General) as well as Cream / Ointment Section (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	Dy. No. 13510: 31-05-2023
	Details of fee submitted	PKR 75,000/-: 10-05-2023
	The proposed proprietary name / brand name	**RUXOLITINIB 1.5% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Ruxolitinib phosphate……15mg
	Pharmaceutical form of applied drug	White to off-white colored cream filled in aluminium tube
	Pharmacotherapeutic Group of (API)	D11AH09: Agents for dermatitis, excluding corticosteroids L01EJ01: Protein Kinase Inhibitors
	Clinical Indications	• OPZELURA is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric

		patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • OPZELURA is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	5g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Opzelura 1.5% cream **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing 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 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Opzelura 1.5% Cream.

	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	RUXO-20220603		
Description of Pack (Container closure system)	Blister in bleach board 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, 1, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001T23	002T23	003T23
Batch Size	90 Tubes	90 Tubes	90 Tubes
Manufacturing Date	02-2023	02-2023	02-2023
Date of Initiation	01-03-2023	01-03-2023	01-03-2023
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)	Firm has referred to their previous PSI inspection conducted for the product Dapazin-M 5/1000 mg Tablet which was considered by Registration Board in its 307th meeting which confirms following: • Firm has 21 CFR compliant HPLC system • Audit trail reports were available • Proper and continuous monitoring record for stability chamber is available along with backup generator.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of the firm (No. Yu 20150075) issued by NMPA China and also verified online from NMPA database. The certificate is valid till 09-08-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate issued by AD (I&E) dated 02-11-2022 specifying 35gm.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied product falls under the pharmacological class of L01 as well as D11, while Registration Board in its 297th meeting decided to allow manufacturing of drugs falling in L01 class in anticancer section only. Clarification is required regarding manufacturing of the applied product in general section.

- The innovator's product contains 15mg roxulitinib as phosphate per gram of cream while you have applied 15mg roxulitinib phosphate per gram. Revise your label claim along with submission of full fee of registration.
- Specify the exact concentration of each solution used in the verification studies of the analytical method of drug substance performed by drug product manufacturer.
- Submit CoA of reference standard actually used in the analysis.
- Submit stability study data of drug substance till assigned shelf life since the submitted data is for 12 months only.
- Submit image / picture / snapshot of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.
- FDA review report of the innovator's product reveals that "The applicant has developed and validated an in-vitro release testing (IVRT) method using a vertical diffusion cell apparatus which will mainly be used for the determination of comparability drug product if post-approval manufacturing changes are made. The proposed IVRT method is not intended for routine release and stability testing". Justify how comparability of your formulation can be made with the innovator's product.
- Specify the exact concentration of each solution used in the verification studies of the analytical method of drug product.
- Submit stability study data till 6 moths, since only 3month stability data is submitted.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division. Moreover, the Board also decided that further deliberation shall be made in upcoming meeting regarding manufacturing requirements for drugs having multiple WHO ATC classification including L01.

387.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate of issued on the basis of inspection dated 08-08-2022.
	Evidence of approval of manufacturing facility	The firm has submitted copy of letter of renewal of DML dated 06-03-2019 specifying Soft Gelatin Capsule 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. 15244: 16-06-2023
	Details of fee submitted	PKR 75,000/-: 29-05-2023
	The proposed proprietary name / brand name	**OCTINO 10mg soft gel capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Alitretinoin……10mg
	Pharmaceutical form of applied drug	Light brown oval shaped soft gelatin capsule containing yellow to orange color viscous suspension
	Pharmacotherapeutic Group of (API)	D11AH04: Agents for dermatitis, excluding corticosteroids L01XF02: Other Antineoplastic Agents

	Clinical Indications	Toctino is indicated for use in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids. Patients in whom the eczema has predominantly hyperkeratotic features are more likely to respond to treatment than those in whom the eczema predominantly presents as pompholyx
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Toctino 10mg Soft Gelatin Capsule **(MHRA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing 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 5°C ± 3°C for 6 months. The real time stability data is conducted at -20°C ± 5°C 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 Toctino Soft Gelatin Capsule.

		Firm has submitted results of CDP studies in 3 medium for their product against Toctino Soft Gelatin Capsule.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	ALI-20171201		
Description of Pack (Container closure system)	Blister in bleach board 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, 1, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	022T18	023T18	024T18
Batch Size	600 Capsule	600 Capsule	600 Capsule
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	16-11-2018	23-11-2018	30-11-2018
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)	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 DML (No. Yu 20150075) issued by CFDA China. The certificate is valid till 09-08-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy ofclearance certificate dated 21-02-2018 which mention 100g alitretinoin.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted HPLC audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	The applied product falls under the pharmacological class of L01 as well as D11, while Registration Board in its 297th meeting decided to allow manufacturing of drugs falling in L01 class in anticancer section only. Clarification is required regarding manufacturing of the applied product in general section.	Applied product falls under L01 as well as D11, but we want to to register the product for the purpose of skin which only falls under D11 for which special section is not required. **Decision of 297th meeting of Registration Board:** Registration Board after thorough deliberation and considering the high-risk

		classification i.e., "Anticancer (L01)", and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrexate etc. in the "Anti-cancer" section only (being high risk products).
2.	Specify the exact concentration of each solution used in the verification studies of the analytical method of drug substance performed by drug product manufacturer.	Firm has submitted verification studies and mentioned %age of each solution
3.	Submit CoA of reference standard actually used in the analysis.	Firm has submitted COA of working standard
4.	Clarification is required how the required storage conditions of the drug substance was met during transportation and storage within the premises since the drug substance shall be stored at -20 degree.	Material was received in air tight sealed container with having multiple ice bag from supplier. We atored the material in pharmaceutical freezer in our premises.
5.	Submit image / picture / snapshot of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.	Submitted the firm
6.	Justify why assay test of alpha-tocopherol is not included in the drug product specificatons while the same test is recommended by the innovator's product.	We have used alpha tocopherol as an excipient and validation study of product shows that there is no effect of testing on alitretinoin.
7.	Provide scientific justification for adaptation of dissolution parameters and dissolution time.	Firm has submitted detailed justification as per USP guidelines.
8.	Specify the exact concentration of each solution used in the verification studies of the analytical method of drug product.	Firm has submitted verification studies and mentioned %age of each solution
9.	CDP studies result show very little drug release in all medium while in dissolution test the drug show more than 85% release in 6.8pH medium. Clarification is required in this regard.	CDP was performed in 3 medium (0.1N HCl pH 1.2, 4.5pH acetate buffer, and 6.8pH phosphate buffer. While in dissolution studies we have used medium borate buffer pH 8.0 containing 0.5% cetrimide 50mg/ml pancreatin.

Decision: Registration Board deferred the case for further deliberation shall be made in upcoming meeting regarding manufacturing requirements for drugs having multiple WHO ATC classification including L01.

388.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals, Plot No. 1, 2, Street S-2, National Industrial Zone Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate of issued on the basis of inspection dated 08-08-2022.
	Evidence of approval of manufacturing facility	The firm has submitted copy of letter of renewal of DML dated 06-03-2019 specifying Soft Gelatin Capsule 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. 15245: 16-06-2023
	Details of fee submitted	PKR 75,000/-: 29-05-2023
	The proposed proprietary name / brand name	**OCTINO 30mg soft gel capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin capsule contains: Alitretinoin……30mg
	Pharmaceutical form of applied drug	Light brown oval shaped soft gelatin capsule containing yellow to orange color viscous suspension
	Pharmacotherapeutic Group of (API)	D11AH04: Agents for dermatitis, excluding corticosteroids L01XF02: Other Antineoplastic Agents
	Clinical Indications	Toctino is indicated for use in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids. Patients in whom the eczema has predominantly hyperkeratotic features are more likely to respond to treatment than those in whom the eczema predominantly presents as pompholyx
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Toctino 10mg Soft Gelatin Capsule **(MHRA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing 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 5°C ± 3°C for 6 months. The real time stability data is conducted at -20°C ± 5°C 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 Toctino Soft Gelatin Capsule. Firm has submitted results of CDP studies in 3 medium for their product against Toctino Soft Gelatin Capsule.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Chongqing Huapont Schengchem Pharmaceutical Co. Ltd., No. 666 Rongjun Road, Nanjin Avenue Hechuan District Chongqing China		
API Lot No.	ALI-20171201		
Description of Pack (Container closure system)	Blister in bleach board 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, 1, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001T19	002T19	003T19
Batch Size	600 Capsule	600 Capsule	600 Capsule
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	08-02-2019	15-02-2019	23-02-2019
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)	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 DML (No. Yu 20150075) issued by CFDA China. The certificate is valid till 09-08-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy ofclearance certificate dated 21-02-2018 which mention 100g alitretinoin.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary

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

Evaluation by PEC:

Sr. No	Shortcomings	Response by the firm
1.	The applied product falls under the pharmacological class of L01 as well as D11, while Registration Board in its 297th meeting decided to allow manufacturing of drugs falling in L01 class in anticancer section only. Clarification is required regarding manufacturing of the applied product in general section.	Applied product falls under L01 as well as D11, but we want to to register the product for the purpose of skin which only falls under D11 for which special section is not required. **Decision of 297th meeting of Registration Board:** Registration Board after thorough deliberation and considering the high-risk classification i.e., "Anticancer (L01)", and reviewing its previous decision decided to allow the manufacturing of such type of drugs which fall in both "Antineoplastic (L01)" & "Immunosuppressants (L04)" class including everolimus and methotrexate etc. in the "Anti-cancer" section only (being high risk products).
2.	Specify the exact concentration of each solution used in the verification studies of the analytical method of drug substance performed by drug product manufacturer.	Firm has submitted verification studies and mentioned %age of each solution
3.	Submit CoA of reference standard actually used in the analysis.	Firm has submitted COA of working standard
4.	Clarification is required how the required storage conditions of the drug substance was met during transportation and storage within the premises since the drug substance shall be stored at -20 degree.	Material was received in air tight sealed container with having multiple ice bag from supplier. We atored the material in pharmaceutical freezer in our premises.
5.	Submit image / picture / snapshot of the innovator's product against which pharmaceutical equivalence and CDP studies were conducted.	Submitted the firm
6.	Justify why assay test of alpha-tocopherol is not included in the drug product specificatons while the same test is recommended by the innovator's product.	We have used alpha tocopherol as an excipient and validation study of product shows that there is no effect of testing on alitretinoin.
7.	Provide scientific justification for adaptation of dissolution parameters and dissolution time.	Firm has submitted detailed justification as per USP guidelines.
8.	Specify the exact concentration of each solution used in the verification studies of the analytical method of drug product.	Firm has submitted verification studies and mentioned %age of each solution
9.	CDP studies result show very little drug release in all medium while in dissolution test the drug show more than 85% release in 6.8pH medium. Clarification is required in this regard.	CDP was performed in 3 medium (0.1N HCl pH 1.2, 4.5pH acetate buffer, and 6.8pH phosphate buffer. While in dissolution studies we have used medium borate buffer pH 8.0 containing 0.5% cetrimide 50mg/ml pancreatin.

Decision: Registration Board deferred the case for further deliberation shall be made in upcoming

meeting regarding manufacturing requirements for drugs having multiple WHO ATC classification including L01.

b. Deferred cases of local manufacturing

389.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7362: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….30mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°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 verification studies of the drug substance and the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle 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%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-01
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
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)	
2.	Approval of API/ DML/GMP certificate of API	Firm has submitted copy of GMP certificate issued

	manufacturer issued by concerned regulatory authority of country of origin.	by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	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[3]:

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

equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.

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

- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

Response by the firm:

Sr. No	Short coming	Annexure
01	GMP certificate /inspection report of the firm conducted within a period of last three years.	Firm has not submitted GMP certificate / inspection report.
02	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.	Firm has **not** submitted QOS as per WHO template.
03	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer
04	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.	Firm has **not** submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
05	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.	Firm has submitted COA of batch number DLP664.
06	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch	Firm has **not** sumitted COA of reference / working standard.

	No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of hese pellets or any other source of reference standard manufacturing.	
07	Section 3.2.S.6 specifies that the API food grade double manufacturer is using polyethylene bag for storing these which are pellets highly sensitive to moisture and light. Justification is required in this regard.	Three polyethylene bag used for packing of pellets. Two transparent and one black color bags along with silica gel.
08	Provide information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.	Firm has submitted information in section 3.2.S.7.1 and 3.2.S.7.2 as CTD per guidance document.
09	The stability study of Vision Dexlansoprazole pellets performed by Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.	Study performed at lab scale and in chamber they placed sample in pet bottle and for commercial they provide polythene bags and drum which is not possible in pet bottle.
10	Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of Dexlansoprazole pellets wherein the manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarifications required in this regard.	DMF provided by vision pharma
11	Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.	Submitted by the firm.
12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be	Firm has submitted information in section 3.2.P.3 as per the guidance document.

	provided e.g., sterilization shall be explained and justified"	
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified"	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has **not** submitted process validation protocols.
19	Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.	Firm has submitted specifications of the drug product in section 3.2.P.5.1.
20	provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarifications required in this regard	Firm has submitted specifications of the drug product in section 3.2.P.5.2.
21	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Firm has **not** submitted complete validation studies of the analytical method of drug product in section 3.2. P.5.3.
22	provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of Dexlansoprazole pellets of	Firm has submitted Batch analysis report of 3 stability batches.

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

	further evaluation may be carried out	
33	submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin • Documents for the procurement of APl with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of both stability chambers	Firm has submitted response against the 6 points checklist as per CTD guidance document.

Decision of 324th meeting: Deferred for following observations:

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

Firm's response:

Sr.#	Observation	Reply
1.	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document	Submitted
2.	Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any procedures for preparation of each type of solution. Furtherore, you have performed 6 replicates in specificity test which is not in line with the	Firm has submitted revised analytical method verification studies performed by M/s Wezen Pharmaceuticals.

	recommendations of ICH.	
3.	Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.
4.	Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established	Firm has submitted revised process validation protocol including the critical steps, sampling plan, and evaluation criteria for the process of capsule filling, sealing and blistering.
5.	Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.	Submitted.
6.	Provide COA of the reference standard in working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard	Firm has submitted COA of working standard form M/s Vision Pharmaceuticals.

Decision of 327th meeting of Registration Board: Deferred for submission of Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product.

Response by the firm: Firm has submitted result of pharmaceutical equivalence and CDP studies against Dexilant 30mg Capsule. Firm has also submitted picture of the pack of the reference product.

Decision: Approved with Innovator's specifications.

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

390.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7363: 16-03-2022

	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°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 verification studies of the drug substance and the drug product.
STABILITY STUDY DATA		
Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle 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%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	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
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)	
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, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	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[3]:

- GMP certificate / inspection report of the firm conducted within a period of last three years.
- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since

you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.

- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be perfomed, since you have mentioned that pharmaceutical equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.
- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".
- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.
- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.

- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specificatiosn of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

Response by the firm:

Sr. No	Short coming	Annexure
01	GMP certificate /inspection report of the firm conducted within a period of last three years.	Firm has not submitted GMP certificate / inspection report.
02	Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.	Firm has **not** submitted QOS as per WHO template.
03	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Active Pharmaceutical Ingredient by both Drug substance & Drug Product	Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer

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

	heading.	
12	Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be performed, since you have mentioned that pharmaceutical equivalence is not required and then you have also provided a brief report of Dexlansoprazole tablet in which all tests are not performed.	Firm has submitted pharmaceutical equivalence studies against the comparator product manufactured by Weatherfolds pharma.
13	Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter	Firm has submitted results of comparative dissolution profile against the brand leader.
14	submit information in section 3.2.P.3 as per the guidance document which specifies that The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified"	Firm has submitted information in section 3.2.P.3 as per the guidance document.
15	Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1	Firm has submitted information in section 3.2.P.3.2 as per the guidance document.
16	Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data t supports this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified"	Firm has submitted information in section 3.2.P.3.3 as per the guidance document.
17	Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."	Firm has submitted information in section 3.2.P.3.4 as per the guidance document.
18	Justify why the process validation protocols does	Firm has **not** submitted process validation

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

	specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter as well as defined by Registration Board in its 293d meeting	
31	provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule	Revised COA are submitted by the firm.
32	provide stability study data in a proper se stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and separators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out	Firm has submitted stability data in a proper sequence.
33	submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin • Documents for the procurement of APl with approval from DRAP (in case of import). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of both stability chambers	Firm has submitted response against the 6 points checklist as per CTD guidance document.

Decision: Deferred for following observations:

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

- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established
- Provide validation studies of the analytical method of drug product in section 3.2. P.5.3.
- Provide COA of the reference standard I working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard

Firm's response:

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

Decision of 327th meeting of Registration Board: Deferred for submission of Pharmaceutical equivalence and Comparative Dissolution Profile (CDP) studies against the innovator's product.

Response by the firm: Firm has submitted result of pharmaceutical equivalence and CDP studies against Dexilant 60mg Capsule. Firm has also submitted picture of the pack of the reference product.

Decision: Approved with Innovator's specifications.

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

391.	Name, address of Applicant / Marketing Authorization Holder	M/s Healthtek (pvt) Ltd., Plot no. 14, Sector 19, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (pvt) Ltd., 581 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. 24043: 16-09-2020
	Details of fee submitted	PKR 50,000/-: 20-04-2020
	Proposed proprietary name / brand name	**Cilomen 500mg injection**
	Strength/ concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem as monohydrate……500mg Cilastatin as sodium...500mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	Anti bacterial / dehydropeptidase inhibitor
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	status in reference regulatory authorities	Primaxin injection (500mg/500mg) by M/s Merck, USFDA Approved.
	For generic drugs (me-too status)	Cilapen 500mg injection by M/s Bosch, Reg. No. 048491
	GMP status of the Finished product manufacturer	GMP certificate issued on 06/12/2019 on the basis of inspection conducted on 16/09/2019. Dry powder injectable (Penicillin, Carbapenem) section is approved.
	Name and address of API manufacturer.	M/s Aurobindo Pharma limited, Unit-V, Plot no. 68-70, 73-91, 95, 96, 260, 261 IDA., Chemical zone, Pashmylaram, Patancheru Mandal, Saga Reddy district, Telangana, 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 drug substance is sterile bulk mixture of Imipenem abd cilastin in a ratio of 1:1.The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies of Drug Substance conditions, duration	• 60 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: EEC0821002, EEC0821003, EEC0821004
	Module-III (Drug Product):	Detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product is submitted.
	Analytical method validation/verification	Th firm has submitted analytical method verification studies. Official monograph for the product is available in USP.
	Comparative dissolution profile/Pharmaceutical Equivalence	

STABILITY STUDY DATA			
Manufacturer of API	M/s Aurobindo Pharma limited, Unit-V, Plot no. 68-70, 73-91, 95, 96, 260, 261 IDA., Chemical zone, Pashmylaram, Patancheru Mandal, Saga Reddy district, Telangana, India. Copy of GMP certificate of API manufacturer is submitted.		
API Lot No.	1605204528		
Description of Pack (Container closure system)	USP type I colorless 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, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	V6001	V7001	V8001
Batch Size	17600 vials	8700 vials	4400 vials
Manufacturing Date	10/2016	08/2017	02/2018
Date of Initiation	25/10/2016	23/08/2017	09/03/2018
No. of Batches	03		

Administrative Portion	
Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate No.
Documents for the procurement of API with approval from DRAP (in case of import).	ADC attested Invoice No. U05/17-18/73 dated 20th, July, 2017
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted supported documents including chromatograms, raw data sheets, COAs summary sheets.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
S.#	**Query**	**Response by the firm**
1	The documents from the API manufacturer in the submitted dossier show that Imipenem as monohydrate 500mg has been used in the manufacturing of blend of Imipenem and Cilastatin as well as the reference product contains Imipenem as monohydrate 500mg while documents from finished product manufacturer show that Imipenem anhydrous 500mg is used, clarify.	According to the firm's response, "It was a typographical error which is corrected from onward as we are procuring the material as monohydrate and our calculations are entirely as per monohydrate material". However, earlier the firm has submitted that the material is received in either form Monohydrate or Anhydrous.
2	Blend of 02 APIs is used for the manufacturing of finished product, for such products potency adjustment becomes very critical because by adjusting the potency of one API would cause the actual potency of the other API to be changed. Therefore, provide procedure for potency adjustment for the applied product.	According to firm "As the material is received in the blend form with ratio of 1:1 so the 100% material contains 50% of Imipenem and 50% of Cilastatin. Considering standard potency of both APIs equal to 50% (500mg) each, theoretical calculations are given in the following. Imipenem: Theoretical quantity= 500mg+2% = 510mg Cilastatin: Theoretical quantity= 500mg+2% = 510mg Total quantity of blend= 510+510 = 1020mg per vial
3	Section 3.2.P.2.2.1 shall include detail of all the quality tests along with the results performed on the developed product against innovator/reference/comparator product foe establishing the pharmaceutical equivalence.	The firm has submitted the required data of pharmaceutical equivalence in relevant section by performing the quality tests against the comparator product Cilapen 500mg by M/s Bosch Pharmaceuticals. The firm has stated that the innovator's product is not available in Pakistan.
4	Valid GMP certificate of API manufacturer is required.	Copy of renewal letter of drug manufacturing license of API manufacturer is submitted. License No.:48/MD/AP/98/B/R Valid till: 31/12/2021
5	Significant change has been observed in real time stability testing of batch number V8001 in assay value of both Imipenem as well as Cilastatin, justify.	According to the reply of the firm has placed 3 more batches in the year 2018 wherein no significant change has been observed, detail of which is given as under. Real time: 30˚C ± 2˚C / 65% ± 5%RH of 03 batches till 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH of 03 batches till 06 months

Batch No.	V8003	V8004	V8005
Batch Size	8900 vials	17540 vials	8900 vials
Manufacturing Date	04/2018	04/2018	08/02018
Date of Initiation	27/04/2018	10/05/2018	29/08/2018

- The diluent mentioned in section 3.2.P.2.6 is Water for Injection while as per the available information regarding innovator/reference product the contents of the vials must be reconstituted by adding approximately 10 mL of the appropriate diluent to the vial.
- List of appropriate diluents are as follows:

0.9% Sodium Chloride Injection
5% Dextrose Injection
5% Dextrose and 0.9% Sodium Chloride
5% Dextrose Injection with 0.225% or 0.45% saline solution

- The submitted testing method for analysis of drug product is different from the method described in USP monograph in terms of standard preparation, assay calculation and formula.

- The test of pH in which the firm specifies that 1gram of sample should be dissolved 100ml of distilled water, however USP specifies that reconstitute as directed in the labelling. The labelling of the innovator / reference product does not recommend reconstitution in WFI.

Decision of 312th meeting:

Registration Board deliberated the case in detail and observed that the contract manufacturer has not performed complete product development studies, the specifications adopted by the manufacturer throughout stability studies were not according to USP. Accordingly, the Board deferred for the case for following submissions:

- Scientific justification for your test of pH which specifies that "reconstitute the sample in 10ml WFI", however USP specifies that reconstitute as directed in the labelling and the labelling of the innovator / reference product does not recommend reconstitution in WFI.
- Scientific justification for having the method of sample solution preparation for the commercial batches which is different from that specified in USP monograph.
- Scientific justification for using an entirely different formula for calculation of assay results of commercial batches from that specified in USP monograph.

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

Submission by the firm:

- The firm has submitted, "Imipenem & Cilastatin material is available and used in blend powder form for injection. For potency adjustment, the lower potency API will be adjusted so the quantity of other API might be slightly adjusted over the target value due to slight difference of potency of both API's.
  Calculations for potency adjustment:
  Batch of blend: AB88390
  Potency of Imipenem: 44.67%
  Potency of Cilastatin: 47.25%
  After considering both Imipenem & Cilastatin at 44.67%
  For the applied product: Cilomen 500mg = $\frac{100 \times 500}{44.67\%}$ = 1119.319 mg/vial
- "We would like to inform you that, we had tested the product according to USP but unfortunately due to some misunderstanding the different formula and concentration were used against USP. We have placed three new batches for stability studies and test it according to USP in all aspects. Revised method and raw data sheets with correct calculation has been attached for your reference".
- The firm has stated, "for the applied product, we have used 10ml of 0.9% Sodium chloride for testing purpose only'.
- The standard solutions have been run for Cilastatin and Imipenem separately for analysis of the sample.
- The chromatographic conditions include 50°C column temperature, 300mm×4.6mm with packing L1, flow rate 2mL/min, wavelength 254nm, Injection volume 10uL. Detail of the tailing factor and theoretical plates not provided by the firm.
- The firm has submitted the data of 03 batches detail of which is given as under;

Batch No.	V1002	V1001	V0003
Batch Size	16000	18340	9000 vials
Manufacturing Date	07/2021	03/2021	11/2020
Date of Initiation	19/07/2021	19/07/2021	19/07/2021
API Lot No.	9900680007E1	DBIMCNF002	AB88390
Attested Invoice no.	Not provided	7000057843 dated 31/12/2020	7000053843 dated 30/09/2020
Source of drug substance	ACS Doofar, Italy	Sun Pharmaceutical industries Ltd., India	Sun Pharmaceutical industries Ltd., India
Frequency	0, 3 (months)	0, 3 (months)	0, 3 (months)

- The formula used for calculation by the firm is given in the following along with complete calculation of a sample.

$$\frac{\text{Area of sp. x wt. of std. x 100 x 100 x Potency}}{\text{Area of std. x 25 x 1 x 10 x 100}} = \_\_\_\_\_ \text{mg of Imipenem / Vial}$$

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

Submission by the firm: Firm has now submitted data of newly manufactured batches in which source of drug substance has been changed to ACS Dobfar Italy. PE studies have been conducted against cilapen injection of Bosch pharma and three batches having batch size of 3530 vials manufactured in April 2022 has been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s ACS Dobfar S.p.A. Viale Addetta, 2s/12-3/5 Tribiano Milano Italy.		
API Lot No.	0069E1		
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, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	V2001	V2002	V2003
Batch Size	3530 vials	3530 vials	3530 vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	16-04-2022	16-04-2022	16-04-2022
No. of Batches	03		

Administrative Portion

Reference of previous approval of applications with stability study data of the firm (if any)	NA
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate No. IT-API/87/H/2022 issued by Italian medicine agency on the basis of inspection dated 03-12-2021.
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate dated 17-03-2022 for import of 12Kg imipenem and cilastatin sodium sterile.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted supported documents including chromatograms, raw data sheets, COAs summary sheets.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted by the firm
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted by the firm

Remarks of the evaluator:

- Significant change i.e. more than 5% change in assay from initial value has bee observed in accelerated stability study for batch V2003.

Decision: Registration Board considering the submitted data of long term stability studies till 24 month time point decided to approve the applied application.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The manufacturer shall apply for post registration variation for the same formulation registered in the name of the firm as well as all contract manufactured products.**
- **The Board further decided that product specific and capacity assessment inspection shall be carried out for the instant product by a panel to be constituted by Chairman Registration Board. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory product specific and capacity assessment of manufacturing and testing facility of the firm.**

Case No. 03 Cases of Form 5

a. New cases

392.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Carbifer 50mg/ml Injection/Infusion
	Composition	Each 1ml ampoule Contains: Iron As Ferric Carboxymaltose…50mg
	Diary No. Date of R& I & fee	Dy No. 27983: 16-08-2018 PKR 50,000/-: 16-08-2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	1ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Bio-Maltose Injection by Bio-Lab
	GMP status	GMP certificate of M/s English Pharmaceutical Industries Lahore valid till 13.07.2024 is submitted
	Remarks of the Evaluator.	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
393.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Carbifer 100mg/2ml Injection/Infusion
	Composition	Each 2ml vial Contains: Iron As Ferric Carboxymaltose…100mg
	Diary No. Date of R& I & fee	Dy No. 27984: 16-08-2018 PKR 50,000/-: 16-08-2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	2ml: As per SRO
	Approval status of product in	Ferinject 50 mg iron/mL solution for injection/infusion. (2ml

	Reference Regulatory Authorities.	vial) MHRA Approved.
	Me-too status	Could not be confirmed
	GMP status	GMP certificate of M/s English Pharmaceutical Industries Lahore valid till 13.07.2024 is submitted
	Remarks of the Evaluator.	• Me-too status could not be confirmed
	Decision: Deferred for evidence of applied formulation/drug in 2ml fill volume 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, .	
394.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan By M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Carbifer 500mg/10ml Injection/Infusion
	Composition	Each 10ml Vial Contains: Iron As Ferric Carboxymaltose…500mg
	Diary No. Date of R& I & fee	Dy No. 27984: 16-08-2018 PKR 50,000/-: 16-08-2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	10ml vial: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Markferi 500mg/10ml Injection by Welmark
	GMP status	GMP certificate of M/s English Pharmaceutical Industries Lahore valid till 13.07.2024 is submitted
	Remarks of the Evaluator.	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

395.	**Name and address of manufacturer / Applicant**	**M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Ncopenem 500mg IV Injection
	Composition	Each Vial Contains: Meropenem As Trihydrate……500mg (Blended with Anhydrous Sodium Carbonate)
	Diary No. Date of R& I & fee	Dy No. 38580: 23-11-2018 PKR 50,000/-: 23-11-2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Meronem injection by Pfizer
	GMP status	GMP certificate of M/s Nicholas Pharmaceuticals issued on the basis of inspection dated 07.04.2021 is submitted
	Remarks of the Evaluator.	•
	Decision: Approved.	
396.	**Name and address of**	**M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera**

	manufacturer / Applicant	**Industrial, Risalpur, KPK By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Ncopenem 1g IV Injection
	Composition	Each Vial Contains: Meropenem As Trihydrate……1g (Blended with Anhydrous Sodium Carbonate)
	Diary No. Date of R& I & fee	Dy No. 38579: 23-11-2018 PKR 50,000/-: 23-11-2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Meronem injection by Pfizer
	GMP status	GMP certificate of M/s Nicholas Pharmaceuticals issued on the basis of inspection dated 07.04.2021 is submitted
	Remarks of the Evaluator.	•
	Decision: Approved.	
397.	**Name and address of manufacturer / Applicant**	**M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Cilasten 500mg IV Injection
	Composition	Each Vial Contains: Each Vial Contains: Imipenem as monohydrate…500mg Cilastatin as Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 38578: 23-11-2018 PKR 50,000/-: 23-11-2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tienam injection by OBS
	GMP status	GMP certificate of M/s Nicholas Pharmaceuticals issued on the basis of inspection dated 07.04.2021 is submitted
	Remarks of the Evaluator.	•
	Decision: Approved.	

b. Deferred cases

398.	**Name and address of Applicant**	**M/s. Highnoon Laboratories Limited, 17.5Km, Multan Road, Lahore**
	Detail of Drug Sale License	**Address:** M/s. Highnoon Laboratories Limited, 17.5Km, Multan Road, Lahore **Validity:** 07-01-2018 **Status:** Valid
	Name and address of manufacturer	M/s. Engelhard Arzneimittel GmbH & Co. KG, Hersbergstr. 3, 61138 Niederdorfelden, Germany

	Name and address of marketing authorization holder	M/s. Engelhard Arzneimittel GmbH & Co. KG, Hersbergstr. 3, 61138 Niederdorfelden, Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.5882 Dated 13/06/2017
	Fee including differential fee	Rs. 50,000/- Dated 06/06/2017
	Brand Name +Dosage Form + Strength	Tyrosur Powder
	Composition	Each gram of powder contains: Tyrothricin……1.0mg
	Finished Product Specification	In House`
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Demanded Price	Not provided
	Pack size	5gm, 20gm
	International availability	Available in Germany as per CoPP
	Me-too status	Not applicable
	Detail of certificates attached	• Original legalized CoPP is attached (Certificate no. DeLP24) certified by Regierungsprasidium Darmstadt issued on 07/12/2016 confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by World Health Organization.
	Remarks of the Evaluator.	The firm has claimed In-House manufacturing specifications and the product is not present in USP/BP.
	Decision of 274th meeting of RB: Deferred for confirmation of the drug whether it falls under the category of pharmaceutical or Biological.	
	Submission by the firm: Firm has submitted that Tyrothricin is an EMA approved dmg and is available worldwide but there is no even single brand of this drug is available in Pakistan but registration ofTyrosur Powder and Tyrosur Gel is pending from a long time.	
	Decision of 330th meeting: Registration Board referred the case to Expert Working Group for the review of "Human Formulations of Pharmaceutical Drug Products" .	
399.	**Name and address of Applicant**	**M/s. Highnoon Laboratories Limited, 17.5Km, Multan Road, Lahore**
	Detail of Drug Sale License	**Address:** M/s. Highnoon Laboratories Limited, 17.5Km, Multan Road, Lahore **Validity:** 07-01-2018 **Status:** Valid
	Name and address of manufacturer	M/s. Engelhard Arzneimittel GmbH & Co. KG, Germany
	Name and address of marketing authorization holder	M/s. Engelhard Arzneimittel GmbH & Co. KG, Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.5881 Dated 13/06/2017
	Fee including differential fee	Rs. 50,000/- Dated 06/06/2017
	Brand Name +Dosage Form + Strength	Tyrosur Gel
	Composition	Each gram of gel contains: Tyrothricin……1.0mg
	Finished Product Specification	Not present in USP/BP
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Demanded Price	Not provided
	Pack size	5gm, 15gm, 25gm
	International availability	Available in Germany as per CoPP
	Me-too status	Not applicable

	Detail of certificates attached	• Copy of CoPP is attached (Certificate no. DeLP23) certified by Regierungsprasidium Darmstadt issued on 07/12/2016 confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by World Health Organization.
	Remarks of the Evaluator.	The firm has claimed In-House manufacturing specifications and the product is not present in USP/BP.
	Decision of 274th meeting of RB: Deferred for confirmation of the drug whether it falls under the category of pharmaceutical or Biological.	
	Submission by the firm: Firm has submitted that Tyrothricin is an EMA approved dmg and is available worldwide but there is no even single brand of this drug is available in Pakistan but registration ofTyrosur Powder and Tyrosur Gel is pending from a long time.	
	Decision of 330th meeting: Registration Board referred the case to Expert Working Group for the review of "Human Formulations of Pharmaceutical Drug Products" .	

Case No. 04 Miscellaneous cases

M/s Gene-Tech Laboratories, Karachi has submitted the following application

Sr. No	Brand Name and composition	Fee details	Dy No
400.	Hyal Forte Each prefilled syringe (2ml) contains: Sodium hyaluronate…..20mg	PKR 100,000 dated 24-03-03-2021	Dy No. 10553, 06-04-2021

The application was initially submitted in BE&R Division, later on the application was forwarded to PE&R Division for confirmation whether the applied product falls under the definition of drugs or otherwise and for confirmation of source of the drug substance whether pharmaceutical or biological.

Decision: Registration Board deliberated the matter in detail and directed Pharmaceutical Evaluation Cell (PEC) to evaluate the complete application and present the detailed evaluation report in the forthcoming meeting.

M/s Mission Pharmacuticals, Karachi

M/s Mission Pharmaceuticals Karachi has informed that they have applied double dossiers of following products by mistake. They have applied for these products on 07-03-2019 while they were already registered.

Sr. No	Brand Name and composition	Fee details	Approved in RB meeting
401.	Elvox Tablet 250mg Each Film Coated Tablet Contains: Levofloxacin Hemihydrate eq to Levofloxacin Base…250mg	Dy No. 15135: 07-03-2019 PKR 20,000/-: 06-03-2019	327
402.	Elvox Tablet 500mg Each Film Coated Tablet Contains: Levofloxacin Hemihydrate eq to Levofloxacin Base…500mg	Dy No. 15146: 07-03-2019 PKR 20,000/-: 06-03-2019	327

The above products are already registered with the firm vide letter dated 28-06-2022, having registration number 112661 and 112662.

Now the firm has requested to cancel these products which were approved in 327th meeting of Board.

Decision: Registration Board acceded the request of the firm and decided to cancel the approval of

following products granted in 327th meeting of Registration Board.

- **Elvox Tablet 250mg**
- **Elvox Tablet 500mg**

Agenda of Evaluator PEC-IV

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

403.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilson's Pharmaceuticals. 387-388, I-9/3, Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, 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. 3337 dated 03-02-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 33800594
	The proposed proprietary name / brand name	**Wilzon 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Metolazone…..…5mg
	Pharmaceutical form of applied drug	Green colored Oval shaped tablets.
	Pharmacotherapeutic Group of (API)	(Diuretic/Saluretic/antihypertensive drug of the quinazoline class)
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	15’s, 30’s, 45’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zaroxolyn Tablet 5mg of (USFDA approved)
	For generic drugs (me-too status)	Metxone tablet 5mg of M/s Genome (Reg.# 090699)
	GMP status of the Finished product manufacturer	cGMP certificated on the basis of evaluation conducted on 28-07-2022 and valid till 27-07-2024.
	Name and address of API manufacturer.	M/s Centaur Pharmaceuticals Pvt Limited. 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. 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 Metolazone is present in USP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of 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 Batches: (1503601P, 1503602P, 15036003PL1)
	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 comparator brand that is 'Metxone tablet 5mg of M/s Genome, by performing quality tests (Assay & Dissolution and Disintegration time). CDP has been performed against the comparator brand that is 'Metxone tablet 5mg of M/s Genome in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Sodium phosphate buffer (pH 7.5) . The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Method Verification studies have submitted including system suitability, linearity, range, accuracy, precision, specificity and stability of solution.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Warrant Pharmaceutical Co., Ltd. Workshop 1 No. 4290, Xingbin Road, Binhai Industrial Zone, Keqiao District, Shaoxing, Zhejiang, P.R. China.
API Lot No.	1803605P
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.	Trial# 02	Trial# 03	Trial# 04
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11.2019	11.2019	11.2019
Date of Initiation	11.2020	11.2020	11.2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML License No. 25-KD/1149 issued by Food and Drug Administration Maharashtra India. Dated: 26-08-2018 and 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, form 3 form 6, form 7 and clearance certificate of mentioning invoice (invoice# CP/EXP/C/030/19-20) dated 12-04-2019 cleared by DRAP Islamabad office dated 25-06-2019 specifying import of Metolozone 0.135Kg (Batch# 1803605P).
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	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance is submitted
4.	3.2.P.5.1	You have not performed	Uniformity of dosage unit by content uniformity

		uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	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.**

b. Deferred cases

404.

Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
Brand Name +Dosage Form + Strength	Tramax 100mg SR Capsule
Composition	Each Sustained Release Capsule Contains: Tramadol Hcl…100mg
Diary No. Date of R& I & fee	Dy.No. 41495 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
Pharmacological Group	Narcotic analgesic
Type of Form	Form 5
Finished product Specification	BP
Pack size & Demanded Price	10's, 20's, 30's: As per SRO
Approval status of product in Reference Regulatory Authorities	CONZIP 100mg Capsules of (USFDA approved)
Me-too status	Zultra SR 100mg of M/s. Wilshire Laboratories
GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
Remarks of the Evaluator	Submit Master formula, manufacturing method, analytical method CIP-TRAMADOL ER (tramadol hydrochloride) extended-release) capsules are a new formulation of tramadol HCl for analgesia. The drug product consists of extended release film coated white beads and an immediate release tablet encapsulated in white opaque, size 1, 0 and 00, hard gelatin capsules

Dosage	Immediate release	Extended release
100 mg	25 mg	75 mg

Previous Decision (M-322): Deferred for review of formulation against the innovator product.

Reply by firm: We want to inform you that we had applied for Tramadol HCl 100mg as "Tablet". There was typographical error in the last reply sent in response to letter number F.1-1/2019/PEC-DRAP (AD PEC-IV) dated: 7th September, 2022. R & I copy of product is attached for reference.
We are also applying for the change in the label claim of the product

Name of Drug with Applied label claim	Name of Drug with Proposed label claim	Fee for change in label claim
Tramax 100mg SR Tablet Each Sustained Release Tablet Contains: Tramadol Hcl…100mg	Tramax 100mg SR Tablet Each Extended Release Film Coated Tablet Contains: Tramadol Hcl…100mg	Deposit slip No# 50754384014 Rs:7500/- Dated: 23-01-2023

Approval status of product in Reference Regulatory Authorities	ULTRAM ER of USFDA

	Remarks: Film coating is not mentioned in ULTRAM ER Master formula and manufacturing method is not submitted.
	Previous Decision (M-326): Registration Board deferred the case for submission of Master formula and manufacturing method.
	Evaluation by PEC: Master formula and manufacturing method as per Innovator is submitted by firm
	Decision: Approved as per following label claim: **"Tramax 100mg SR Tablet** **Each Extended Release Film Coated Tablet Contains:** **Tramadol HCl…100mg"** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

New case

M/s Oncogen Pharma Private Limited . (New DML)
CLB in its 287th meeting held on 24th June 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following Two (02) sections to M/s Oncogen Pharma Private Limited.

1) Tablet (Oncology)
2) Capsule (Oncology)

Sr. No	Section	Molecules for consideration in 329th meeting	Products for consideration in 329th meeting
1	Tablet (Oncology)	01	01

405.	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma Private Limited. Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.
	Name, address of Manufacturing site.	M/s Oncogen Pharma Private Limited. Plot No # WH 26 and 27-A3, Korangi Creek Industrial Park Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2102 dated 23-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 249111749877
	The proposed proprietary name / brand name	**Imaver Tablet 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imatinib Mesylate Ph. Eur. equivalent to Im ……..…. 100 mg.
	Pharmaceutical form of applied drug	Dark yellow to brownish orange color, round shape film coated tablet, debossing '100' on one side and plain on other side,

	Pharmacotherapeutic Group of (API)	Antineoplastic (Protein Kinase Inhibitors) L01EA01
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1 x 10's (10's) 3 x 10's (30's) 6 x 10's (60's) 12 x 10's (120's)
	Proposed unit price	1 x 10's (10's) = 17,000/- 3 x 10's (30's) = 51,000/- 6 x 10's (60's) = 102,000/- 12 x 10's (120's) = 204,000/-
	The status in reference regulatory authorities	Gleevec Tablets 100mg by M/s Novartis Pharmaceuticals corporation, New Jersey USA USFDA Approved.
	For generic drugs (me-too status)	Glivec Tablets 100mg by M/s Novartis Pharmaceuticals Pakistan. (Reg. No.: 033196)
	GMP status of the Finished product manufacturer	Last DML Inspection dated 08-06-2022 concludes as 'GOOD' based on designed and established at an acceptable level of compliance of GMP requirements. Tablet (Anti-cancer) and Capsule (Anti-cancer) sections were approved.
	Name and address of API manufacturer.	M/s CDYMAX (India) Pharma Private Limited (Formerly known as Acebright (India) Pharma Pvt. Ltd.) 116/117, KIDAB, Indl. Area, Jigani 2nd Phase, Jigani, Bangalore-560 105 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 Imatinib Mesylate is available in European Pharmacopeia. Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch 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 18 months Accelerated: 40°C±2°C/75±5%RH for 6 months Batches: (IMBE21001, IMBE21002, IMBE21003)
	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 innovator's product Glivec 100mg Tablet, Batch LM8549 by Novartis Pharmaceuticals Germany by performing quality tests (Appearance, Assay, Dissolution and Impurities). CDP has been performed against the innovator's product that is Glivec 100mg Tablet Batch LM8549 by Novartis Pharmaceuticals Germany, in Acidic medium (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method Verification studies have submitted including system suitability, linearity, range, accuracy, precision, specificity and stability of solution.

STABILITY STUDY DATA			
Manufacturer of API	M/s CDYMAX (India) Pharma Private Limited (Formerly known as Acebright (India) Pharma Pvt. Ltd.) 116/117, KIDAB, Indl. Area, Jigani 2nd Phase, Jigani, Bangalore-560 105 India.		
API Lot No.	IMBE21001 and IMBE21002		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 30's, 60's and 120'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	M/s CDYMAX (India) Pharma Private Limited (Formerly known as Acebright (India) Pharma Pvt. Ltd.) 116/117, KIDAB, Indl. Area, Jigani 2nd Phase, Jigani, Bangalore-560 105 India.		
Batch No.	001NS04	001NS05	001NS06
Batch Size	3639 Tablets	3639 Tablets	3639 Tablets
Manufacturing Date	09-09-2022	20-09-2022	20-09-2022
Date of Initiation	05-10-2022	05-10-2022	05-10-2022
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.	Firm has submitted copy of Drug Manufacturing License (DML) License no. KTK/25/506/2005 issued by Govt. of Karnataka, Drug control department, India. (valid till 14-07-2025).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 was issued to firm bearing no. K-734956897361 issue date: 21-07-2022 to import the Imatinib Mesylate 2.7 Kg from CDYMAX (India) Pharma Private Limited (Formerly known as Acebright (India) Pharma Pvt. Ltd.) 116/117, KIDAB, Indl. Area, Jigani 2nd Phase, Jigani, Bangalore-560 105 India for manufacturing of

		Trial and stability batches
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 along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance certificate of HPLC software and 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 & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.4	Which Polymorphic form was chosen for the manufacturing of the finished product.	This is to inform you that the polymorphic form of imatinib Mesylate used by Oncogen Pharma is 13-beta form and the same polymorphic form is used by innovator in Gleevec 100mg tablet (Novartis). We are enclosing the COA of drug substance manufacturer confirming the polymorphic form and Innovator product reference document.
2.	3.2.P.5.1	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 85% in 20 minutes"	This is to inform you that our product specification is in-house and not available in any pharmacopeia. Therefore, dissolution sampling time point was set as 20mins. We have performed Comparative dissolution profile (CDP) which shows that tablets were dissolved more than 85% within 15 minutes in acidic medium such as 0.IN HCI. We hereby commit that we will revise the dissolution sampling time on commercial specifications of our product in line with innovator specifications. CDP data is attached.

Decision: Approved. Firm shall submit revised drug product specifications with sampling time of 15 minutes for dissolution test along with fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

M/s Swera Pharmaceuticals. (New DML)

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following six (06) sections to M/s Swera Pharmaceuticals

1	Tablet(General)	4	Cream/ Gel (General)
2	Capsule (General)	5	Lotion Section (General)
3	Sachet (General)	6	Dry Powder Injection (General)

Tablet (General)
01 Molecules/ 02 Products

406.	Name, address of Applicant / Marketing Authorization Holder	M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, National Industrial Zone, Rawat, Islamabad
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals. Plot No. 27, Street No. 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 DML letter issued dated; 16-09-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 16-09-2021 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3937 dated 10-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 6071839530
	The proposed proprietary name / brand name	**Terbiera 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine as HCl…… 125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White to off white colored uncoated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL 125mg Tablet by Novartis Pharmaceuticals of (TGA Approved)
	For generic drugs (me-too status)	LAMISIL 125mg Tablet by M/s Novartis Pharma (Pakistan) Ltd Reg #013208
	Name and address of API manufacturer.	M/s Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, 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: Real time: 30°C ± 2°C / 65% ± 5%RH for 36

		months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TH0131216, TH0141216, TH0151216)
	Module-III Drug Product:	Official monograph of Terbinafine HCL is present in BP. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 'Lamisil tablet 125mg of M/s Novartis pharma, by performing quality tests (Identification, weight variation, disintegration, Assay & Dissolution). CDP has been performed against the 'Lamisil tablet 125mg of M/s Novartis pharma, in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Sodium phosphate buffer (pH 7.5) . The f2 values 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	M/s Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, India.		
API Lot No.	TH0010122		
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-T007	RD-T008	RD-T009
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	24-05-2022	24-05-2022	24-05-2022
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	Firm has submitted copy of GMP Certificate (No.L.DIS. No.111050/TS/2023 dated 21-02-2023

	authority of country of origin.	issued by Drugs Control Administration Government of Telegana India. Valid till 20-02-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 5 and clearance certificate no # E-1226082941489 , dated;21-05-2022 specify commercial invoice 2223/SL/009 on 20-04-2022 specifying 1Kg of Terbinafine batch # TH0010122.
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 testin	Not 21CFR 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:

S.No	Section	Shortcoming communicated	Reply
1.	1.6.5	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin submitted.
2.	3.2.P.3.5	Process validation protocol does not include sampling plan.	Process validation protocol including sampling plan submitted.
3.	3.2.P.5.2	Submit complete standard and sample preparation method in assay method	Complete standard and sample preparation method in assay method submitted.
4.	3.2.P.8	Submit COA's of all time points.	COA's of all time points 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.**

407.	Name, address of Applicant / Marketing Authorization Holder	M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, National Industrial Zone, Rawat, Islamabad
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals. Plot No. 27, Street No. 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 DML letter issued dated; 16-09-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 16-09-2021 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3930 dated 10-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 99479327
	The proposed proprietary name / brand name	**Terbiera 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine as HCl…… 250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White to off white colored uncoated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL 250mg Tablet by Novartis Pharmaceuticals of (USFDA Approved)
	For generic drugs (me-too status)	LAMISIL 250mg Tablet by M/s Novartis Pharma (Pakistan) Ltd Reg #013209
	Name and address of API manufacturer.	M/s Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, 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: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TH0131216, TH0141216, TH0151216)
	Module-III Drug Product:	Official monograph of Terbinafine HCL is present in BP. Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 'Lamisil tablet 250mg of M/s Novartis pharma, by performing quality tests (Identification, weight variation, disintegration, Assay & Dissolution). CDP has been performed against the 'Lamisil tablet 250mg of M/s Novartis pharma, in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Sodium phosphate buffer (pH 7.5) . The f2 values 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	M/s Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, India.		
API Lot No.	TH0010122		
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-T010	RD-T011	RD-T012
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	30-05-2022	30-05-2022	30-05-2022
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.	Firm has submitted copy of GMP Certificate (No.L.DIS. No.111050/TS/2023 dated 21-02-2023 issued by Drugs Control Administration Government of Telegana India. Valid till 20-02-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 5 and clearance certificate no # E-1226082941489 , dated;21-05-2022 specify commercial invoice 2223/SL/009 on 20-04-2022 specifying 1Kg of Terbinafine batch # TH0010122.
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 21CFR 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:

S.No	Section	Shortcoming communicated	Reply
1.	1.6.5	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin submitted.
2.	3.2.P.3.5	Process validation protocol does not include sampling plan.	Process validation protocol including sampling plan submitted.
3.	3.2.P.5.2	Submit complete standard and sample preparation method in assay method	Complete standard and sample preparation method in assay method submitted.
4.	3.2.P.8	Submit COA's of all time points.	COA's of all time points 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.**

Cream/ Gel (General)
01 Molecule/ 01 product

408.	Name, address of Applicant / Marketing Authorization Holder	M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, National Industrial Zone, Rawat, Islamabad
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals. Plot No. 27, Street No. 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 DML letter issued dated; 16-09-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 16-09-2021 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3932 dated 10-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 669914589
	The proposed proprietary name / brand name	Terbiera 10g Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram cream contains: Terbinafine as HCl……10mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White to off white semisolid filled in Aluminum tube

	Reference to Finished product specifications	JP
	Proposed Pack size	1 x 10gm Tube
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL 1% w/w Cream by GlaxoSmithKline Consumer Healthcare of (MHRA Approved)
	For generic drugs (me-too status)	LAMISIL 1% w/w Cream by M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd Reg #084005
	Name and address of API manufacturer.	M/s Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, 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:	Official monograph of Terbinafine HCL is present in BP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TH0131216, TH0141216, TH0151216)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 'Lamisil cream 1% of M/s Glaxo smith Klien, by performing quality tests (Identification, weight variation, 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 Saptagir Laboratories Address: Sy.No.Parts of 27, 46 %0 to 56 Ananthasagar (Vill), Chegunta (Mandal) Medak (district, Telegana, India.		
API Lot No.	TH0010122		
Description of Pack (Container closure system)	Aluminium Tube filled with cream		
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-TC001	RD-TC002	RD-TC003
Batch Size	300 Tubes	300 Tubes	300 Tubes
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	18-05-2022	18-05-2022	19-05-2022
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.	Firm has submitted copy of GMP Certificate (No.L.DIS. No.111050/TS/2023 dated 21-02-2023 issued by Drugs Control Administration Government of Telegana India. Valid till 20-02-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 5 and clearance certificate no # E-1226082941489 , dated;21-05-2022 specify commercial invoice 2223/SL/009 on 20-04-2022 specifying 1Kg of Terbinafine batch # TH0010122.
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 21CFR 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:

S.No	Section	Shortcoming communicated	Reply
1.	1.6.5	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin submitted.
2.	3.2.P.3.5	Process validation protocol does not include sampling plan.	Process validation protocol including sampling plan submitted.

3.	3.2.P.8	• Submit COA's of all time points • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	COA's of all time points 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.**

M/s Pine Pharmaceuticals. (New DML)
CLB in its 285th meeting held on 17th and 18th March 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following three (03) sections to M/s Pine Pharmaceuticals

1.	Tablet (General)
2.	Capsule (General)
3.	Cream Ointment (General)

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

Tablet (General)
01 Molecules/ 01 Products

409.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8830 dated 31-03-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 4362231089
	The proposed proprietary name / brand name	**Terbipine 125mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Terbinafine as HCl …….125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White color, round, uncoated tablets
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 125mg tablet MHRA/TGA Approved.

	For generic drugs (me-too status)	Lamisil 125mg Tablet by M/s Novartis Pharma Pakistan, Reg. No. 013208
	Name and address of API manufacturer.	M/s Tagoor Laboratories Pvt. Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dis-534341, A.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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Terbinafine HCl is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TBH0131216, TBH0141216, TBH0151216)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Lamisil 125mg tablet by M/S Novartis Pharama Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Lamasil 125mg tablet by M/S Novartis Pharma Pakistan 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	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. Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dis-534341, A.P, India		
API Lot No.	TBH-0020421		
Description of Pack (Container closure system)	Alu-Alu 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.	TB01	TB02	TB03
Batch Size	2,000 tabs	2,000 tabs	2,000 tabs
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	22-09-2022	22-09-2022	22-09-2022
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 (WC-0494) dated 23-02-2022 issued by Central Drugs Standard Control Organization India. Valid till 26/02/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial Invoice # EXP/034/21-22, dated; 02-08-2021 specify approved by DRAP Islamabad office date: 08-09-2021 specifying 50Kg of Terbinafine HCl batch # TBH-0020421
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	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.

Remarks of Evaluator:

S.No	Section	Shortcoming communicated	Reply
1.	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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
2.	3.2.P.6	COA of primary / secondary reference standard including source and lot number of shall be provided	COA of primary / secondary reference standard including source and lot number

3.	3.2.P.8	• Documents for the procurement of API with approval from DRAP readable form. • Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• Documents for the procurement of API with approval from DRAP submitted. • An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**

410.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8831 dated 31-03-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 2054672522
	The proposed proprietary name / brand name	**Terbipine 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Terbinafine as HCl …….250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Pharmaceutical form of applied drug	White color, round, uncoated tablets
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 250mg tablet MHRA/TGA Approved.
	For generic drugs (me-too status)	Lamisil 250mg Tablet by M/s Novartis Pharma Pakistan, Reg. No. 013209
	Name and address of API manufacturer.	M/s Tagoor Laboratories Pvt. Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dis-534341, A.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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Terbinafine HCl is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TBH0131216, TBH0141216, TBH0151216)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Lamisil 250mg tablet by M/S Novartis Pharama Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Lamasil 250mg tablet by M/S Novartis Pharma Pakistan 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	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. Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dis-534341, A.P, India
API Lot No.	TBH-0020421

Description of Pack (Container closure system)	Alu-Alu 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.	TB04	TB05	TB06
Batch Size	2,000 tabs	2,000 tabs	2,000 tabs
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	22-09-2022	22-09-2022	22-09-2022
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 (WC-0494) dated 23-02-2022 issued by Central Drugs Standard Control Organization India. Valid till 26/02/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial Invoice # EXP/034/21-22, dated; 02-08-2021 specify approved by DRAP Islamabad office date: 08-09-2021 specifying 50Kg of Terbinafine HCl batch # TBH-0020421
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	Our 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:

S.No	Section	Shortcoming communicated	Reply
1.	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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
2.	3.2.P.6	COA of primary / secondary reference standard including source and lot number of shall be provided	COA of primary / secondary reference standard including source and lot number
3.	3.2.P.8	• Documents for the procurement of API with approval from DRAP readable form. • Borrowing of API is letter is attached but did not specify from whom API is borrowed.	• Documents for the procurement of API with approval from DRAP submitted. • An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies submitted.

		• Submit COA's of all time points for real and Accelerated stability studies.	

Decision: Approved.

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

411.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4619 dated 17-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 137767840718
	The proposed proprietary name / brand name	**Ciprapine 5mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as Oxalate …….5mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors [SSRI] (Anti-depressant)
	Pharmaceutical form of applied drug	White to off white, round, scored, film coated tablets
	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	Cipralex 5mg tablet by M/s Lundbeck Limited, MHRA Approved.
	For generic drugs (me-too status)	Precipra 5mg Tablet by M/s Pfizer, Reg. No.067361
	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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Escitalopram oxalate is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DSNBC-2 17001, DSNBC-2 17002, DSNBC-2 17003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Precipra 5mg tablet by Pfizer Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Precipra 5mg tablet by Pfizer 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Shodana Laboratories Private Limited Plot No 24,25,26, Phase 1, Jeedimetla, Hyderabad-50055 Telangana India
API Lot No.	EO-095/21
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7'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.	T01E	T02E	T03E
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-05-2022	14-05-2022	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)	
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 (L, Dis,No,86774/TS/2022) dated 25-05-2022 issued by Drug control Administration Government of Telangana India. Valid till 24/05/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # 2021-22/EXP054, dated; 12-10-2022 specify approved by DRAP Islamabad office date: 04-11-2021 specifying 5Kg of Escitalopram Oxalate batch # EO-095/21. .(Panacea pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming 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 Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
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	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted

		submitted.	
5.	3.2.P.2.2.1	Pharmaceutical equivalence and CDP not performed against innovator product. Clarification is required.	We have performed Pharmaceutical Equivalence and CDP against Brand Name Pracepra 5mg Tablet by Pfizer which have same formulation as per Innovator product.
6.	3.2.P.5.2	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	We have performed uniformity of dosage units by content uniformity as recommended by USP General Chapter <905>.the uniformity test has included in COA's.
7.	3.2.P.6	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution shall be provided	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution is submitted.
8.	3.2.P.8	• Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**

412.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4620 dated 17-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 90021944419
	The proposed proprietary name / brand name	**Ciprapine 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as Oxalate …….10mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors [SSRI] (Anti-depressant)
	Pharmaceutical form of applied drug	White to off white, round, scored, film coated tablets

	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	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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Escitalopram oxalate is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DSNBC-2 17001, DSNBC-2 17002, DSNBC-2 17003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Cipralex 10mg tablet by M/s Lundbeck Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Cipralex 10mg tablet by M/s Lundbeck Pakistan 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Shodana Laboratories Private Limited Plot No 24,25,26, Phase 1, Jeedimetla, Hyderabad-50055 Telangana India		
API Lot No.	EO-095/21		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7'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.	T04E	T05E	T06E
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-05-2022	14-05-2022	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)	
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 (L, Dis, No,617/A2/201) dated 23-02-2022 issued by Drug Control Administration Government of Telangana India. Valid till 18/09/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # 2021-22/EXP054, dated; 12-10-2022 specify approved by DRAP Islamabad office date: 04-11-2021 specifying 5Kg of Escitalopram Oxalate batch # EO-095/21. .(Panacea pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming 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	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 submitted.

		regulatory authority of country of origin.	
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
5.	3.2.P.2.2.1	In CDP Cipralex Tablet and Lexapro Tablet both are mentioned. Clarify which product is used for CDP.	CDP has been performed against the brand that is Cipralex 10mg tablet by M/s Lundbeck Pakistan. Lexapro is a typoerror.
6.	3.2.P.5.2	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	We have performed uniformity of dosage units by content uniformity as recommended by USP General Chapter <905>.the uniformity test has included in COA's.
7.	3.2.P.6	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution shall be provided	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution is submitted.
8.	3.2.P.8	• Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**

413.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4621 dated 17-02-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 56751684435
	The proposed proprietary name / brand name	**Ciprapine 20mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as Oxalate …….20mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors [SSRI] (Anti-depressant)
	Pharmaceutical form of applied drug	White to off white, round, scored, film coated tablets
	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	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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Escitalopram oxalate is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DSNBC-2 17001, DSNBC-2 17002, DSNBC-2 17003)
	Module-III Drug Product:	Firm has submitted data of drug product including

		its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Cipralex 20mg tablet by M/s Lundbeck Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Cipralex 20mg tablet by M/s Lundbeck Pakistan 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shodana Laboratories Private Limited Plot No 24,25,26, Phase 1, Jeedimetla, Hyderabad-50055 Telangana India		
API Lot No.	EO-095/21		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7'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.	T07E	T08E	T09E
Batch Size	1500 tabs	1500 tabs	1500 tabs
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-05-2022	14-05-2022	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)	
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 (L,Dis,No,617/A2/201) dated 23-02-2022 issued by Drug control Administration Government of Telangana India. Valid till 18/09/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # 2021-22/EXP054, dated; 12-10-2022 specify approved by DRAP Islamabad office date: 04-11-2021 specifying 5Kg of Escitalopram Oxalate batch # EO-095/21. .(Panacea pharmaceuticals)

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming 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 Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
5.	3.2.P.5.2	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	We have performed uniformity of dosage units by content uniformity as recommended by USP General Chapter <905>.the uniformity test has included in COA's.
6.	3.2.P.6	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution shall be provided	COA of primary / secondary reference citalopram Hydrobromide standard used for dissolution is submitted.
7.	3.2.P.8	• Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**

414.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8829 dated 31-03-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 11276382865
	The proposed proprietary name / brand name	**Acepine 100mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Aceclofenac …….100mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and antirheumatic.
	Pharmaceutical form of applied drug	White color, round, film coated tablets
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aceclofenac 100mg film caoted tablet MHRA/UK Approved.
	For generic drugs (me-too status)	Airtal 100mg Tablet by M/s Highnoon Laboratories Limited, Reg. No. 015398
	Name and address of API manufacturer.	M/s Aarti Drugs Limited, W-61,W-60(B), 71(B), 73(B), M.I.D.C. Tarapur District Thane, Maharashta, 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:	Official monograph of Aceclofenac is present in BP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ACE/1002/0004A, ACE/1002/0005A, ACE/1002/0006A)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Airtal 100mg tablet by M/s Highnoon Laboratories Limited by performing quality tests (Identification, Assay, Disintegration time, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Airtal 100mg tablet by M/s Highnoon Laboratories Limited 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Aarti Drugs Limited, W-61,W-60(B), 71(B), 73(B), M.I.D.C. Tarapur District Thane, Maharashta, INDIA		
API Lot No.	ACF/10100169		
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.	ACF01	ACF02	ACF03
Batch Size	1,500 tabs	1,500 tabs	1,500 tabs
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	12-05-2022	14-05-2022	15-05-2022
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.	Firm has submitted copy of GMP Certificate (NEW-WHO-GMP/CERT/KD/103280/2021/11/37083) dated issued by Food and Drug Administration Maharashtra India. Valid till 15/08/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # EXP/2240/20-21, dated; 10-11-2020 approved by DRAP Islamabad office date: 08-12-2020 specifying 100Kg of Aceclofenac batch # ACF/10100169.(Panacea pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming 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 Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
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.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
5.	3.2.P.8	• Borrowing of API letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**		
415.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8496 dated 28-03-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 5526106688
	The proposed proprietary name / brand name	**Ebaspine 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine …….10mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Pharmaceutical form of applied drug	White to off white, round, unscored, film coated tablets
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ebastine 10 film coated tablets 10mg Netherland Approved. EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	For generic drugs (me-too status)	Kestine 10mg tablets by M/s Highnoon Laboratories Limited, Reg. No. 017681
	Name and address of API manufacturer.	M/s Bal Pharma Unit 2 61-B, Bommasandra Industrial Area Banglore-560099, Karantaka 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Official monograph of Ebastine is present in BP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (EB/161005, EB/161006, EB/161007)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Kestine 10mg tablet by M/S Highnoon Laboratories limited Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Kestine 10mg tablet by M/S Highnoon Laboratories limited Pakistan 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Bal Pharma Unit 2 61-B, Bommasandra Industrial Area Banglore-560099, Karantaka State, India		
API Lot No.	5017072109004		
Description of Pack (Container closure system)	Alu-Alu 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.	TE01	TE02	TE03

Batch Size	1,500 tabs	1,500 tabs	1,500 tabs
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	03-06-2022	05-06-2022	06-06-2022
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)	
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).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # M02/2122/EXP/AEX/00219, dated; 27-10-2021 approved by DRAP Islamabad office date: 18-11-2021 specifying 10Kg of Ebastine batch # 5017072109004.(Panacea pharmaceuticals)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming communicated	Response of the Firm
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 Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
4.	3.2.P.5.2	You have not performed uniformity of dosage unit by content uniformity, as recommended. Justification shall be submitted in this regard.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
5.	3.2.P.8	• Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**		
416.	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot# 40,Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 29-04-2022
	Evidence of approval of manufacturing facility	New DML letter issued dated; 29-04-2022 in which Tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 8497 dated 28-03-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 2873022521
	The proposed proprietary name / brand name	**Ebaspine 20mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine …….20mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Pharmaceutical form of applied drug	White to off white, round, unscored, film coated tablets
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ebastine 20 film coated tablets 10mg Netherland Approved.
	For generic drugs (me-too status)	Kestine 20mg tablets by M/s Highnoon Laboratories Limited, Reg. No. 025432
	Name and address of API manufacturer.	M/s Bal Pharma Unit 2 61-B, Bommasandra Industrial Area Banglore-560099, Karantaka 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Ebastine is present in BP.

		Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (EB/161005, EB/161006, EB/161007)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 brand leader that is Kestine 20mg tablet by M/S Highnoon Laboratories limited Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Kestine 20mg tablet by M/S Highnoon Laboratories limited Pakistan 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	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Bal Pharma Unit 2 61-B, Bommasandra Industrial Area Banglore-560099, Karantaka State, India		
API Lot No.	5017072109004		
Description of Pack (Container closure system)	Alu-Alu 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.	TE04	TE05	TE06
Batch Size	1,500 tabs	1,500 tabs	1,500 tabs

Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	03-06-2022	05-06-2022	06-06-2022
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)	
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).	A letter to additional director/Secretary written for borrowing of API was attached. Firm has submitted copy of Commercial Invoice # M02/2122/EXP/AEX/00219, dated; 27-10-2021 approved by DRAP Islamabad office date: 18-11-2021 specifying 10Kg of Ebastine batch # 5017072109004.(Panacea pharmaceuticals
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming communicated	Response of the Firm
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 Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer is required.	Copies of the Drug substance specifications both Drug substance & Drug Product manufacturer are submitted.
3.	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.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
4.	3.2.P.5.2	You have not performed uniformity of dosage unit by content uniformity, as recommended. Justification shall be submitted in this regard.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted
5.	3.2.P.8	• Borrowing of API is letter is attached but did not specify from whom API is borrowed. • Submit COA's of all time points for real and Accelerated stability studies.	• An agreement of API's Loan between Pine pharmaceuticals and panacea pharmaceuticals submitted. • COA's of all time points for real and Accelerated stability studies 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.**

M/s Fortune Pharma Private Limited. (New DML)

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

1.	Tablet (General)	2.	Liquid Ampoule (General)
3.	Liquid Syrup (General)	4.	Liquid Vial (General)
5.	Capsule (General)	6.	Tablet (Psychotropic)
7.	Ointment (General) Section	8.	Capsule (Psychotropic)
9.	Sachet (General)	10.	Liquid Ampoule (Psychotropic)

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

Tablet (General)
01 Molecules/ 01 Products

417.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Head Office Suit # 731, 7th Floor Mashriq Centre, Opp National Stadium Road Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML letter issued dated; 22-02-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 22-02-2021 in which Sachet Powder (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14703 dated 12-06-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 971774668
	The proposed proprietary name / brand name	**Mon-Kast 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast as Sodium…..4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Pharmaceutical form of applied drug	White to off white semisolid filled in Aluminum tube
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR granules for powder 4mg of (MHRA Approved)

	For generic drugs (me-too status)	Lucast powder for Solution by M/s AGP Limited Reg #048716
	Name and address of API manufacturer.	M/s Morpen Laboratories Limited Address: Masulkana Parwanoo, Distt. Solan Himachal 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:	Official monograph of Montelukast Sodium is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MTN14-8015, MTN14-9001, MTN14-9036)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 'Lucast 4mg of M/s AGP Limited, by performing quality tests Identification, average weight, Assay & Dissolution). CDP has been performed against the 'singulair 4mg of M/s MSD Thailand (importer), in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Sodium phosphate buffer (pH 7.5) . The f2 values 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	M/s Morpen Laboratories Limited Address: Masulkana Parwanoo, Distt. Solan Himachal Pradesh India.	
API Lot No.	MS/2017003	
Description of Pack (Container closure system)	Filled in sealed printed 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.	MK/4-001	MK/4-002
Batch Size	5000	5000
Manufacturing Date	01-2022	01-2022
Date of Initiation	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)	
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.L.HFW-hDrugs) 93/91 dated 23-02-2022 issued by Health and family Welfare Department Himachel Pradesh Baddi, District, Solan India. Valid till 11-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our 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:

S.No	Section	Shortcoming communicated	Response of the Firm
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Firm submit the Trial Form of two batches.
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.	Firm submitted the Analytical Method Verification studies.
3.	3.2.S.5	COA of primary / secondary reference standard including source and lot number of montelukast	Firm submitted the COA of reference standard montelukast dicyclohexylamine.

		dicyclohexylamine shall be provided	
4.	3.2.P.2.2.1	• Pharmaceutical equivalence is not conducted against Innovator product. • CDP and pharmaceutical equivalence is performed against two different products. Clarify.	Firm in their reply stated that the innovator product was not available at the time of studies, so brand leader was procured and PE studies was conducted. Later on, as singular was available CDP was conducted.
5.	3.2.P.8	Documents for the procurement of API with approval from DRAP.	Firm submitted the DRAP attested invoice.

Decision: Approved.

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

M/s WALLACE PHARMA. (New DML)

CLB in its 284th meeting held on 16th December 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following six (06) sections to M/s WALLACE PHARMA

1.	Capsule (Penicilline) Section
2.	Oral Dry powder Suspension (Penicilline) Section
3.	Injection (Carbapenem)
4.	Dry Powder Injection (Penicilline)Section

Dry Powder Injection (Penicilline) Section
01 Molecules/ 02 Products

418.	Name, address of Applicant / Marketing Authorization Holder	M/S Wallace Pharma Evolutions, Kalawala Stop, 20-Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/S Wallace Pharma Evolutions, Kalawala 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	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 11794 dated 15-05-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 20835349
	The proposed proprietary name / brand name	TAZOCIN 2.25gm Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium (USP) ……..... 2000mg Tazobactam Sodium (USP) …….....250mg (Product Complies USP Specs)
	Pharmacotherapeutic Group of (API)	combination medication containing the antibiotic Penicillins and the β-lactamase inhibitor tazobactam

	Pharmaceutical form of applied drug	Sterile, preservative-free, clear, white to off white to yellow color, Powder, free from foreign particles in a vial with rubber stopper and seals in unit carton.
	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	Tazocin 2 g / 0.25 g powder for solution for infusion by Pfizer Limited of MHRA approved
	For generic drugs (me-too status)	Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China (Peviously Qilu Tianhe Pharmaceuticals co.,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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Piperacillin + Tazobactam is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (HF7001D1, HF7001D2, HF7001D3)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 is A Tanzo 2.25gm injection by M/s Bosch Pharmaceuticals (Pvt) Ltd. by performing quality tests (Identification, pH,

		Sterility, 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	Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	HF2065D3		
Description of Pack (Container closure system)	Sterile, preservative-free, clear, white to off white to yellow colour, Powder, free from foreign particles in a vial with rubber stopper and seals 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.	T01	T02	T03
Batch Size	460 packs	460 packs	460 packs
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	07.10.22	07.10.22	07.10.22
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.	Copy of GMP certificate No. 2018001 issued by Shandong Food and Drug Administration valid till 24/07/2023.(Qilu Tianhe Pharmaceuticals co.,Ltd)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to AD R-II was written from M/s Stallion Pharmaceuticals that they lend Piperacilline and Tazobactum 15kg Batch # HF2065D3 to M/s Wallace Pharma Evolution on dated: 04-10-2022 Firm has submitted copy of Clearnce certificate # E-2669242824625 specifying Commercial Invoice # WWM220705, dated; 30-08-2020 issue by DRAP Lahore office date: 15-11-2022 specifying 210Kg of Piperacilline Sodium and Tazobactum Sodium Sterile batch # HF2065D3.(Stallion Pharmaceuticals Pvt Ltd)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	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	Shortcoming communicated

1.	2.3.R.1.1	Piperacillin Sodium and Tazobactam Sodium are in premixed for (8:1) than how separately dispensed per Vial.
2.	3.2.S.4.1	Copies of the Drug substance specifications 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.
5.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.
6.	3.2.P.1	Clarify it is ready to fill form or further processing is done by you with addition of excipients.
7.	3.2.P.2.6	Compatibility studies with diluent 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.5.3	Analytical method verifications protocols for drug product shall be submitted.
9.	3.2.P.5.4	Water determinations was not done on all the 3 batches as mentioned in USP monograph. Clarification is required.
10.	3.2.P.8	• Submit packaging list of import of material. • Water determinations was not done in both Real and accelerated stability studies as mentioned in USP monograph. Clarification is required.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

419.	Name, address of Applicant / Marketing Authorization Holder	M/S Wallace Pharma Evolutions, Kalawala Stop, 20-Km, Lahore Jaranwala Road, Lahore
	Name, address of Manufacturing site.	M/S Wallace Pharma Evolutions, Kalawala 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	New DML letter issued dated; 27-12-2021
	Evidence of approval of manufacturing facility	New DML letter issued dated; 27-12-2021 in which Dry Powder Injection (Penicilline)Section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 12218 dated 18-05-2023
	Details of fee submitted	PKR 30,000/- Deposit slip# 49660971
	The proposed proprietary name / brand name	TAZOCIN 4.5gm Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium (USP) ……..... 4000mg Tazobactam Sodium (USP) …….....500mg (Product Complies USP Specs)
	Pharmacotherapeutic Group of (API)	a combination medication containing the antibiotic piperacillin and the β-lactamase inhibitor tazobactam
	Pharmaceutical form of applied drug	Sterile, preservative-free, clear, white to off white to yellow color, Powder, free from foreign particles in a vial with rubber stopper and seals in unit carton.

	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	Tazocin 4 g / 0.5 g powder for solution for .infusion by Pfizer Limited of MHRA approved
	For generic drugs (me-too status)	Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China (Peviously Qilu Tianhe Pharmaceuticals co.,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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Official monograph of Piperacillin + Tazobactam is present in USP. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (HF7001D1, HF7001D2, HF7001D3)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 is A Tanzo 4.5gm injection by M/s Bosch Pharmaceuticals (Pvt) Ltd. by performing quality tests (Identification, pH, Sterility, 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	Shandong Anxin Pharmaceutical Co., Ltd. Address: No. 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	HF2065D3		
Description of Pack (Container closure system)	Sterile, preservative-free, clear, white to off white to yellow colour, Powder, free from foreign particles in a vial with rubber stopper and seals 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.	T04	T05	T06
Batch Size	460 packs	460 packs	460 packs
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	07.10.22	07.10.22	07.10.22
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.	Copy of GMP certificate No. 2018001 issued by Shandong Food and Drug Administration valid till 24/07/2023.(Qilu Tianhe Pharmaceuticals co.,Ltd)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	A letter to AD R-II was written from M/s Stallion Pharmaceuticals that they lend Piperacilline and Tazobactum 15kg Batch # HF2065D3 to M/s Wallace Pharma Evolution on dated: 04-10-2022 Firm has submitted copy of Clearnce certificate # E-2669242824625 specifying Commercial Invoice # WWM220705, dated; 30-08-2020 issue by DRAP Lahore office date: 15-11-2022 specifying 210Kg of Piperacilline Sodium and Tazobactum Sodium Sterile batch # HF2065D3.(Stallion Pharmaceuticals Pvt Ltd)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	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	Shortcoming communicated
1.	2.3.R.1.1	Piperacillin Sodium and Tazobactam Sodium are in premixed for (8:1) than how separately dispensed per Vial.
2.	3.2.S.4.1	Copies of the Drug substance specifications 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.
5.	3.2.S.4.4	Which specifications are followed by drug product manufacturer for drug substance.
6.	3.2.P.1	Clarify it is ready to fill form or further processing is done by you with addition of excipients.
7.	3.2.P.2.6	Compatibility studies with diluent 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.5.3	Analytical method verifications protocols for drug product shall be submitted.
9.	3.2.P.5.4	Water determinations was not done on all the 3 batches as mentioned in USP monograph. Clarification is required.
10.	3.2.P.8	• Submit packaging list of import of material. • Water determinations was not done in both Real and accelerated stability studies as mentioned in USP monograph. Clarification is required.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Deferred case

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

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

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

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

420.	Name, address of Applicant / Marketing Authorization Holder	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5894 dated 02-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 543749515652
	The proposed proprietary name / brand name	**Relpride Tablet 25mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride ……. 25 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Sulvoric 25mg Tablet of M/s High-Q Reg. No.070484
	GMP status of the Finished product manufacturer	New license granted on 19th Feburary 2021.
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, 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 Levosulpiride is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ALC/LSP/170203, ALC/LSP/170204, ALC/LSP/170205)
	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 is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AP0909Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).

	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.		
API Lot No.	BLEVS210029		
Description of Pack (Container closure system)	Alu-Alu blister packed		
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	2000	2000
Manufacturing Date	01-22	01-22	01-22
Date of Initiation	05-01-22	05-01-22	05-01-22
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 No# S-GMP/22113654 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 04-11-2022 and valid until 03-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy form 5 and invoice (invoice# AB/I/00101/21-22) dated: 01-09-2021 attested by DRAP Islamabad dated: 13-9-2021 specifying import of 10Kg Levosulpiride (Batch# BLEVS210029)
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)	Not submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.

5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP as submitted Commercial Invoice is not in readable form. • Batch size is not mentioned • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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 by PEC:

S.No	Section	Shortcomings Communicated	Reply
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	We are new license facility and there fore till date our GMP inspection is not yet carried out by DRAP.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	GMP certificate of API manufacturer is attached. *Copy of GMP certificate No# S-GMP/22113654 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 04-11-2022 and valid until 03-11-2024.*
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	Copy of BMR of three batches is attached.
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Drug substance specifications of Nagarsons Pharmaceutical submitted.
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Drug substance analytical procedure of Nagarsons Pharmaceutical submitted.

6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.	• Pharmaceutical equivalence and CDP studies have been performed against Levopraid tablet which is the brand leader in Pakistan, since the innovator's product is not registered in Pakistan. Moreover, the comparator brand Levopraid is registered in Pakistan under the License of a reference product Levopraid tablet of Ravizza Farmaceutici Italy. • CDP studies have been performed using 6 units of each, since we have 12 basket dissolution apparatus and all our products have been registered by Registration Board in which CDP studies have been performed using 12 basket apparatus. Moreover, we undertake to procure dissolution apparatus with 24 baskets for CDP studies in future. • Revised CDP with 75RPM in three media i.e in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8.(*initially firm used 50 RPM so higher than 85% at 30 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8*)
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.	There was some typo error while drafting our specifications are as innovator's product since no USP or BP monograph exist for this product
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.	Analytical method validation studies are provided.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP as submitted Commercial Invoice is not in readable form. • Batch size is not mentioned • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Commercial Invoice attested by DRAP Islamabad submitted. • Batch size of our stability batches is 2000. *(Batch size in BMR is 2000 mentioned while on Raw data sheets of stability studies data Batch size of 2500 Tablets mentioned.)* • Our HPLC system is not 21 CFR compliant therefore audit trail report is not available. However, we have maintained complete log of he equipment as well as product testing as per GMP requirements. • Record of Digital data logger is 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.**		
421.	Name, address of Applicant / Marketing Authorization Holder	M/s. Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Name, address of Manufacturing site.	M/s. Nagarsons Pharmaceutical (Pvt) Ltd Plot No.34, street No. NS-2, National Industries Zone, Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5895 dated 02-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 91709832
	The proposed proprietary name / brand name	Relpride Tablet 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains; Levosulpiride ……. 50 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Propulsive/Prokinetics
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Sulvoric 50mg Tablet of M/s High-Q Reg. No.070485
	GMP status of the Finished product manufacturer	New license granted on 19th Feburary 2021.
	Name and address of API manufacturer.	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, 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 Levosulpiride is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers,

		description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ALC/LSP/170203, ALC/LSP/170204, ALC/LSP/170205)
	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 is established against the brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	M/s Alcon Biosciences Private Ltd. A-1/2014, Phase-III, G.I.D.C Vapi, District Valsad Gujrat, India.		
API Lot No.	BLEVS210029		
Description of Pack (Container closure system)	Alu-Alu blister packed		
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	2500/2000	2500/2000	2500/2000
Manufacturing Date	01-22	01-22	01-22
Date of Initiation	05-01-22	05-01-22	05-01-22
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 No# S-GMP/20102297 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 22-10-2020 and valid until 21-10-2022.

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)	Not submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. (Clear Commercial Invoice). • Batch size is not mentioned • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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 by PEC:

S.No	Section	Shortcomings Communicated	Reply
1.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	We are new license facility and there fore till date our GMP inspection is not yet carried out by DRAP.

2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	GMP certificate of API manufacturer is attached. *Copy of GMP certificate No# S-GMP/22113654 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 04-11-2022 and valid until 03-11-2024.*
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	Copy of BMR of three batches is attached.
4.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Drug substance specifications of Nagarsons Pharmaceutical submitted.
5.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Drug substance analytical procedure of Nagarsons Pharmaceutical submitted.
6.	3.2.P.2.2.1	• Justification shall be submitted for not carrying the CDP against the innovator's brand • Details and picture/image/ snapshot of product against which Pharmaceutical Equivalence and CDP conducted. • 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of Comparative dissolution. • As per Innovator product in CDP percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8 while as per your CDP data higher than 85% at 30 minutes. Justification is required.	• Pharmaceutical equivalence and CDP studies have been performed against Levopraid tablet which is the brand leader in Pakistan, since the innovator's product is not registered in Pakistan. Moreover, the comparator brand Levopraid is registered in Pakistan under the License of a reference product Levopraid tablet of Ravizza Farmaceutici Italy. • CDP studies have been performed using 6 units of each, since we have 12 basket dissolution apparatus and all our products have been registered by Registration Board in which CDP studies have been performed using 12 basket apparatus. Moreover, we undertake to procure dissolution apparatus with 24 baskets for CDP studies in future. • Revised CDP with 75RPM in three media i.e in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) percentage dissolved is higher than 85% at 15 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8.(*initially firm used 50 RPM so higher than 85% at 30 minutes in all the 03 media i.e HCl 0.1N, 4.5 and pH 6.8*)
7.	3.2.P.5.1	Applied formulations in section 1.5.6 are Innovator while in this section USP specifications are clamed. Clarify.	There was some typo error while drafting our specifications are as innovator's product since no USP or BP monograph exist for this product
8.	3.2.P.5.3	Analytical method verification submitted while product is not available in any pharmacopeia.	Analytical method validation studies are provided.
9.	3.2.P.8	• Documents for the procurement of API with approval from DRAP as submitted Commercial	• Commercial Invoice attested by DRAP Islamabad submitted. • Batch size of our stability batches is 2000. *(Batch size in BMR is 2000 mentioned while*

		Invoice is not in readable form. • Batch size is not mentioned • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	*on Raw data sheets of stability studies data Batch size of 2500 Tablets mentioned.)* • Our HPLC system is not 21 CFR compliant therefore audit trail report is not available. However we have maintained complete log of he equipment as well as product testing as per GMP requirements. • Record of Digital data logger is 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.**

422.	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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 195 dated 03-01-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 94816553563
	The proposed proprietary name / brand name	**Pirogm 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatin capsule contains: Piroxicam…….20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Feldene 20 mg Capsule by M/s Pfizer of USFDA Approved
	For generic drugs (me-too status)	Feldene 20 mg Capsule by M/s Pfizer Reg#006349
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Alcon Biosciences Pvt Ltd. A-1/2104, Phase-III, GIDC, VAPI, 396195, District Valsad, Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties,

		solubility's, 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 Piroxicam is present in BP. 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: (ALC/PCM/131205, ALC/PCM/131206, ALC/PCM/131207)
	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 leader that is Feldene capsule 20mg by Pfizer by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Feldene capsule 20mg by Pfizer in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Alcon Biosciences Pvt Ltd. A-1/2104, Phase-III, GIDC, VAPI, 396195, District Valsad, Gujrat India.		
API Lot No.	PCM-22041		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10'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.	TRC001	TRC002	TRC003
Batch Size	1500	2000	2000
Manufacturing Date	27-11-21	29-11-21	30-11-21
Date of Initiation	30-11-21	30-11-21	30-11-21

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 No# S-GMP/20102297 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 22-10-2020 and valid until 21-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# AV/I/00062/22-23) dated: 13-11-2021 specifying import 200gm Piroxicam (Batch# PCM-22041)
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: During Evaluation it was observed that AGM pharmaceuticals, Gujranwala and Pharman Pharmaceutical, Gujranwala DML have same Name of Production in charge.

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.	Not submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed by drug product manufacturer.	USP specifications was applied for API testing that's why HPLC AMV studies were submitted. Evaluation: Firm claimed BP specification in COA of drug substance and limits are also according to BP i.e Assay limits applied are 98.5% to 101.0% which are according to BP specifications while USP specifications for Assay are 97.0% to 103.0%
3.	3.2.P.1	DC granular used as excipient in formulation. Explain what is DC granular.	DC lactose granular was used but lactose word was skipped. It is a typographical error. Revised documents submitted.
4.	3.2.P.5.1	Submit complete Specifications as per USP monograph.	Specification as per USP monograph are attached
5.	3.2.P.5.2	Submit analytical testing method of drug product instead of USP monograph presentation.	Analytical testing method of drug product submitted.
6.	3.2.P.5.4	Water content as per USP monograph not Performed. Clarification is required.	Water content is tested on next time point and report is attached.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP.	Commercial invoice without DRAP approval submitted.

Previous Decision (M-326): Deferred for following:

- Submission of 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.
- Justification for applying USP monograph for the drug substance analysis and analytical method
- verification studies whereas drug product manufacturer has claimed BP specifications for the drug
- substance.
- Documents for the procurement of API with approval from DRAP.

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

Evaluation by PEC:

S.No	Reason of deferment	Reply
1)	Submission of valid Drug Manufacturing License or valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Drug Manufacturing License And valid Good Manufacturing Practice (GMP) Certificate is attached
2)	Justification for applying USP monograph for the drug substance analysis and analytical method verification studies whereas drug product manufacturer has claimed BP specifications for the drug substance.	We are applying USP monograph for Drug Substance and Drug Product with all parameters. Due to typographical mistake on claimed BP Specification
3)	Documents for the procurement of API with approval from DRAP.	We used Loan material from Batala Pharma. Loan letter is attached. Commercial invoice #2020-21/000447 dated: 05-11-2020 Approved by DRAP Lahore dated: 04-12-2020 specifying import of

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

Justification:

We, M/s AGM Pharmaceuticals, ensure that during the hiring process of technical staff for the positions of Production Incharge and Quality Control, we abide by the Manual of Drug Law. Both the CEO and the technical staff are required to sign an undertaking stating that they are full-time employees of our firm and do not work elsewhere. In case of any violation, the responsible person will face necessary action from DRAP (Drug Regulatory Authority of Pakistan).

Furthermore, we have also made changes to our technical staff and have applied for an approval letter from the Licensing Department of DRAP. Attached is the evidence of our application for the approval of the technical staff.

Decision: Approved. Registration letter will be issued upon submission of fee of Rs. 7,500/- for pre-approval change in drug substance 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.**

423.	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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	**Ag-CIP 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl…250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 50MG film coated tablet. Manufactured M/s Aurobindo Phrma-Milpharm Ltd. MHRA Approved.
	For generic drugs (me-too status)	NOVIDAT 250mg tab by M/s Sami Pharma #011836
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	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. 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 Ciprofloxacin Hydrochloride 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 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CPH1402007, CPH1402008, CPH1402009)
	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 leader that is Novidat 250mg tablet BY SAMI Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ciprofloxacin 250mg tablet Tablet by SAMI Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

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 packed in unit carton (2×10'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.	TRT-019	TRT-020	TRT-021
Batch Size	1500	1500	1500
Manufacturing Date	12-21	13-12-21	14-12-2021
Date of Initiation	15-12-21	15-12-21	15-12-21
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 issued by DRAP on the basis of Evaluation conducted on 17-12-2020 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.	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
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
2.	3.2.S.4.2	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 for drug substance(s) shall be submitted.
4.	3.2.S.4.4	In COA by drug product manufacturer result for water content shows comply instead of value. Justify
5.	3.2.S.2.2.1	In CDP time points are up to 5,10,15,20,25,30 minutes while in calculation of F1 and F2 up to 5,10,15,20,25, 45 minutes are mentioned. Clarify. .
6.	3.2.P.5.3	Submit Protocols of Analytical method verifications.
7.	3.2.P.6	COA of reference standard Ciprofloxacin Ethylenediamine Analoge
8.	3.2.P.8	Purchase documents for Ciprofloxacin HCl. COA's of all time points does not match with stability summary sheets abd raw data. Clarification is required. In raw data sheets Batch NO TRC-019, TRC-020, TRC-021 while in all other documents Batch no # TRT-019, TRT-020, TRT-021. Clarify

Previous Decision (M-326): 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 was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

Evaluation by PEC: A fee of Rs: 7500/- deposit slip # 54345238 for pre RegistrationVariation

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Specifications by Drug Product are submitted.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures of Drug substance are submitted
3.	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.	Analytical Method Verification of drug substance performed by the Drug Product are submitted.
4.	3.2.S.4.4	In COA by drug product manufacturer result for water content shows comply instead of value. Justify	Test was performed but at the time of documentation value was skipped. Revised certificate of analysis is submitted
5.	3.2.S.2.2.1	In CDP time points are up to 5,10,15,20,25,30 minutes while in calculation of f1 and f2 up to 5,10,15,20,25, 45 minutes are mentioned. Clarify. .	Revised CDP with correct calculation of f1 and f2 with time points 5,10,15,20,25,30 are submitted
6.	3.2.P.5.3	Submit Protocols of Analytical method verifications.	Protocols of Analytical method verifications are submitted

7.	3.2.P.6	COA of reference standard Ciprofloxacin Ethylenediamine Analogue	For stability testing, system suitability solution was not used. After registration, we will use system suitability solution and will follow the method as per the USP monograph.
8.	3.2.P.8	• Purchase documents for Ciprofloxacin HCl. • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • In raw data sheets Batch, NO TRC-019, TRC-020, TRC-021 while in all other documents Batch no # TRT-019, TRT-020, TRT-021. Clarify	05 kg Purchase Invoice of Ciprofloxacin HCl. From Citi pharma is attached Our stability trail batch Nos. is TRT-019, TRT-020, TRT-021 and all other documents raw data analysis sheets mentioned batch no. in typographic error. Revised documents are attached

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

Justification:
We, M/s AGM Pharmaceuticals, ensure that during the hiring process of technical staff for the positions of Production Incharge and Quality Control, we abide by the Manual of Drug Law. Both the CEO and the technical staff are required to sign an undertaking stating that they are full-time employees of our firm and do not work elsewhere. In case of any violation, the responsible person will face necessary action from DRAP (Drug Regulatory Authority of Pakistan).
Furthermore, we have also made changes to our technical staff and have applied for an approval letter from the Licensing Department of DRAP. Attached is the evidence of our application for the approval of the technical staff.

Decision: Approved. Registration letter will be issued upon submission of fee of Rs. 7,500/- for pre-approval change in drug substance 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.**

424.	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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	**G-Mol 500mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	20×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated
1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Film coated Tablet) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of application.

Previous Decision (M-326): Registration Board deferred the application for submission of Product development, Pharmaceutical Equivalence ,CDP, Batch manufacturing record and complete stability studies for revised formulation of "uncoated tablet".

Evaluation by PEC: A fee of Rs: 7500/- deposit slip # 7593549277 for pre-Registration Variation

S.No	Shortcomings Communicated	Reply
1.	Product Development	We, M/s AGM Pharma, during the product development of G-Mol 500mg Tablet (Paracetamol), followed the British Pharmacopeia monograph/method for an uncoated tablet. However, unintentional mistakes were made during the preparation of the CTD Dossier documentation from our side. Further we have submitted the fee for the preregistration variation as per the SRO.
2.	Pharmaceutical Equivalence with CDP	Fresh Pharmaceutical Equivalence with comparative Dissolution Profile is Attached.
3.	Batch Manufacturing Record	Revised Batch Manufacturing Record is attached
4.	Complete stability studies for revised formulation of uncoated tablet	Stability studies of G-Mol 500mg Tablet (Paracetamol) were also conducted for the uncoated tablet formulation. Complete stability study Record is Attached

Evaluation of application

	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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	**G-Mol 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	20×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 500MG tablet of USFDA Approved.
	For generic drugs (me-too status)	Panadol 500mg Tablet of M/s GSK
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	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. 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)	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 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TRT016, TRT017, TRT018)
	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 leader that is Panadol 500mg capsules BY GSK Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is PARACETAMOL TABLET 500MG capsule by GSK in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable

		range.		
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.		
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.		PGP21-401		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (2×10'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.		TRT016	TRT017	TRT018
Batch Size		1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date		01-12-21	02-12-21	03-12-21
Date of Initiation		04-12-2021	04-12-2021	04-12-2021
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 GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.		
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.	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).		
Decision: Deferred for submission of complete new pharmaceutical development data including the stability data of newly formulated trial batches along with full fee of registration.				

b. New/Additional section(s)
Deferred case

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

1.Oral liquid Section (General) Additional

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

425.	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 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/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.2	In 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/3 replicates 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
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.5.2	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.
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/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.
5.	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

Decision: Deferred for following clarifications:

- **Manufacturing facility along with details of equipmentswherein 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.**

426.	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 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/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
2.	3.2.P.2.2.1	In Pharmaceutical Equivalence Test product is tested on USP specifications while GSK product (Reference/Comparator) tested on BP Specifications. Clarify why different specifications are used.
3.	3.2.P.5.3	In Drug Product Precision parameter of Analytical method verification is not conducted as per ICH Q2(R1) guidelines. Which states "a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each) while you have used 6 determinations (3 concentrations /2 replicates each).
4.	3.2.P.8	Purchase Documents for Paracetamol. Compliance Record of HPLC software 21CFR & audit trail reports on product testing

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 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.
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

Decision: Deferred for following clarifications:

- **Manufacturing facility along with details of equipments 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.**

M/s Crystolite Pharmaceuticals. (New Section)
CLB in its 290th meeting held on 28th April 2023, has approved the following 04 additional sections of M/s Crystolite Pharmaceuticals.

1. Dry Vial Section (Cephalosporin)
2. Dry Vial Section (Carbapenem)
3. Oral Dry Powder Suspension Section (Cephalosporin)
4. Capsule Section (Cephalosporin)

Sr. No	Section	Molecules for consideration in 330th meeting	Products for consideration in 330th meeting
1	Dry Vial Section (Carbapenem)	03	05

427.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	**Erapam 1gm Powder for concentrate for solution for**

		infusion
	Composition	Each Vial Contains: Ertapenem…….1gm
	Diary No. Date of R& I & fee	Dy.No 8218 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	INVANZ (ertapenem for injection) for intravenous (IV) or intramuscular (IM) use by M/s Merck Sharp & Dohme USA (USFDA Approved)
	Me-too status	Ernem Injection of M/s Genix Pharma, (Reg.# 081179)
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator	• Approval of section/manufacturing facility (carbapenem section) by the Central Licensing Board. • In reference as sodium while applied without sodium clarify, otherwise revise your formulation with submission of applicable fee
	Previous Decision (M-324): Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (Carbapenem) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.	
	Evaluation by PEC: Firm submitted section approval letter dated:12-07-2023 for Dry Vial Injection Section (Carbapenem)	
	Decision: Approved with innovator's specifications as per following label claim: **"Each Vial Contains:** **Ertapenem as sodium…….1gm"** **Firm shall submit fee of Rs. 30,000/- for pre-approval correction/change in salt form of rug substance, before issuance of registration letter.**	
428.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cinipem IV 250mg/250mg Powder for solution for infusion
	Composition	Each Vial Contains: Imipenem (as 265mg Imipenem Monohydrate)..……..250mg Cilastatin (as 265mg cilastatin sodium salt)……250mg (Sterile mixture also contains sodium bicarbonate as buffer)
	Diary No. Date of R& I & fee	Dy.No 8315 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PRIMAXIN® (imipenem and cilastatin) for Injection, For intravenous use. USFDA approved
	Me-too status	Cilapen 250mg Injections of M/s Bosch Pharmaceuticals,
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator	Approval of section/manufacturing facility (carbapenem section) by the Central Licensing Board.

	Previous Decision (M-324): Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (Carbapenem) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.	
	Evaluation by PEC: Firm submitted section approval letter dated:12-07-2023 for Dry Vial Injection Section (Carbapenem)	
	Decision: Approved.	
429.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cinipem IV 500mg/500mg Powder for solution for infusion
	Composition	Each Vial Contains: Imipenem (as 530mg Imipenem Monohydrate)..……..500mg Cilastatin (as 530mg cilastatin sodium salt)……500mg (Sterile mixture also contains sodium bicarbonate as buffer)
	Diary No. Date of R& I & fee	Dy.No 8302 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PRIMAXIN® (imipenem and cilastatin) for Injection, For intravenous use. USFDA approved
	Me-too status	Cilapen 500mg Injections of M/s Bosch Pharmaceuticals,
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator	Approval of section/manufacturing facility (carbapenem section) by the Central Licensing Board.
	Previous Decision (M-324): Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (Carbapenem) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.	
	Evaluation by PEC: Firm submitted section approval letter dated:12-07-2023 for Dry Vial Injection Section (Carbapenem)	
	Decision: Approved.	
430.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Merolite 500mg Powder for solution for injection or infusion
	Composition	Each Vial Contains: Meropenem (as 570.78mg Meropenem Trihydrate eq to Anhydrous Meropenem)….. ……500mg (with anhydrous Sodium Carbonate)
	Diary No. Date of R& I & fee	Dy.No 8305 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM® IV (meropenem for injection) 500mg, for intravenous use. US-FDA approved
	Me-too status	Olver Injection of M/s Genix

	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator	Approval of section/manufacturing facility (carbapenem section) by the Central Licensing Board.
	Previous Decision (M-324): Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (Carbapenem) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.	
	Evaluation by PEC: Firm submitted section approval letter dated:12-07-2023 for Dry Vial Injection Section (Carbapenem)	
	Decision: Approved **Registration letter will be issued after submission of evidence of Atomic absorption spectrophotometer along with its IQ, OQ and PQ reports.**	
431.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Merolite 1g Powder for solution for injection or infusion
	Composition	Each Vial Contains: Meropenem (as 1141.56mg Meropenem Trihydrate eq to Anhydrous Meropenem) …… 1g (with anhydrous Sodium Carbonate)
	Diary No. Date of R& I & fee	Dy.No 8308 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM® IV (meropenem for injection) 1g, for intravenous use. US-FDA approved
	Me-too status	Olver Injection of M/s Genix
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator	Approval of section/manufacturing facility (carbapenem section) by the Central Licensing Board.
	Previous Decision (M-324): Deferred for submission of evidence of approval of required manufacturing facility i.e., Dry powder injection (Carbapenem) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of Form 5F, within six months.	
	Evaluation by PEC: Firm submitted section approval letter dated:12-07-2023 for Dry Vial Injection Section (Carbapenem)	
	Decision: Approved. Registration letter will be issued after submission of evidence of atomic absorption spectrophotometer along with its IQ, OQ and PQ reports.	

Case no. 05 Registration applications of categories to be considered on priority

a. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

Deferred case:

432.	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)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7346 dated 15/03/2022
	Details of fee submitted	PKR 75,000/-: Deposit slip # 4577578069
	The proposed proprietary name / brand name	PRIMLA (Topical Cream 5%)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Lidocaine Base USP.... 25mg Prilocaine Base USP… 25mg
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	Local Anesthetics
	Reference to Finished product specifications	USP
	Proposed Pack size	30 gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LIDOCAINE AND PRILOCAINE Cream of M/s Tolmar Inc of USFDA approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted 0n 27 -09-2021 and valid for 2 years. (Section Sterile Eye Ointment/Topical Cream mentioned)
	Name and address of API manufacturer.	Lidocaine and Prilocaine : Shandong Chengui Shuangda Pharmaceutical Co., ltd. Address: Economic Development zone, Pingyuan County, Dezhou City, Shandong Province253100, China Shandong Chengui Shuangda Pharmaceutical Co., ltd.
	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)	Lidocaine: Official monograph of Lidocaine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubility's,, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

		Prilocaine : Official monograph of Prilocaine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubility's,, physical form, 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
	Stability studies	Stability study conditions: Lidocaine: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (17050301, 17061502, 17062203) Prilocaine : Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (16091101, 16091702, 16092303)
	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 Emla Topical cream by performing quality tests (Appearance, Identification, pH, Fill volume Drug Release).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, specificity, robustness.

STABILITY STUDY DATA			
Manufacturer of API	Lidocaine and Prilocaine : Shandong Chengui Shuangda Pharmaceutical Co., ltd. Address: Economic Development zone, Pingyuan County, Dezhou City, Shandong Province253100, China Shandong Chengui Shuangda Pharmaceutical Co., ltd.		
API Lot No.	Lidocaine: 21081605 Prilocaine : 21091206		
Description of Pack (Container closure system)	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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TB-101	TB-102	TB-103
Batch Size	3Kg (100 Tubes)	3Kg (100 Tubes)	3Kg (100 Tubes)
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	02-01-2019	02-01-2019	02-01-2019
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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	Section	Shortcomings Communicated
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by the 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.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient (Lidocaine and Prilocaine) 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 (Lidocaine and Prilocaine) shall be submitted.
5.	3.2.P.2.2.1	• Details , origin and procurement documents of product against which Pharmaceutical equivalence is established. • Assay was not conducted of both test product and reference product in Pharmaceutical equivalence. Clarification is required. • Provide reference of Drug release performed in Pharmaceutical equivalence.
6.	3.2.P.3.5	A brief description of process validation including the proposed protocol shall be Submitted.
7.	3.2.P.5.1	Microbial Enumeration tests and test for specified organism is not included in specification however USP monograph include these tests.
8.	3.2.P.8	• 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. • Date of Initiation 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)

Previous 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.

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License or	Firm has submitted copy of DML (Lu20170365)

		Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by the relevant regulatory authority of country of origin.	dated 12-10-2022 issued by Shandong Drug administration China. Valid till 11/10/2027.
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 is submitted.
3.	3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient (Lidocaine and Prilocaine) by Drug Product manufacturer is required.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient (Lidocaine and Prilocaine) by Drug Product manufacturer are submitted.
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 (Lidocaine and Prilocaine) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance (Lidocaine and Prilocaine submitted.
5.	3.2.P.2.2.1	• Details , origin and procurement documents of product against which Pharmaceutical equivalence is established. • Assay was not conducted of both test product and reference product in Pharmaceutical equivalence. Clarification is required.	• Emla Topical cream by Aspen pharma used for pharmaceutical Equivalence. • Revised pharmaceutical equivalence with assay submitted.
6.	3.2.P.3.5	A brief description of process validation including the proposed protocol shall be Submitted.	A brief description of process validation including the proposed protocol Submitted.
7.	3.2.P.5.1	Microbial Enumeration tests and test for specified organism is not included in specification however USP monograph include these tests.	Revised specification with microbial enumeration tests and test for specified organism submitted.
8.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Date of Initiation 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)	• Commercial Invoice # 30112018 dated 30-11-2018 approved by DRAP Karachi dated: 31-12-2018 submitted. • Date of Initiation of stability study. • 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.**

b. Export facilitation

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD) " M/s Focus & Rulz Pharmaceuticals Pvt Ltd. Islamabad have achieved benchmark of USD 533,670.4 as defined in the Board's decision during fiscal year 2021-2022. In this regard, please find the (1 molecule) 01 products applications submitted by the firm."		
433.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-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. 9554 dated 14-04-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 021123001804
	The proposed proprietary name / brand name	**M-Fer Drops 50mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Iron III Hydroxide Polymaltose Complex Equuvalent to elemental iron……50mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Iron Supplement (Iron Prepartion)
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MALTOFER DROPS by Vifor Pharma Pty Ltd, TGA Approved.
	For generic drugs (me-too status)	RubiferOral Drops 50mg/ml by M/s AGP Pvt. .Ltd., Reg# 031051
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 29-12-2020 and valid for two (02) years
	Name and address of API manufacturer.	Chemiworld Pvt. Ltd. Plot No. 97, J- Industrial Estate Jamrud Peshawar 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'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 Iron III Hydroxide Polymaltose Complex is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties,

		solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (106-IPC-001, 106-IPC-002, 106-IPC-003)
	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 Rubifer Oral by AGP Ltd by performing quality tests (Physical Appearance, identification, Color, pH, Assay).
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Chemiworld Pvt. Ltd. Plot No. 97, J- Industrial Estate Jamrud Peshawar Pakistan.		
API Lot No.	A21-IPC-473		
Description of Pack (Container closure system)	Amber colored 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 (Months)		
Batch No.	21DT05	21DT06	21DT07
Batch Size	200 Bottles	200 Bottles	200 Bottles
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-05-2021	05-05-2021	05-05-2021
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.	The firm has submitted copy of GMP Certificate # F.3-20/2017-DRAP-90 on the basis of inspection conducted on 29-11-2016 for M/S Chemiworld Pvt. Ltd. issued by DRAP. The firm has submitted application for issuance of new GMP certificate.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice # 2909 Dated:02-02-2021 from chemiworld Pvt Ltd specifying Polymaltose complex Batch # A21-IPC-473
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	Titration is used.
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
8.	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	The firm has submitted copy of GMP Certificate # F.3-20/2017-DRAP-90 on the basis of inspection conducted on 29-11-2016 for M/S Chemiworld Pvt. Ltd. issued by DRAP. The firm has submitted application for issuance of new GMP certificate.
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 the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 submitted.
10.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) submitted
11.	3.2.P.5.2	Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture and drug product manufacturer submitted.
12.	3.2.S.5	Certificate of analysis of reference standard show validity up to Feb 2015	Valid Certificate of Analysis of reference standard submitted.
13.	3.2.P.5.2	In assay 10ml Syrup contains 100mg of iron. Clarify how 10ml contains 100mg of Iron while applied formulations contains 50mg/ml.	We have our registered product for Iron polymaltose (M-Fer Syrup), and the Standard operating for Iron ploy maltose syrup was provided mistakenly in Module 3.2.P.5.2 of the CTD instead of Iron polymaltose drops. We apologies for the mistaken and revised SAP is enclosed.
14.	3.2.P.5.3	Analytical method validation of different product submitted i.e that is syrup. Submit Analytical method validation of 50mg/ml drops.	We have our registered product for Iron polymaltose (M-Fer Syrup), and the Analytical method validation for Iron ploy maltose syrup was provided mistakenly in Module 3.2.P.5.2 of the CTD instead of Iron polymaltose drops. We apologies for the mistaken and revised Analytical method validation is enclosed
15.	3.2.P.8	Purchase documents for Iron III Hydroxide Polymaltose	Purchase documents for Iron III Hydroxide Polymaltose Complex submitted.

		Complex.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Agenda of Evaluator PEC-IX

Case No. 1: New DML and New sections

The Central Licensing Board in its 289th meeting approved following new sections of M/s Getz Pharma (Pvt) Ltd (DML No. 000933 dated 20-05-2021);

i. Tablet (Cephalosporin)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Dry Powder Vial Injection (Cephalosporin)
v. Product development laboratory (Cephalosporin)
vi. Warehouse (Cephalosporin)
vii. Quality Control Laboratory (Cephalosporin)

434.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13166 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 02532889343 dated 19.01.2023
	The proposed proprietary name / brand name	**Primget 250mg (IM/IV) Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Sterile Cefepime HCl with L-Arginine equivalent to Cefepime……250mg
	Pharmaceutical form of applied drug	White to off-white powder, filled in clear glass USP type II vial with blue coloured flip-off seal on top of

		grey coloured rubber stopper. Supplied with 5ml sterile water for injection.
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin. ATC Code: J01DE01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 400/-
	The status in reference regulatory authorities	Could not be verified for 250mg strength.
	For generic drugs (me-too status)	Cefstar Powder for Injection 250mg Reg No. 076005 M/s Barrett Hodgson Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang. Copy of GMP certificate No. HE20190059 dated 11.06.2019, issued by Hebei Drug Administration, valid till 10.06.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: H2231608001, H2231608002, H2231608003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefepime IV/IM Powder for Injection 250mg** Batch No. C010DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** CefStar Injection 250mg, Batch No. D2521, Mfg date: Jul-2022, Exp. Date: June 2024. of M/s Barrett Hodgson Pakistan. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator CefStar Injection 250mg, Batch No. D2521, Mfg date: Jul-2022, Exp. Date: June 2024. of M/s Barrett Hodgson Pakistan by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang.		
API Lot No.	H2232207001		
Description of Pack (Container closure system)	White to off-white powder, filled in a clear glass USP type II Vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75% ± 5%RH** Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real time: 0, 3, 6 months** **Accelerated: 0, 3, 6 months**		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C010DS01	C010DS02	-
Batch Size	2000 vials	2000 vials	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20190059 dated 11.06.2019 in the name of M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang, issued by Hebei Drug Administration, valid till 10.06.2024 is submitted.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefepime Hydrochloride (L-Arginine)** Batch No.: H2232207001 Mfg. Date: 10.07.2022 Exp. Date: 06.2024

		Quantity: 20Kg Invoice No.: 20220602-2 dated: 24.08.2022
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	Submitted
12.	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.	1.5.9	RRA could not be verified for strength of 250mg	The firm vide letter No. RA-QL/316/0723 dated 07.07.2023 has submitted following justification; *"This is to inform you that Cefepime Injection 250mg is available in local market with the brand name of CefStar Injection 250mg (Reg. No.: 076005) manufactured by M/s Barrett Hodgson Pakistan (Pvt.) Ltd since December 2013. Further, this is to inform you that 250mg is the lowest strength while its higher strengths i.e., 500mg, 1g and 2g are already approved by RRAs as notified by DRAP. Considering availability and approval of 250mg by DRAP and higher strengths by RRAs / DRAP, it is evident that 250mg strength is safe."*
2.	1.6.5	The list of API given in GMP certificate of API manufacturer doesn't mention that Cefepime HCl will be with L-Arginine.	The firm has submitted a copy of letter of Hebei Food and drug administration China that indicates approval for manufacturing of Cefepime dihydrochloride with L-Arginine.
3.	3.2.S.4.5	In justification of specifications,API name is mentioned as Cefepime dihydrochloride L arginine. Is it dihydrochloride or monohydrochloride? At other points its only mentioned as hydrochloride, the USP reference standard is also of Cefepime hydrochloride.	The firm has stated that name of Cefepime as per USP, BP and Ph. Eur. is as follows; USP: Cefepime Hydrochloride. BP: Cefepime Hydrochloride monohydrate Ph. Eur: Cefepime Dihydrochloride monohydrate. There is only difference in the naming of said API among different pharmacopoeias while there is no change in molecular formula or molecular weight. The reply of firm is verifiable.
4.		Documents for the procurement of API with approval from DRAP (Import license and AD attested invoice) are required.	Submitted.
5.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/280/0623 dated 21.06.2023

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 further decided that the applicant shall submit the response within 1 month after publication of the minutes, .		
435.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13167 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 675786217 dated 17.01.2023
	The proposed proprietary name / brand name	**Primget 500mg (IM/IV) Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Sterile Cefepime HCl with L-Arginine equivalent to Cefepime……500mg
	Pharmaceutical form of applied drug	White to off-white powder, filled in clear glass USP type II vial with blue coloured flip-off seal on top of grey coloured rubber stopper. Supplied with 5ml sterile water for injection.
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin. ATC Code: J01DE01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 800/-
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Cefstar Powder for Injection 500mg Reg No. 030953 M/s Barrett Hodgson Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang. Copy of GMP certificate No. HE20190059 dated 11.06.2019, issued by Hebei Drug Administration, valid till 10.06.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: H2231608001, H2231608002, H2231608003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefepime IV/IM Powder for Injection 500mg** Batch No. C011DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** CefStar Injection 500mg, Batch No. D3590, Mfg date: Oct-2022, Exp. Date: Sep 2025. of M/s Barrett Hodgson Pakistan. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator CefStar Injection 500mg, Batch No. D3590, Mfg date: Oct-2022, Exp. Date: Sep 2025. of M/s Barrett Hodgson Pakistan by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA	
Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang.
API Lot No.	H2232207001

Description of Pack (Container closure system)	White to off-white powder, filled in a clear glass USP type II Vial.		
Stability Storage Condition	Real time: 30°C ± 2°C / **75% ± 5%RH** Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C011DS01	C011DS02	-
Batch Size	2000 vials	2000 vials	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20190059 dated 11.06.2019 in the name of M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang, issued by Hebei Drug Administration, valid till 10.06.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefepime Hydrochloride (L-Arginine)** Batch No.: H2232207001 Mfg. Date: 10.07.2022 Exp. Date: 06.2024 Quantity: 20Kg Invoice No.: 20220602-2 dated: 24.08.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	The list of API given in GMP certificate of API manufacturer doesn't mention that Cefepime HCl will be with L-Arginine.	The firm has submitted reply vide letter No. RA-QL/317/0723. The firm has submitted a copy of letter of Hebei Food and drug administration China that indicates approval for manufacturing of Cefepime dihydrochloride with L-Arginine.
2.	3.2.S.4.5	In justification of specifications, API name is mentioned as Cefepime dihydrochloride L arginine. Is it dihydrochloride or	The firm has stated that name of Cefepime as per USP, BP and Ph. Eur. is as follows; USP: Cefepime Hydrochloride. BP: Cefepime Hydrochloride monohydrate

		monohydrochloride? At other points its only mentioned as hydrochloride, the USP reference standard is also of Cefepime hydrochloride.	Ph. Eur: Cefepime Dihydrochloride monohydrate. There is only difference in the naming of said API among different pharmacopoeias while there is no change in molecular formula or molecular weight. The reply of firm is verifiable.
3.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
4.	3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence studies against innovator product.	The firm has stated that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use," to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator/ reference/ comparator product including the results of all the quality tests shall be submitted and discussed.'* The firm has further stated that they have established pharmaceutical equivalence with comparator product as innovator brand is currently not available in Pakistan.
5.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/281/0623 dated 21.06.2023

Decision: Registration Board approved the application of Primget 500mg (IM/IV) Powder for Injection.

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

436.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13168 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 086803416 dated 17.01.2023
	The proposed proprietary name / brand name	**Primget 1g (IM/IV) Powder for Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Sterile Cefepime HCl with L-Arginine equivalent to Cefepime……1g
	Pharmaceutical form of applied drug	White to off-white powder, filled in clear glass USP type II vial with blue coloured flip-off seal on top of grey coloured rubber stopper. Supplied with 10ml sterile water for injection.
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin. ATC Code: J01DE01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 1300/-
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Cefstar Powder for Injection 1g Reg No. 030954 M/s Barrett Hodgson Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang. Copy of GMP certificate No. HE20190059 dated 11.06.2019, issued by Hebei Drug Administration, valid till 10.06.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: H2231608001, H2231608002, H2231608003
	Module-III (Drug Product):	The firm has submitted detail of the description and

		composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefepime IV/IM Powder for Injection 1g** Batch No. C012DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** CefStar Injection 1g, Batch No. D0675, Mfg date: June-2022, Exp. Date: May 2025. of M/s Barrett Hodgson Pakistan. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator CefStar Injection 1g, Batch No. D0675, Mfg date: June-2022, Exp. Date: May 2025. of M/s Barrett Hodgson Pakistan by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang.		
API Lot No.	H2232207001		
Description of Pack (Container closure system)	White to off-white powder, filled in a clear glass USP type II Vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75% ± 5%RH** Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real time: 6 months** **Accelerated: 6 months**		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C012DS01	C012DS02	-
Batch Size	2000 vials	2000 vials	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20190059 dated 11.06.2019 in the name of M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang, issued by Hebei Drug Administration,

		valid till 10.06.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefepime Hydrochloride (L-Arginine)** Batch No.: H2232207001 Mfg. Date: 10.07.2022 Exp. Date: 06.2024 Quantity: 20Kg Invoice No.: 20220602-2 dated: 24.08.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	The list of API given in GMP certificate of API manufacturer doesn't mention that Cefepime HCl will be with L-Arginine.	The firm has submitted reply vide letter No. RA-QL/318/0723. The firm has submitted a copy of letter of Hebei Food and drug administration China that indicates approval for manufacturing of Cefepime dihydrochloride with L-Arginine.
2.	3.2.S.4.5	In justification of specifications, API name is mentioned as Cefepime dihydrochloride L arginine. Is it dihydrochloride or monohydrochloride? At other points its only mentioned as hydrochloride, the USP reference standard is also of Cefepime hydrochloride.	The firm has stated that name of Cefepime as per USP, BP and Ph. Eur. is as follows; USP: Cefepime Hydrochloride. BP: Cefepime Hydrochloride monohydrate Ph. Eur: Cefepime Dihydrochloride monohydrate. There is only difference in the naming of said API among different pharmacopoeias while there is no change in molecular formula or molecular weight. The reply of firm is verifiable.
3.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
4.	3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence studies against innovator product.	The firm has stated that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use," to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator/ reference/* ***comparator product*** *including the results of all the quality tests shall be submitted and discussed.'* The firm has further stated that they have established pharmaceutical equivalence with comparator product as innovator brand

			is currently not available in Pakistan.
5.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/282/0623 dated 21.06.2023

Decision: Registration Board approved the application of Primget 1g (IM/IV) Powder for Injection.

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

437.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13169 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 64112975 dated 17.01.2023
	The proposed proprietary name / brand name	**Primget 2g (IM/IV) Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Sterile Cefepime HCl with L-Arginine equivalent to Cefepime……2g
	Pharmaceutical form of applied drug	White to off-white powder, filled in clear glass USP type II vial with blue coloured flip-off seal on top of grey coloured rubber stopper. Supplied with 10ml sterile water for injection.
	Pharmacotherapeutic Group of (API)	Fourth generation cephalosporin. ATC Code: J01DE01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 3000/-
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Maxum Powder for Injection 2g Reg No. 073339 M/s Highnoon Laboratories Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.

	Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang. Copy of GMP certificate No. HE20190059 dated 11.06.2019, issued by Hebei Drug Administration, valid till 10.06.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: H2231608001, H2231608002, H2231608003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefepime IV/IM Powder for Injection 2g** Batch No. C023DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Maxum Injection 2g, Batch No. 2180070, Mfg date: Apr-2021 Exp. Date: Mar 2023. of M/s Highnoon limited. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator Maxum Injection 2g, Batch No. 2180070, Mfg date: Apr-2021 Exp. Date: Mar 2023 of M/s Highnoon limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.

	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang.		
API Lot No.	H2232207001		
Description of Pack (Container closure system)	White to off-white powder, filled in a clear glass USP type II Vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75% ± 5%RH** Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C023DS01	C023DS02	-
Batch Size	2000 vials	2000 vials	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20190059 dated 11.06.2019 in the name of M/s NCPC Hebei Huamin Pharmaceutical Co. Ltd. No. 18, Yangzi Road, Economic & Technological Development Zone Shijiazhuang, issued by Hebei Drug Administration, valid till 10.06.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefepime Hydrochloride (L-Arginine)** Batch No.: H2232207001 Mfg. Date: 10.07.2022 Exp. Date: 06.2024 Quantity: 20Kg Invoice No.: 20220602-2 dated: 24.08.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	The list of API given in GMP certificate of API manufacturer	The firm has submitted reply vide letter No. RA-QL/319/0723.

		doesn't mention that Cefepime HCl will be with L-Arginine.	The firm has submitted a copy of letter of Hebei Food and drug administration China that indicates approval for manufacturing of Cefepime dihydrochloride with L-Arginine.
2.	3.2.S.4.5	In justification of specifications, API name is mentioned as Cefepime dihydrochloride L arginine. Is it dihydrochloride or monohydrochloride? At other points its only mentioned as hydrochloride, the USP reference standard is also of Cefepime hydrochloride.	The firm has stated that name of Cefepime as per USP, BP and Ph. Eur. is as follows; USP: Cefepime Hydrochloride. BP: Cefepime Hydrochloride monohydrate Ph. Eur: Cefepime Dihydrochloride monohydrate. There is only difference in the naming of said API among different pharmacopoeias while there is no change in molecular formula or molecular weight. The reply of firm is verifiable.
3.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
4.	3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence studies against innovator product.	The firm has stated that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use," to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator/ reference/ comparator product including the results of all the quality tests shall be submitted and discussed.'* The firm has further stated that they have established pharmaceutical equivalence with comparator product as innovator brand is currently not available in Pakistan.
5.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/283/0623 dated 21.06.2023

Decision: Registration Board approved the application of Primget 2g (IM/IV) Powder for Injection.

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

438.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13171 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 031027465325 dated 19.01.2023
	The proposed proprietary name / brand name	**Getaclor 125mg/5ml Powder for Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5ml contains; Cefaclor monohydrate equivalent to Cefaclor …….125mg
	Pharmaceutical form of applied drug	Pink colour granular powder filled in white HDPE plastic bottle with marked line on the bottle for addition of water for reconstitution. Packed in carton along with a packaging insert.
	Pharmacotherapeutic Group of (API)	Second generation cephalosporin ATC Code: J01DC04
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (60ml)
	Proposed unit price	Rs. 500/-
	The status in reference regulatory authorities	KEFTID 125MG/5ML SUSPENSION, CEFACLOR 125MG/5ML SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	Ceclor Powder for suspension 125mg/5ml Reg No. 098676 M/s AGP Limited Karachi.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Suspension (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China. Copy of GMP certificate No. ZJ20190147 dated 30.11.2019, issued by National Medical Products Administration, valid till 29.11.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: DBC-1010-202108001, DBC-1010-202108002, DBC-1010-202108003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: GETACLOR Powder for Suspension 125mg/5ml** Batch No. C001DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Ceclor Suspension 125mg/5ml Batch No. A8189, Mfg date: Oct-2022 Exp. Date: Mar 2024. of M/s AGP Limited. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator Ceclor Suspension 125mg/5ml Batch No. A8189, Mfg date: Oct-2022 Exp. Date: Mar 2024 of M/s AGP Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China		
API Lot No.	DBC-1010-202111017		
Description of Pack (Container closure system)	Pink granular powder filled in white HDPE plastic bottles.		
Stability Storage Condition	Real time: 30˚C ± 2˚C **/ 75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real time: 6 months** **Accelerated: 6 months**		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C001DS01	C001DS02	-
Batch Size	2000 bottles	2000 bottles	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190147 dated 30.11.2019 in the name of M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China, issued by issued by National Medical Products Administration, valid till 29.11.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefaclor USP 43** Batch No.: DBC-1010-202111017 Mfg. Date: 27.11.2022 Exp. Date: 26.11.20240 Quantity: 35kg Invoice No.: 20220602-1 dated: 29.07.2022.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	2.2	It is not clearly mentioned that what will be the colour of HDPE plastic bottle, how will it be marked for addition of water for reconstitution. This needs to be clearly mentioned.	The firm vide letter No. RA-QR/324/0623 dated 03.07.2023 has submitted that the colour of HDPE bottle is white with marked line on the bottle for addition of water for reconstitution.
2.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
3.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/290/0623 dated 21.06.2023
4.	3.2.P.8	In-use stability studies data is not provided.	Submitted. The product was kept at 2℃ to 8℃ after reconstitution and was tested on 7th day and 14th day. Results indicate that product remained stable in above conditions for 14 days.

Decision: Registration Board approved the application of Getaclor 125mg/5ml Powder for Suspension.

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

439.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.

	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13172 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 29132963599 dated 19.01.2023
	The proposed proprietary name / brand name	**Getaclor 250mg/5ml Powder for Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 5ml contains; Cefaclor monohydrate equivalent to Cefaclor …….250mg
	Pharmaceutical form of applied drug	Pink colour granular powder filled in white HDPE plastic bottle with marked line on the bottle for addition of water for reconstitution. Packed in carton along with a packaging insert.
	Pharmacotherapeutic Group of (API)	Second generation cephalosporin ATC Code: J01DC04
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (60ml)
	Proposed unit price	Rs. 900/-
	The status in reference regulatory authorities	KEFTID 250MG/5ML SUSPENSION, CEFACLOR 250MG/5ML SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	Ceclor Powder for suspension 250mg/5ml Reg No. 098678 M/s AGP Limited Karachi.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Suspension (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China. Copy of GMP certificate No. ZJ20190147 dated 30.11.2019, issued by National Medical Products Administration, valid till 29.11.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: DBC-1010-202108001, DBC-1010-202108002, DBC-1010-202108003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: GETACLOR Powder for Suspension 250mg/5ml** Batch No. C002DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Ceclor Suspension 250mg/5ml Batch No. A8195, Mfg date: Oct-2022 Exp. Date: Mar 2024. of M/s AGP Limited. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator Ceclor Suspension 250mg/5ml Batch No. A8195, Mfg date: Oct-2022 Exp. Date: Mar 2024 of M/s AGP Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China
API Lot No.	DBC-1010-202111017
Description of Pack (Container closure system)	Pink granular powder filled in HDPE plastic bottles.
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C002DS01	C002DS02	-
Batch Size	2000 bottles	2000 bottles	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190147 dated 30.11.2019 in the name of M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China, issued by issued by National Medical Products Administration, valid till 29.11.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefaclor USP 43** Batch No.: DBC-1010-202111017 Mfg. Date: 27.11.2022 Exp. Date: 26.11.20240 Quantity: 35kg Invoice No.: 20220602-1 dated: 29.07.2022.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	2.2	It is not clearly mentioned that what will be the colour of HDPE plastic bottle, how will it be marked for addition of water for reconstitution. This needs to be clearly mentioned.	The firm vide letter No. RA-QR/324/0623 dated 03.07.2023 has submitted that the colour of HDPE bottle is white with marked line on the bottle for addition of water for reconstitution.
2.	-	Copy of AD attested invoice of API clearance and import license is required.	Submitted.
3.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/291/0623 dated 21.06.2023
4.	3.2.P.8	In-use stability studies data is not provided.	Submitted. The product was kept at 2℃ to 8℃ after reconstitution and was tested on 7th day and

			14th day. Results indicate that product remained stable in above conditions for 14 days.

Decision: Registration Board approved the application of Getaclor 250mg/5ml Powder for Suspension.

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

440.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13170 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 3962864342 dated 19.01.2023
	The proposed proprietary name / brand name	**Getaclor 50mg/ml Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each reconstituted 1ml contains; Cefaclor monohydrate equivalent to Cefaclor …….50mg
	Pharmaceutical form of applied drug	Pink colour granular powder filled in white HDPE plastic bottle with marked line on the bottle for addition of water for reconstitution. Packed in carton along with a packaging insert.
	Pharmacotherapeutic Group of (API)	Second generation cephalosporin ATC Code: J01DC04
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's (15ml)
	Proposed unit price	Rs. 300/-
	The status in reference regulatory authorities	PMS-CEFACLOR 250 - PWS 50MG/ML Health Canada: Cancelled Post Market
	For generic drugs (me-too status)	Ceclor Drops 50mg/ml Reg No. 098675 M/s AGP Limited Karachi.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Suspension (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.

	Name and address of API manufacturer.	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China. Copy of GMP certificate No. ZJ20190147 dated 30.11.2019, issued by National Medical Products Administration, valid till 29.11.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: DBC-1010-202108001, DBC-1010-202108002, DBC-1010-202108003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: GETACLOR Drops 50mg/ml** Batch No. C003DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Ceclor Drops 50mg/ml Batch No. A8192, Mfg date: Oct-2022 Exp. Date: Mar 2024. of M/s AGP Limited. (Images of Pack are provided) Pharmaceutical Equivalence is established against the comparator Ceclor Drops 50mg/ml Batch No. A8192, Mfg date: Oct-2022 Exp. Date: Mar 2024. of M/s AGP Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, pH test and related substances). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China		
API Lot No.	DBC-1010-202111017		
Description of Pack (Container closure system)	Pink granular powder filled in HDPE plastic bottles.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	**Real time: 6 months** **Accelerated: 6 months**		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C003DS01	C003DS02	-
Batch Size	2000 bottles	2000 bottles	-
Manufacturing Date	09.2022	09.2022	-
Date of Initiation	11.10.2022	11.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190147 dated 30.11.2019 in the name of M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China, issued by issued by National Medical Products Administration, valid till 29.11.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefaclor USP 43** Batch No.: DBC-1010-202111017 Mfg. Date: 27.11.2022 Exp. Date: 26.11.20240 Quantity: 35kg Invoice No.: 20220602-1 dated: 29.07.2022.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.9	The evidence of RRA (Health Canada) is cancelled (post market). Proper RRA reference is required.	The firm vide letter No. RA-QR/333/0723 dated 07.07.2023 has submitted following response; *"This is to inform you that Cefaclor 50mg/ml (presentation of 250mg/5ml) is a MHRA approved drug product with the*

			brand name 'KEFTID' by M/s Strides Pharma UK Ltd., UK. Please refer to Annexure 1 for evidence of RRA."
2.	2.2	It is not clearly mentioned that what will be the colour of HDPE plastic bottle, how will it be marked for addition of water for reconstitution. This needs to be clearly mentioned.	The firm has submitted that the colour of HDPE bottle is white with marked line on the bottle for addition of water for reconstitution.
3.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
4.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/289/0623 dated 21.06.2023
5.	3.2.P.8	In-use stability studies data is not provided.	Submitted. The product was kept at 2℃ to 8℃ after reconstitution and was tested on 7th day and 14th day. Results indicate that product remained stable in above conditions for 14 days.

Decision: Registration Board approved the application of Getaclor 50mg/ml Oral Drops.

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

441.		
	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13173 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 79327798736 dated 19.01.2023
	The proposed proprietary name / brand name	**Getaclor Capsule 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Cefaclor monohydrate equivalent to Cefaclor…….250mg
	Pharmaceutical form of applied drug	Hard gelatin capsule, containing white to off-white coloured crystalline powder. Packed in Alu-PVC blister.
	Pharmacotherapeutic Group of (API)	Second generation cephalosporin ATC Code: J01DC04

	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	12's
	Proposed unit price	Rs. 700/-
	The status in reference regulatory authorities	CEFACLOR CAPSULES 250MG, KEFTID CAPSULES 250MG MHRA Approved.
	For generic drugs (me-too status)	Ceclor Capsules 250mg Reg No. 098681 M/s AGP Limited Karachi.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Capsule (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China. Copy of GMP certificate No. ZJ20190147 dated 30.11.2019, issued by National Medical Products Administration, valid till 29.11.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: DBC-1010-202108001, DBC-1010-202108002, DBC-1010-202108003
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefaclor Capsule 250mg** Batch No.

	dissolution profile	C004DS01 Mfg 26.09.2022 Exp 26.09.2024**.** **Reference Product:** Ceclor Capsules 250mg Batch No. A7387, Mfg date: May-2022 Exp. Date: April.2024. of M/s AGP Limited. (Images of Pack are provided) **Comparative Dissolution profile: Comparable at all pH** pH 1.2 HCl solution: 89.62% released in 15mins F2 NA pH 4.5 Acetate buffer: 93.56% release in 15mins, F2 NA pH 6.8 Phosphate buffer:90.38% released in 15mins F2 NA Pharmaceutical Equivalence is established against the comparator Ceclor Capsules 250mg Batch No. A7387, Mfg date: May-2022 Exp. Date: April.2024. of M/s AGP Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, disintegration, dissolution and related substances) Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China		
API Lot No.	DBC-1010-202111017		
Description of Pack (Container closure system)	Hard gelatin capsule, containing white to off-white crystalline powder. In Alu-PVC blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C004DS01	C004DS02	-
Batch Size	5000 capsules	5000 capsules	-
Manufacturing Date	26.09.2022	26.09.2022	-
Date of Initiation	06.10.2022	06.10.2022	-
No. of Batches	02 batches		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190147 dated 30.11.2019 in the name of M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China, issued by issued by National Medical Products Administration, valid till 29.11.2024 is submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefaclor USP 43** Batch No.: DBC-1010-202111017 Mfg. Date: 27.11.2022 Exp. Date: 26.11.20240 Quantity: 35kg Invoice No.: 20220602-1 dated: 29.07.2022.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of AD attested invoice of API clearance is required.	The firm has submitted required documents vide letter No. RA-QR/323/0723 dated 03.07.2023.
2.	3.2.P.5.3	Protocol and report for Dissolution method validation/verification is required.	Required report is submitted.
3.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/287/0623 dated 21.06.2023

Decision: Registration Board approved the application of Getaclor 250mg Capsule.

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

442.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13174 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 636587917 dated 19.01.2023
	The proposed proprietary name / brand name	**Getaclor Capsule 500mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Cefaclor monohydrate equivalent to Cefaclor…….500mg
	Pharmaceutical form of applied drug	Hard gelatin capsule, containing white to off-white coloured crystalline powder. Packed in Alu-PVC blister.
	Pharmacotherapeutic Group of (API)	Second generation cephalosporin ATC Code: J01DC04
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	12's
	Proposed unit price	Rs. 1200/-
	The status in reference regulatory authorities	CEFACLOR 500MG CAPSULES, DISTACLOR 500MG CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Ceclor Capsules 500mg Reg No. 098682 M/s AGP Limited Karachi.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Capsule (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China. Copy of GMP certificate No. ZJ20190147 dated 30.11.2019, issued by National Medical Products Administration, valid till 29.11.2024 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 24 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: DBC-1010-202108001, DBC-1010-202108002, DBC-1010-202108003

	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefaclor Capsule 500mg** Batch No. C005DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Ceclor Capsules 500mg Batch No. A7388, Mfg date: May-2022 Exp. Date: April.2024. of M/s AGP Limited. (Images of Pack are provided) **Comparative Dissolution profile: Comparable at all pH** pH 1.2 HCl solution: 89.66% released in 15mins F2 NA pH 4.5 Acetate buffer: 89.65% release in 15mins, F2 NA pH 6.8 Phosphate buffer:89.90% released in 15mins F2 NA Pharmaceutical Equivalence is established against the comparator Ceclor Capsules 500mg Batch No. A7388, Mfg date: May-2022 Exp. Date: April.2024. of M/s AGP Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, disintegration, dissolution and related substances) Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China		
API Lot No.	DBC-1010-202111017		
Description of Pack (Container closure system)	Hard gelatin capsule, containing white to off-white crystalline powder. In Alu-PVC blister. Packed in secondary carton along with package insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C005DS01	C005DS02	-
Batch Size	5000 capsules	5000 capsules	-
Manufacturing Date	27.09.2022	27.09.2022	-
Date of Initiation	06.10.2022	06.10.2022	-
No. of Batches	02 batches		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20190147 dated 30.11.2019 in the name of M/s Zhejiang Dongbang Pharmaceutical Co. Ltd, Pharm-Chem Zone, Duqiao Linhai, Taizhou, Zhejiang China, issued by issued by National Medical Products Administration, valid till 29.11.2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefaclor USP 43** Batch No.: DBC-1010-202111017 Mfg. Date: 27.11.2022 Exp. Date: 26.11.20240 Quantity: 35kg Invoice No.: 20220602-1 dated: 29.07.2022.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of AD attested invoice of API clearance is required.	The firm has submitted required documents vide letter No. RA-QR/323/0723 dated 03.07.2023.
2.	3.2.P.5.3	Protocol and report for Dissolution method validation/verification is required.	Required report is submitted.
3.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/288/0623 dated 21.06.2023

Decision: Registration Board approved the application of Getaclor 500mg Capsule.

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

443.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 11781 dated 15.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 289600129801 dated 01.02.2023
	The proposed proprietary name / brand name	**Getofin 2g IV Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium USP equivalent to Ceftriaxone……..2g
	Pharmaceutical form of applied drug	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 1200/-
	The status in reference regulatory authorities	CEFTRIAXONE 2 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 34985/0008 MHRA Approved.
	For generic drugs (me-too status)	Cefxone Injection 2g Reg No. 055911 M/s Bosch Pharmaceuticals (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town Jinwan district, Zhuhai, Guangdong, China. Copy of GMP certificate No. GD20180909 dated 06.12.2018, issued by CFDA, valid till 05.12.2013 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 36 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: 3051408011, 3051408012, 3051408013
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Getofin Injection 2g** Batch No. C009DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Oxidil I.V Injection 2g Batch No. 010H, Mfg date: Aug-2022 Exp. Date: july.2024. of M/s Healthtek (Pvt.) Ltd (Images of Oxidil 2g IV Injection are provided) Pharmaceutical Equivalence is established against the comparator Oxidil I.V Injection 2g Batch No. 010H, Mfg date: Aug-2022 Exp. Date: july.2024 of M/s Healthtek (Pvt.) Ltd by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, and related substances) Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town Jinwan district, Zhuhai, Guangdong, China.		
API Lot No.	3052206016		
Description of Pack (Container closure system)	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / **75%** ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C009DS01	C009DS02	-
Batch Size	2000 Vials	2000 Vials	-
Manufacturing Date	20.09.2022	20.09.2022	-
Date of Initiation	08.10.2022	08.10.2022	-
No. of Batches	02 batches		

Administrative Portion		
1.	Reference of previous approval of applications	Not Submitted.

	with stability study data of the firm (if any)	The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town Jinwan district, Zhuhai, Guangdong, China. Copy of GMP certificate No. GD20180909 dated 06.12.2018, issued by CFDA, valid till 05.12.2013 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Ceftriaxone Sodium Sterile USP** Batch No.: 3052206016 Mfg. Date: 08.06.2022 Exp. Date: 05.2025 Quantity: 10Kg Invoice No.: CEF220712AZ dated: 12.07.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of AD attested invoice of API clearance is required.	Firm has submitted required documents vide letter No. RA-QR/315/0723 dated 03.07.2023.
2.	-	Copy of GMP certificate of API manufacturer submitted was valid till 31.10.2018. Latest GMP status f API manufacturer is required.	Firm has submitted valid GMP certificate of drug substance manufacturer vide letter No. RA-QR/315/0723 dated 03.07.2023.
3.	3.2.P.2	In pharmaceutical equivalence study, reference product mentioned is Rocephin Injection 2g whereas snapshots attached are of Oxidil 2g IV injection. Clarification is required along with snapshots of correct reference product.	Vide letter No. RA-QR/315/0723 dated 03.07.2023, the firm has stated that pharmaceutical equivalence study was performed against Oxidil IV Injection 2g and have resubmitted documents with corrected name of comparator product and 2g injection is currently not available in local market.
4.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RARA-SD/270 /0623 dated 21.06.2023

Decision: Registration Board approved the application of Getofin 2g IV Injection.

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

444.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.

	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13163 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 62047203 dated 17.01.2023
	The proposed proprietary name / brand name	**Cefastola 250mg Powder for Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cefotaxime sodium equivalent to Cefotaxime……..250mg
	Pharmaceutical form of applied drug	Off-white to pale yellow crystalline powder, filled in a clear glass USP type II vial. Supplied with 2ml Ampoule of diluent (Sterile water for injection)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin ATC Code: J01DD01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 200/-
	The status in reference regulatory authorities	CEFOTAXIMA NORMON 250 mg POLVO Y DISOLVENTE PARA SOLUCION INYECTABLE IV EFG CIMA Spain Approved.
	For generic drugs (me-too status)	Claforan 250mg Reg No. 006056 M/s Sanofi-Aventis Pakistan Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30°C ± 2°C / 75% ± 5%RH for 36 months **Accelerated**: 40°C ± 2°C / 75% ± 5%RH for 6 months **Batches**: S012012001, S012012002, S012012003, S012012004, S012012005, S012012006
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefotaxime Injection 250mg** Batch No. C013DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Claforan Injection 250mg Batch No. AA043, Mfg date: June-2022 Exp. Date: May.2024 of M/s Sanofi-Aventis Pakistan Limited (Images are provided) Pharmaceutical Equivalence is established against the comparator Claforan Injection 250mg Batch No. AA043, Mfg date: June-2022 Exp. Date: May.2024 of M/s Sanofi-Aventis Pakistan Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, and related substances) Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA	
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China
API Lot No.	S012204021
Description of Pack (Container closure system)	Off white to pale yellow crystalline powder, filled in clear glass USP type II vial along with 2ml sterile water for injection.

Stability Storage Condition	Real time: 30°C ± 2°C / **75%** ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C013DS01	C013DS02	-
Batch Size	2000 Vials	2000 Vials	-
Manufacturing Date	23.07.2022	23.07.2022	-
Date of Initiation	15.10.2022	15.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefotaxime Sodium Sterile USP40** Batch No.: S012204021 Mfg. Date: 24.04.2022 Exp. Date: 23.04.2024 Quantity: 10Kg Invoice No.: 20220602-1 dated: 29.07.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.9	RRA could not be verified for strength of 250mg	The firm vide letter No. RA-QR/321/0623 dated 03.07.2023 has submitted that product is approved in CIMA Spain. The reference is verifiable.
2.	-	Copy of AD attested invoice of API clearance is required.	Documents are submitted.
3.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/284/0623 dated 21.06.2023

Decision: Registration Board approved the application of Cefastola 250mg Powder for Injection.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
445.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13164 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 82261897032 dated 17.01.2023
	The proposed proprietary name / brand name	**Cefastola 500mg Powder for Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cefotaxime sodium USP equivalent to Cefotaxime……..500mg
	Pharmaceutical form of applied drug	Off-white to pale yellow crystalline powder, filled in a clear glass USP type II vial. Supplied with 2ml Ampoule of diluent (Sterile water for injection)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin ATC Code: J01DD01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1’s
	Proposed unit price	Rs. 300/-
	The status in reference regulatory authorities	Cefotaxime 500mg and 1000mg Powder for Solution for Injection or Infusion - PL 25975/0043-4; UK/H/1401/001-2/DC MHRA Approved.
	For generic drugs (me-too status)	Claforan 500mg Reg No. 020483 M/s Sanofi-Aventis Pakistan Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.
	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.

	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 36 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: S012012001, S012012002, S012012003, S012012004, S012012005, S012012006
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefotaxime Injection 500mg** Batch No. C014DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Claforan Injection 500mg Batch No. AA045, Mfg date: July-2022 Exp. Date: June.2024 of M/s Sanofi-Aventis Pakistan Limited (Images are provided) Pharmaceutical Equivalence is established against the comparator Claforan Injection 500mg Batch No. AA045, Mfg date: July-2022 Exp. Date: June.2024 of M/s Sanofi-Aventis Pakistan Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, and related substances) Results of both the products are comparable with each other.
	Analytical method validation/verification of	Method verification studies are submitted including

	product	specificity, linearity and range.	
STABILITY STUDY DATA			
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China		
API Lot No.	S012204021		
Description of Pack (Container closure system)	Off-white to pale yellow crystalline powder, filled in a clear glass USP type II vial along with 2ml Sterile water for injection.		
Stability Storage Condition	Real time: 30°C ± 2°C / **75%** ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C014DS01	C014DS02	-
Batch Size	2000 Vials	2000 Vials	-
Manufacturing Date	23.07.2022	23.07.2022	-
Date of Initiation	15.10.2022	15.10.2022	-
No. of Batches	02 batches		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 is submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefotaxime Sodium Sterile USP40** Batch No.: S012204021 Mfg. Date: 24.04.2022 Exp. Date: 23.04.2024 Quantity: 10Kg Invoice No.: 20220602-1 dated: 29.07.2022	
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:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of AD attested invoice of API clearance is required.	Submitted.
2.	3.2.P.8	For drug product, stability studies data	The firm has submitted complete stability

		of only 3 months is submitted. Stability studies data of 6 months is required.	data for 6 months vide letter No. RA-SD/285/0623 dated 21.06.2023

Decision: Registration Board approved the application of Cefastola 500mg Powder for Injection.

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

446.	Name, address of Applicant / Marketing Authorization Holder	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s. Getz Pharma (Pvt.) ltd. (DML No. 000933) Plot No. 1, Sector 25, Korangi Industrial Area, 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. 13165 dated 29.05.2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0119079070 dated 17.01.2023
	The proposed proprietary name / brand name	**Cefastola 1g Powder for Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cefotaxime sodium USP equivalent to Cefotaxime……..1g
	Pharmaceutical form of applied drug	Off-white to pale yellow crystalline powder, filled in a clear glass USP type II vial. Supplied with 4ml Ampoule of diluent (Sterile water for injection)
	Pharmacotherapeutic Group of (API)	Third generation cephalosporin ATC Code: J01DD01
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	Rs. 400/-
	The status in reference regulatory authorities	Cefotaxime 500mg and 1000mg Powder for Solution for Injection or Infusion - PL 25975/0043-4; UK/H/1401/001-2/DC MHRA Approved.
	For generic drugs (me-too status)	Claforan 1g Reg No. 006058 M/s Sanofi-Aventis Pakistan Ltd.
	GMP status of the Finished product manufacturer	**Manufacturer:** M/s. Getz Pharma (Pvt.) ltd. Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. New section granted in February 2023.

	Evidence of section approval.	Dry Powder Vial Injection (Cephalosporin) issued vide letter No. F.2-9/2014-Lic (Vol-I) dated 27.02.2023.
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 36 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: S012012001, S012012002, S012012003, S012012004, S012012005, S012012006
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, 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	**Test product: Cefotaxime Injection 1g** Batch No. C015DS01 Mfg 09.2022 Exp 09.2024**.** **Reference Product:** Claforan Injection 1g Batch No. AA017, Mfg date: May-2022 Exp. Date: April.2024 of M/s Sanofi-Aventis Pakistan Limited (Images are provided) Pharmaceutical Equivalence is established against the comparator Claforan Injection 1g Batch No. AA017, Mfg date: May-2022 Exp. Date: April.2024 of M/s Sanofi-Aventis Pakistan Limited by performing quality tests (Physical attributes, Identification, Assay, Uniformity of dosage unit, water content, and related substances) Results of both the products are comparable with each

		other.
	Analytical method validation/verification of product	Method verification studies are submitted including specificity, linearity and range.

STABILITY STUDY DATA

Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China		
API Lot No.	S012204021		
Description of Pack (Container closure system)	Off-white to pale yellow crystalline powder, filled in a clear glass USP type II vial along with 2ml Sterile water for injection.		
Stability Storage Condition	Real time: 30°C ± 2°C / **75%** ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C015DS01	C015DS02	-
Batch Size	2000 Vials	2000 Vials	-
Manufacturing Date	26.07.2022	26.07.2022	-
Date of Initiation	15.10.2022	15.10.2022	-
No. of Batches	02 batches		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. The applications are of new sections. There are no previous registrations in these sections.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Sinopharm Weiqida Pharmaceutical Co. Ltd., Economic & Technological Development Zone, Firt Medical Zone, Datong, Shanxi, China Copy of GMP certificate No. SX20180229 dated 06.06.2018, issued by Shanxi Province FDA, valid till 05.06.2023 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance: Cefotaxime Sodium Sterile USP40** Batch No.: S012204021 Mfg. Date: 24.04.2022 Exp. Date: 23.04.2024 Quantity: 10Kg Invoice No.: 20220602-1 dated: 29.07.2022
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:

Sr. No.	Section	Observation	Reply by the firm
1.	-	Copy of AD attested invoice of API	Submitted

		clearance is required.	
2.	3.2.P.8	For drug product, stability studies data of only 3 months is submitted. Stability studies data of 6 months is required.	The firm has submitted complete stability data for 6 months vide letter No. RA-SD/286/0623 dated 21.06.2023

Decision: Registration Board approved the application of Cefastola 1g Powder for Injection.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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 Central Licensing Board in its 277th meeting approved following new section of M/s Ferozsons Laboratories Ltd (DML No. 000038);

i. Cream/ointment/Gel Section (Steroid)

2. The above new section were granted vide letter No. F.3-14/2004-Lic (Vol-I) dated 26.10.2020.

447.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd, Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd, Amangarh, Nowshera, Khyber Pakhtunkhwa. DML No. 000038
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate dated 25.08.2021 valid till 09.08.2023 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section No. F.3-14/2004-Lic (Vol-I) dated 26.10.2020. specifying Cream/Ointment/gel Section (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	Dy. No 5809 dated 01.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 015638058904 Dated 15.02.2022
	The proposed proprietary name / brand name	**CRISA 2% TOPICAL OINTMENT**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains; Crisaborole……20mg
	Pharmacotherapeutic Group of (API)	Agents for dermatitis, excluding corticosteroids ATC Code: D11AH06
	Pharmaceutical form of applied drug	Topical ointment White coloured ointment filled in Aluminium tube.
	Reference to Finished product specifications	Innovator's Specification.
	Proposed Pack size	5g, 10g, 15g, 30g, 50g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Eucrisa ointment FDA Approved.

	For generic drugs (me-too status)	Not available.
	Name and address of API manufacturer.	M/s Honour Lab Limited (Unit III) Plot No.4, Hetero Infrastructure Ltd., SEZ, N. Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District - 531 081, 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'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 (CS20120002) 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. Batches: 18070002, 18070003, 18070004.
	Module-III Drug Product:	Firm has submitted data of drug product including 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 product Eucrisa Ointment 2% Batch No. PMEK, mfg date: -, Exp date: 09.2022 manufactured by M/s Pfizer labs (spain). Tests like physical characteristics and Assay were performed and results of both products are comparable. Firm has not performed tests like viscosity, content uniformity Dissolution: Acid stage F2: 69.04, Acetate buffer F2: 68.50, Phosphate buffer F2: 70.60 Firm has used Tefose 63 premix (Polyoxyl 6 Stearate Type I, Ethylene Glycol Stearates and Polyoxyl 32 Stearate Type I) instead of mixture of mono and di glycerides (used by innovator), rest of the formulation is same.

		Pictorial evidence of pack of Reference product is provided but batch No. and expiry are not visible.
	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 Honour Lab Limited (Unit III) Plot No.4, Hetero Infrastructure Ltd., SEZ, N. Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District - 531 081, Andhra Pradesh, INDIA		
API Lot No.	CS20120002		
Description of Pack (Container closure system)	White coloured ointment filled in 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.	057NS04	057NS05	057NS06
Batch Size	60 tubes	60 tubes	60 tubes
Manufacturing Date	04.2022	04.2022	04.2022
Date of Initiation	27.04.2022	27.04.2022	27.04.2022
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)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of manufacturing license vide No. HMF07-14051/289/2020-Tech-DCA valid till 09.04.2023 issued by Drugs Control Administration Andhra Pradesh India is submitted. GMP certificate is not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Crisaborole Quantity: 0.280 kg Batch No. CS20120002 Mfg. Date: 12.2020 Exp date: 11.2024 Clearance date: 12.11.2021 Invoice No. G2203SE-384 Invoice date: 18.10.2021
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:

Sr. No.	Section	Observation	Reply by the firm

1.	-	Product is non-steroidal, the section approval is for steroidal topical products, justification is required.	The firm vide letter No PDFLL-1417317032 dated 13.07.2023 has submitted section approval letter of topical general section. The section was granted vide letter No. 03-14/2004-Lic(pt) dated 09.04.2020. It was approved in 274th meeting.
2.	-	Copy of GMP certificate of drug substance manufacturer is required.	Submitted. Cert No. HMF 07-14051/1220/2022-ADMN-DCA, issued on 15.12.2022. Valid till15.12.2025 Issued by Drugs Control Administration Andhra Pradesh India.
3.	3.2.P.8	Clear image of reference product pack is required in which batch No and expiry shall be readable.	Submitted; Eucrisa Ointment 2% Made in Spain Distributed by Pfizer Lot No. PMEK EXP: Sep 2022.

Decision: Registration Board approved the application of CRISA 2% Topical Ointment.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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 Central Licensing Board in its 278th meeting approved following new sections of M/s Wezen Pharmaceuticals (DML No. 000880);

i. Tablet (General)
ii. Capsule (General)
iii. Sachet (General)
iv. Ointment/ Cream/ Gel (General)

2. The above new sections were granted vide letter No. F.1-30/2014-Lic dated 30.12.2020.

448.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat. DML No. 000882
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3224 dated 03.02.2023
	Details of fee submitted	PKR 30,000/- Slip No. 94847755 Dated

		01.01.2023
	The proposed proprietary name / brand name	**ROSTA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin……5mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Pharmaceutical form of applied drug	White, round, biconvex 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	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
	For generic drugs (me-too status)	Rovista Tablet 5mg Reg No. 044043 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) 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. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
	Module-III Drug Product:	Firm has submitted data of drug product including 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 product Rovista 5mg Tablet Batch No. F05008, mfg date: 04.2022, Exp date: 04.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 96, Acetate buffer F2: 98, Phosphate buffer F2: 97 Pictorial evidence of pack of Reference product is not attached
	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 Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.		
API Lot No.	RT12-9058		
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10'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(Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22
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)	Not Submitted New DML DML was issued in Feb 2023
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. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh Indua. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schdule M of the Drugs * Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from **WNSFEILD Pharmaceuticals Hattar.** Quantity: 4kg Batch No. RT12-9058

		Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
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 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:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution and what is its strength.	
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	
7.		Only a list of previous approval of applications with stability study data in tablet section is required.	

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

449.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat. DML No. 000882
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3124 dated 02.02.2023

	Details of fee submitted	PKR 30,000/- Slip No. 82189200836 Dated 31.01.2023
	The proposed proprietary name / brand name	**ROSTA 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin……10mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Pharmaceutical form of applied drug	White, round, biconvex 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	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
	For generic drugs (me-too status)	Rovista Tablet 10mg Reg No. 044044 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) 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. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
	Module-III Drug Product:	Firm has submitted data of drug product including 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 product Rovista 10mg Tablet Batch No. F06026, mfg date: 04.2022, Exp date: 04.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 93, Acetate buffer F2: 97, Phosphate buffer F2: 95. Pictorial evidence of pack of Reference product is not attached
	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 Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.		
API Lot No.	RT12-9058		
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10'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(Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22
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)	Not Submitted New DML DML was issued in Feb 2023
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. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh Indua. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schdule M of the Drugs * Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from **WNSFEILD Pharmaceuticals Hattar.** Quantity: 4kg

		Batch No. RT12-9058 Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
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 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:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.	
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	
7.		Only a list of previous approval of applications with stability study data in tablet section is required.	

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

450.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat. DML No. 000882
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm was granted Tablet (General) section on 30.12.2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30.12.2020 specifying Tablet (general) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 3125 dated 02.02.2023
	Details of fee submitted	PKR 30,000/- Slip No. 895013356553 Dated 31.01.2023
	The proposed proprietary name / brand name	**ROSTA 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Rosuvastatin calcium equivalent to Rosuvastatin……20mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Pharmaceutical form of applied drug	White, round, biconvex 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	Rosuvastatin 5 mg, 10 mg, 20 mg and 40 mg Film-Coated Tablets (rosuvastatin calcium) - PL 08553/0590-593 MHRA Approved.
	For generic drugs (me-too status)	Rovista Tablet 20mg Reg No. 044045 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Village Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (RT12-9058) 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. Batches: RT-12-KL-0001, RT-12-KL-0002, RT-12-KL-0003.
	Module-III Drug Product:	Firm has submitted data of drug product including 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 product Rovista 20mg Tablet Batch No. F06042, mfg date: 02.2022, Exp date: 02.2025 manufactured by M/s Getz Pharma Karachi. Tests like Appearance, DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 92, Acetate buffer F2: 96, Phosphate buffer F2: 93. Pictorial evidence of pack of Reference product is not attached
	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 Malkumajra (Morepen Village), Baddi Nalagarh Road, Badi Solan, Himachal Pradesh, India.		
API Lot No.	RT12-9058		
Description of Pack (Container closure system)	Alu-Alu Blister of 1x10'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(Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 tablets	1200 tablets	1200 tablets
Manufacturing Date	06.22	06.22	06.22
Date of Initiation	26.06.22	26.06.22	26.06.22
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)	Not Submitted New DML DML was issued in Feb 2023
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. 173205) dated 04.02.2019 issued by Health and Family Welfare Department, Himachal Pradesh Indua. The certificate specifies that the firm complies with GMP as stipulated under the provisions of Revised Schdule M of the Drugs * Cosmetic Rules 1945 in respect of category of Bulk Drugs. Certificate was valid till 03.02.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Rosuvastatin Calcium IH grade Taken loan from **WNSFEILD Pharmaceuticals Hattar.**

		Quantity: 4kg Batch No. RT12-9058 Mfg. Date: Sept 2019 Clearance date: August 2023 Invoice No. MBE20192000256 Invoice date: 27.09.2019
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 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:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.P.2.2.1	Pictorial evidence of pack of product used in CDP is required. The batch No. of the product used shall be visible and readable.	
2.	3.2.P.2.2.1	Pharmaceutical equivalence is established against brand leader. Clarification is required why is it not established against innovator product.	
3.	3.2.P.5.2	In analytical procedure, photocopy of monograph is attached. Verified testing method (Standard Analytical Procedure) is required wherein it should be mentioned that how many tablets are being taken for preparation of sample solution, how it is prepared for different and what is its strength.	
4.	3.2.P.5.2	Detailed Standard Analytical Procedure for performing dissolution test along with its verification report is required.	
5.		Record of digital data logger for temperature and humidity monitoring of stability chambers is required	
6.		Compliance Record of HPLC software 21CFR & audit trail reports on product testing are required.	
7.		Only a list of previous approval of applications with stability study data in tablet section is required.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.			

<u>Case No. 02 Priority registration of Isoflurane Inhalational Solution</u>

DRAP in its 143rd meeting of Authority held on 05th August, 2022, keeping in view of essentiality, criticality of isoflurane and pursuance from Government of Punjab to ensure its availability in Pakistan decided that registration application of Isoflurane shall be considered "out of queue" by the Registration Board. Available applications of Isoflurane 100ml & 250ml liquid for inhalation, are presented below:

451.	**Name, address of Applicant / Importer**	M/s MAFHH Enterprises, Shop No. A-71, Rabia Palace Block-10A, Gulshan-e-Iqbal, Karachi.
	Details of Drug Sale License of importer	**License No**: 0302 **Address**: MAFHH Enterprises, Shop No. A-71, Rabia Place Block-10A, Gulshan-e-Iqbal, Karachi. (a) Shop No. A-71, Rabia Place Block-10A, Gulshan-e-Iqbal, Karachi (b) A-42 Bukhari Town, Block 10-A, Gulshan-e-Iqbal, Karachi. **Validity**: 08.01.2028 **Status**: License to sell Drugs by way of Wholesale.
	Name and address of marketing authorization holder (abroad)	M/s Pharmastars Pharmaceuticals, 24 Ahmed Tayseer St, Ard El Golf, Caro, Egypt.

	Name, address of manufacturer(s)	**M/s Sunny Pharmaceutical** Address: Badr City- 1-00, Acre Zone- Piece No. 37 & 38 Cairo- Egypt.
	Name of exporting country	Arab Republic of Egypt
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized CoPP certificate (No. 01017/2023/H) dated 06.04.2023 issued by the Egyptian Drug Authority. Name and dosage form on the CoPP certificate mentioned is "Isoflurane-Pharmastars Pharmaceuticals Volatile liquid for inhalation" and name of the product license holder is **Pharmastars Pharmaceuticals, 24 Ahmed Tayseer St, Ard El Golf Cairo, Egypt**. 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. The validity of COPP is not mentioned. **GMP:** Applicant has submitted **Copy** of GMP certificate No. P-850/2022 dated 11.10.2022 issued by Egyptian Drug Authority in the name of M/s Sunny Pharmaceutical, Parts No. (37, 38), Industrial Zone (100 Fadan Shark El Roubaky)- Badr City-Cairo having its manufacturing site at same address. The certificate confirms that manufacturing facility complies with the principles and guidelines for the pharmaceutical dosage form categories and/or activities listed in the part 2. (in part 2 Production line for liquid anesthetics for inhalation is mentioned under heading of non-sterile products.) The certificate is valid till 11.10.2023
	Details of letter of authorization / sole agency agreement	Firm has submitted **Copy** of Authorization letter. The letter specifies that product license holder i.e. M/s Pharmastars Pharmaceuticals, 24 Ahmed Tayseer Street, Ard El Golf, Helipolis, Cairo, Egypt **authorizes** M/s MAFHH Enterprises, Suit No. A-71, Rabia Palace, Gulshan-e-Iqbal Block 10/A, Main Rashid minhas Road, Karachi to register Pharmastars product "Isoflurane-Volatile Liquid for inhalation", trade name "MAFRANE" at the Drug Regulatory Authority of Pakistan (DRAP and import it exclusively to the market of Pakistan The authorization is valid till 31.12.2028.
	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. 14077 dated 06-06-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 9621641780 Dated: 17-05-2023
	The proposed proprietary name / brand name	MAFRANE liquid for inhalation.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 100ml bottle contains:** Isoflurane……100%
	Pharmaceutical form of applied drug	Volatile liquid for inhalation
	Pharmacotherapeutic Group of (API)	ANESTHETICS, GENERAL, Halogenated hydrocarbons. ATC Code: N01AB06
	Reference to Finished product specifications	Ph. Eur. Specifications.
	Proposed Pack size	100ml/bottle. 1's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	AERRANE 100% LIQUID INHALATION VAPOUR MHRA Approved.
	For generic drugs (me-too status)	FORANE LIQUID FOR INHALATION Reg No. 011081 M/s Getz Pharma 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 verification, 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 Times Pharmaceutical Co. Ltd. No. 1 North outer ring road, Feixian county, Shandong Province, China.
	Module-III Drug Substance:	Firm has submitted partial data. (3.2.S.2.2, 3.2.S.2.3, 3.2.S.2.4, 3.2.S.2.5, 3.2.S.2.6 & 3.2.S.3 not provided) Firm has not submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process & controls and container closure system. Firm has submitted specifications (3.2.S.4.1), analytical procedures (3.2.S.4.2) and its verification (3.2.S.4.3.1), batch analysis (3.2.S.4.4) and justification of specification, reference standard (3.2.S.5). The firm has submitted Certificate of Suitability to the Monograph of the European Pharmacopoeia (CEP) issued by EDQM. The certificate of suitability is issued vide No. R1-CEP 2010-078 - Rev 00 dated 22.04.2016. The certification is valid as per online record of EDQM (Substance No. 1673)
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted. Long term: 25±2°C, RH 60%±5% (Zone II) 36 months Accelerated: 40±2°C, RH 75%±5% 6 months. Batches: 090401G, 090402G, 090403G

		Degradation studies are also submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description , manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (20392, 20393, 20394), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test Product:** Isoflurane- Pharmastars **Reference Product:** Aerrane Details of batch numbers and comparison of test parameters is not provided. The firm has claimed that their product is equivalent to innovator product A As per EMA guideline on the investigation of bioequivalence "if the product is a gas for inhalation, bioequivalence studies are not required."
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Carton box containing amber glass bottle (Type III) containing 100ml liquid, covered with screw cap with inner liner made of polypropylene and violet polyethylene plastic collar with insert leaflet.
	Stability study data of drug product, shelf life and storage conditions	Shelf life 24 months Storage conditions: store at temperature not exceeding 30°C Stability Studies conditions: Long term: 30°C ± 2°C, RH 65% ± 5% (upto 12 months) Accelerated: 40°C ± 2°C, RH 75% ± 5% (upto 6 months) Batches: 20392, 20393, 20394 (Commercial batches)
	Therapeutic indications in USFDA.	FORANE (isoflurane, USP) may be used for induction and maintenance of general anesthesia. Adequate data have not been developed to establish its application in obstetrical anesthesia.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.		Copies of following documents are submitted, their original legalized copies are required; i. COPP. ii. GMP certificate. iii. Authorization Letter.	• The firm has submitted legalized COPP. • GMP certificate is not legalized but is verifiable from official website of Egyptian Drug Authority. • p-850-2022.pdf (edaegypt.gov.eg) • Notarized Authorization letter is submitted.
2.	**3.2.S.7**	Stability studies of drug substance done by drug substance manufacturer as per ICH guidelines for Zone-IVa along with details of container closure system are required.	Submitted. Long term: 25±2°C, RH 60%±5% (Zone II) Accelerated: 40±2°C, RH 75%±5%

3.	**3.2.P.2.2.1**	It is mentioned that your product is pharmaceutically equivalent to innovator product Aerrane. Batch Numbers, manufacturing date, expiry date and comparison of both products is not provided. Further pictorial evidence of Aerrane used for comparison is required indicating its batch number, manufacturing date and expiry date.	The MA holder has submitted Pharmaceutical equivalence studies, **Test product:** Isoflurane-Pharmastars Pharmaceuticals. Batch No. 220814, 220815, 220816. **Reference product:** Isoflurane-Genomics Batch No. 22655001, manufactured by The Arab Company for Gelatin and Pharmaceutical Products – Egypt. **Parameters compared:** Appearance, solubility, Identification, Limit tests for Chloride, impurities, fill volume and assay. As per comparison, both products are pharmaceutically equivalent.
4.	**3.2.P.5.1**	Finished product specifications are claimed to be Ph. Eur Specifications but assay specifications are mentioned as USP. Clarification is required.	The reply of firm is reproduced below; "Regarding assay specifications, there is no actual chemical test for the assay in both EP and the USP monographs. The only chemical test is for the quantification of impurities. Only the USP monograph states that assay is calculated by subtracting the sum of percentages of the impurities from 100% and gives a limit of 99.9%-100% The finished product specifications adopted this method of calculation from the USP monograph." The reply of firm is satisfactory.
5.	**3.2.P.5.2**	In procedure for Identification by IR it is written that sample shall be applied to scanning lens of FT-IR apparatus by using glass pipette indicating acquisition of spectra in liquid phase, whereas as per European Pharmacopoeia identification test spectra is to be acquired in gaseous state. Clarification is required for deviation from the pharmacopoeial procedure. Further submit the following; i. Ph. Eur reference spectrum of Isoflurane. ii. IR Spectra of 3 batches of Isoflurane acquired by drug product manufacturer. iii. Evidence of FT-IR equipment capable of acquiring spectra in gaseous phase/ FTIR gas analyser being available with drug product manufacturer.	The drug product manufacturer has given following reply; *"Kindly be informed that identification of isoflurane by FT-IR is done using Bruker Alpha IR instrument in liquid phase due to lack of an instrument capable of measuring the sample in gaseous phase.* *Identification is done using isoflurane EDQM reference standard measured and saved in the instrument library, comparing spectrum of sample with that of standard is done automatically by software"* The drug product manufacturer has deviated from pharmacopoeial testing method for identification of isoflurane due to lack of required instrument.
6.	**3.2.P.8.3**	Shelf life claimed is of 24 months, whereas real time stability data of 3 batches is only submitted for up to 12 months. Complete stability studies data for whole of shelf life of mentioned batches is required.	Required data is submitted for batch No. 20392, 20393 & 20394
Decision: Approved as per Policy for inspection of Manufacturer abroad.			

Case No. 3:

The Authority in its 165th meeting held on 20th July 2023 approved out of que consideration

of Form-5F applications of Carbamazepine tablet received/applied till 31st December 2023 keeping in view of their repaeated shortage/ non-availability reports in the market and to ensure timely access of these drugs to public.

452.	**Name, address of Applicant / Importer**	M/s We Care, Flat B 6, Block 12D, 2nd Floor, G-8 Markaz, Islamabad.
	Details of Drug Sale License of importer	**License No**: DHO-ISB-930 **Address**: We-Care Revolution in Health Care, Flat No. B-6, 2nd Floor, Block D-12, Sector G-8 Markaz, Islamabad. (b) Nil **Validity**: 18.06.2025 **Status**: Distribution License.
	Name and address of marketing authorization holder (abroad)	M/s. Troikaa Pharmaceuticals Ltd. C-1 Sara Industrial Estate, Selaqui, Dehradun, Uttarakhand India.
	Name, address of manufacturer(s)	M/s. Troikaa Pharmaceuticals Ltd. C-1 Sara Industrial Estate, Selaqui, Dehradun, Uttarakhand India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted notarized copy of CoPP certificate (No. WHO-GMP-CERT/17P/1/58/2006/5039) dated 24.06.2022 issued by Directorate General of Medical Health Services, Uttarakhand, India. Name and dosage form on the CoPP certificate mentioned is "TROYPOFOL (PROPOFOL INJECTION BP IV (1% W/V) 20ML VIAL" and name of the product license holder is **Troikaa Pharmaceuticals Ltd. C-1 Sara Industrial Estate, Selaqui, Dehradun, Uttarakhand India.** 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. Validity: 27.05.2024 **GMP:** Applicant has submitted Notarized **Copy** of GMP certificate No. 17P/1/58/2006 dated 01.06.2021 issued by Directorate General of Medical Health Services, Uttarakhand, India in the name of M/s **Troikaa Pharmaceuticals Ltd. C-1 Sara Industrial Estate, Selaqui, Dehradun, Uttarakhand India** having its manufacturing site at same address. The certificate confirms that the firm is following Good Manufacturing practices as per WHO TRS Guidelines. (SVP Ampoule & Vial Non beta lactam) The certificate is valid till 27.05.2024
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of Authorization letter. The letter specifies that product license holder i.e. M/s Troikaa Pharmaceuticals Ltd, **office:** Commerece house – 1, Satya marg, bodakdev Ahmedabad Gujrat India **manufacturing site**: C-1 Sara Industrial Estate, Selaqui, Dehradun, Uttarakhand India **authorizes** M/s We Care, Flat B 6, Block 12D, 2nd Floor, G-8 Markaz,

		Islamabad **as exclusive distributor** for product "Troypofol (Propofol Injecton BP I.V (1%W/V)" in Paksitan The authorization is valid till revoked by Troikaa Pharmaceuticals Ltd.
	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. 6543 dated 08-03-2023.
	Details of fee submitted	PKR 150,000/- vide slip No. 3123580695 Dated: 22-02-2023
	The proposed proprietary name / brand name	**Troypofol 10mg/ml(1%W/V) IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 20ml Vial Contains** Propofol BP…….200mg **Excipients:** Soybean oil USP Glycerol BP Egg Lecithin Water for injection BP
	Pharmaceutical form of applied drug	Emulsion for IV injection or Infusion.
	Pharmacotherapeutic Group of (API)	Other general anesthetics ATC Code: N01AX10
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	1's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	PROPOFOL-LIPURO 1% (10 MG/ML) MHRA Approved.
	For generic drugs (me-too status)	Propofol Lipuro 1% (10mg/ml) 20ml Reg No. 033126 M/s B Braun.
	Module-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 verification, 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 BACHEM SA, Succursale de Vionnaz, Route du Simplon 22 1895 Vionnaz, Switzerland. & M/s Neuland Laboratories Ltd. Unit-II, Plot No. 92-94, 257-259, IDA, Pashamylaram, Isnapur Village, Patancheru Mandal, Sangareddy District, Telangana State, India. (Manufacturer has mentioned 2 source of API)
	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 and 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 studies are submitted; Long term conditions: 5 ± 3°C & 25°C- 60% RH, for 5 years Accelerated = 40°C-75% RH for 6 months. Batches: L-22270-411-003, L-22270-411-004, L-22270-411-005, L-22270-411-021, L-22270-411-022, L-22270-411-024, 5001761, 5002651, 5003446, 5004093, 5004824, 5005445, 1000005184, 1000012637, 1000018794, 1000028887.
	Module-III Drug Product:	Firm has submitted data of drug product including its description , manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (**T236788, T236789, T236790**) justification of specifications, reference standard and materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test Product:** Troypofol (propofol) 10mg/ml Emulsion for injection. Batch No. T236585, Expiry date: 02.21. **Reference Product:** Disoprivan 1% (2ml Vial) Batch No. R16009A, Expiry: 06.2019 manufactured by M/s AstraZeneca GmBH Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Disoprivan 1% (2ml Vial) Batch No. R16009A, Expiry: 06.2019 manufactured by M/s AstraZeneca GmBH by performing following tests; Appearance/description, pH, Assay, Globule Size, Lysolecithin content, Free fatty acid content, Propofol J impurity, and propofol dimer.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	**Primary Packing:** 20mL USP type 1 flint glass vial with bromo butyl rubber closure and blue flip off aluminium seal. **Secondary packing:** 1 vial packed in printed carton along with package insert.

	Stability study data of drug product, shelf life and storage conditions	Shelf life 24 months Storage conditions: Store below 30°C and do not freeze. **Stability Studies conditions:** Long term: 30°C ± 2°C, RH 75% ± 5% (up to 24 months) Accelerated: 40°C ± 2°C, RH 75% ± 5% (up to 6 months) **Batches:** T236585, T236586, T236587 (Commercial batches manufactured from API of M/s Bachem SA) **Batches:** T236560, T236561, T236562 (Commercial batches manufactured from API of M/s Neuland Laboratories)
	Therapeutic indications in MHRA	Diprivan 1% is a short-acting intravenous general anaesthetic for: • Induction and maintenance of general anaesthesia in adults and children >1 month. • Sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children >1 month. • Sedation of ventilated patients >16 years of age in the intensive care unit.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.		Legalized copies of following documents are required; i. COPP ii. GMP certificate of drug product manufacturer.	

Decision: **Approved as per policy for inspection of manufacturer abroad. Registration letter shall be issued upon submission of legalized Original CoPP & Notarized copy of letter of authorization.**

453.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore. DML No. 000799
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate dated 15.12.2022 valid till 11.12.2024 is submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 03.07.2014 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 363 dated 04.01.2023

	Details of fee submitted	PKR 30,000/- Slip No. 30359710551 Dated 07.02.2022
	The proposed proprietary name / brand name	**CARBALIS 200mg TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Carbamazepine……200mg
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide derivatives, ATC Code: N03AF01
	Pharmaceutical form of applied drug	Round biconvex shape, white coloured **film coated tablets**, Alu-PVC blister of 100x10's. Packed in cardboard carton.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	5x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CARBAMAZEPINE NOUMED 200 MG TABLETS - PL 44041/0035 MHRA Approved.
	For generic drugs (me-too status)	Togra 200mg Tablets Reg. No. 085387 M/s Rotex Pharma (Pvt.) Ltd. Islamabad.
	Name and address of API manufacturer.	M/s Zhejiang Jiuzhou Pharmaceutical Co. Ltd. No. 99 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (200100A200310) 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 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 / 75% ± 5% RH for 48 months. Batches: W160612316, W160613317, W160614318.
	Module-III Drug Product:	Firm has submitted data of drug product including 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 product Tegral 200mg tablet Batch No. RK7M, mfg date: 11.2021, Exp date: 11.2023 manufactured by M/s Novartis Pharma (Pakistan) Limited. Tests like DT, Weight variation, Identification, Dissolution and Assay were performed and results of both products are comparable. Dissolution: Acid stage F2: 69.04, Acetate buffer F2: 68.50, Phosphate buffer F2: 70.60 Pictorial evidence of pack of Reference product is not attached
	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 Jiuzhou Pharmaceutical Co. Ltd. No. 99 Waisha Road, Jiaojiang District, Taizhou City, Zhejiang Province, China.		
API Lot No.	200100A200310		
Description of Pack (Container closure system)	Round biconvex shape, white coloured film coated tablets, Alu-PVC blister of 100x10's. Packed in cardboard 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.	20324	20325	20326
Batch Size	233,333 tablets	233,333 tablets	233,333 tablets
Manufacturing Date	06.20	06.20	06.20
Date of Initiation	07.06.22	07.06.22	07.06.22
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)	Not Submitted Submission is optional
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. ZJ220018) dated 26.01.2022 issued by Zhejiang Medical Products Administration China. The certificate specifies that the firm complies with the requirements of the Chinese GMP (=GMP of EU, WHO/ICH Q7). Certificate was valid till 25.01.2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	CARBAMAZEPINE Quantity: 2125 kg Batch No. 200100A200309, 200100A200310 Mfg. Date: 03.2020 Clearance date: 20.03.2020 Invoice No. 20SJ03052 Invoice date: 18.03.2020 API imported for manufacturing of product registered for export purpose.
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:

Sr. No.	Section	Observation	Reply by the firm
1.	2.3.P.5	In description its mentioned that product will be film coated. In Form-5F, the product is not mentioned as film coated tablet. In all other sections of module 3, product is mentioned as film coated. -Innovator product is not film coated whereas the product manufactured for trials is film coated. Clarification is required.	The firm vide letter No. R.A/TP/2023/113 dated 12.07.2023 has stated their product is aqueous film coated. They have said that their product is pharmaceutically equivalent to brand leader Tegral 200mg Tablet. -The firm has not provided any evidence of RRA approved product that is film coated.
2.	3.2.P.5.3	Analytical method validation protocol/Report for dissolution is required.	Submitted vide letter No. R.A/TP/2023/113 dated 12.07.2023

Decision: The Board deferred the case for submission of product development & stability studies data for revised formulation as per innovator drug product i.e., uncoated tablet along with full fee of registration as per SRO 496(I)/2023 dated 17.04.2023.

Case No. 4: Deferred Cases.

454.	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	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. 1305-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.206764738781 Dated 27/12/2021
	The proposed proprietary name / brand name	Estresto 50 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 24.3 mg Valsartan ----------25.7 mg
	Pharmaceutical form of applied drug	Violet color, Oblong shape, plain on both side, film coated tablet
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and

		valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 50 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 24.3/25.7mg tablet of M/s Getz Parma, Karachi. Registration No.093110
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.
	Name and address of API manufacturer.	**Sacubitril & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Valsartan:** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not

		more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, 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	**Sacubitril Sodium:** Stability study conditions (Zone IVb). Real time: 30°C ± 2°C / 75% ± 5%RH for 24 months 0, 3, 6, 9, 12, 18, 24 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **Valsartan:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	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 Savesto 50mg tablet of Getz Pharma, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Savesto 50 mg tablet, batch No. 007FB2 by Getz 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	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.		
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-50-ST-001	EST-50-ST-002	EST-50-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
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. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone Huangyan Taizhou, Zhejiang, China, attested 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.	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:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23

2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given in the analytical method of the drug product manufacture are not the same.	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23
3.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it was a mistake and has submitted correct report vide letter No. HB/0039/DRAP/PEC/23
4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.
6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.** **Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB 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.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th meeting: Keeping in view the request of the firm, the Registration Board further extended time for submission of shortcomings within a period of 6 months of publication of minutes of instant meeting.

455.	Name, address of Applicant / Marketing Authorization Holder	M/S Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)

	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. 1306-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.6954377589 Dated 27/12/2021
	The proposed proprietary name / brand name	Estresto 100 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 48.6 mg Valsartan ----------51.4 mg
	Pharmaceutical form of applied drug	Oval shaped, pale-yellow colored, film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto tablets 100 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 49/51mg tablet of M/s Getz Parma, Karachi. Registration No.093111
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.
	Name and address of API manufacturer.	**Sacubitril Sodium & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Valsartan:** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, 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	**Sacubitril Sodium:** Stability study conditions (Zone IVb). Real time: 30°C ± 2°C / 75% ± 5%RH for 24 months 0, 3, 6, 9, 12, 18, 24 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **Valsartan:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	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 Uperio 100mg tablet (Batch No. TAY84) of Novartis Pharma (Pakistan), Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand 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	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.		
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-100-ST-001	EST-100-ST-002	EST-100-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
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. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone

		Huangyan Taizhou, Zhejiang, China, attested 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.	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:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23
2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given in the analytical method of the drug product manufacture are not the same.	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23
3.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it was a mistake and has submitted correct report vide letter No. HB/0039/DRAP/PEC/23
4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.
6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.**

		complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB 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.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th meeting: Keeping in view the request of the firm, the Registration Board further extended time for submission of shortcomings within a period of 6 months of publication of minutes of instant meeting.

456.	Name, address of Applicant / Marketing Authorization Holder	M/s Herbion Pakistan Pvt Ltd Islamabad.
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd Industrial Triangle Kahuta road, Islamabad. (DML No. 000795)
	Status of the applicant	☒ Manufacturer l ☐ 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. 1307-R & I, Dated 14/01/2022
	Details of fee submitted	PKR 30,000/- vide online deposit slip No.718801025572 Dated 27/12/2021
	The proposed proprietary name / brand name	**Estresto 200 mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril ---------- 97 mg Valsartan ----------103 mg
	Pharmaceutical form of applied drug	Oblong shaped, light-pink colored, film coated tablet, break-line on one side, other side plain, no irregularity.
	Pharmacotherapeutic Group of (API)	Sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker indicated: to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection frac
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	1* 14's (14's) 2*14's (28's)
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Entresto tablets 200 mg Novartis Pharmaceuticals (FDA Approved)
	For generic drugs (me-too status)	Savesto 97/103mg tablet of M/s Getz Parma, Karachi. Registration No.093112
	GMP status of the Finished product manufacturer	Most recent GMP inspection report conducted within last three years required.
	Name and address of API manufacturer.	**Sacubitril Sodium & Valsartan:** Zhejiang Tianyu Pharmaceutical Co., Ltd. Address No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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)	**Sacubitril sodium:** Official monograph of sacubitril sodium does not exist so firm has followed in house specifications. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity SCB-4-Imp-1, SCB-5-Imp-2, SCB-5-I Sodium (chiral isomer, SCB-5-II Sodium (chiral isomer SCB-5-III Sodium (chiral isomer) specifications, analytical procedures and its validation , batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Valsartan:** Official monograph of valsartan exists in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity Valsartan Related Compound A: Not more than (NMT) 1.0% Valsartan Related Compound B: Not more than (NMT) 0.2% Valsartan Related Compound C: Not more than (NMT) 0.1% Any other individual impurity: Not more than (NMT) 0.1% Total impurities: Not more than (NMT) 0.3%, 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	**Sacubitril Sodium:** Stability study conditions (Zone IVb). Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months 0, 3, 6, 9, 12, 18, 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months at 0, 1, 2, 3, 6 months Batches: (13700-181001, 13700 -181002, 13700-181003) **Valsartan:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months 0, 3, 6, 9, 12, 18, 24, 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (201207301, 201207302, 201207303)
	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 Uperio 200mg tablet (Batch No. THU47) of Novartis Pharma (Pakistan), Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand 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	**Sacubitril Sodium:** Method validation studies including linearity, range, accuracy, precision, intermediate precision, repeatability, robustness, specificity, LOD and LOQ. **Valsartan:** Verification studies for valsartan including Linearity, range, accuracy, precision (repeatability) and specificity along with chromatograms and raw data sheets submitted.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China.
API Lot No.	Sacubitril Sodium (222920-210103) & Valsartan (10252-210201)
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's) (2×14's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	EST-100-ST-001	EST-100-ST-002	EST-100-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	3-08-2021	3-08-2021	3-8-2021
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. 201904044 issued by Zhejiang Medicine Center for Economic Development valid till 02/06/2022. Scope of inspection include (Sacubitril Sodium Valsartan).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. TY121266 dated 19-03-2021 for import of 1.6kg Sacubitril Sodium and 1.7kg Valsartan USP from Zhejiang Tianyu Pharmaceutical Co., Ltd. Jiangkou Development Zone Huangyan Taizhou, Zhejiang, China, attested 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.	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:-(PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.4	Peak areas given for replicates 2-5 of standard injections for assay determination of Sacubitril sodium are different than those mentioned in corresponding chromatograms (sample information).	Revised calculation sheet submitted vide letter No. HB/0039/DRAP/PEC/23
2.		The assay calculation formula as given in the analytical procedure by the drug product manufacturer is different than that given in analytical method validation protocol/data of the drug product manufacturer. Moreover, the assay calculation formula as mentioned in the analytical method of the drug substance manufacturer and that given in the analytical method of the drug product manufacture are not the same.	Corrected formula submitted vide letter No. HB/0039/DRAP/PEC/23

3.		The run time for Valsartan USP given as 40 minutes in analytical method by the drug substance manufacturer, while the chromatograms for method verification data showed run time around 15-20 minutes. Moreover, retention time of valsartan in method verification chromatograms/data is about 5.5 minutes while the chromatograms for assay determination of valsartan (Batch No.10252-210201) has Retention time of 13.1 minutes.	Firm has stated vide letter No. HB/0039/DRAP/PEC/23 dated 22.06.2023 that analysis was performed according to USP; drug substance manufacturer method claims 40 minutes but USP does not recommend 40 minutes The standard retention time in verification studies is 5.5 minutes updated analysis is attached having same retention time i.e. 5.5 minutes While previous submitted analysis having 13.1 retention time was due to human error & instrumental error. Although both reports having same and satisfactory results.
4.	3.2.P.2.2.1	In the procedure for CDP, the time point for sample withdrawal mentioned as 45 minutes, while in dissolution parameters for CDP and raw data sheets, the time points mentioned as 10, 15, 20, 30, 45 and 60 minutes.	Firm has stated that it's a typographic error and has been corrected
4.	3.2.P.5.2	Wavelength mentioned as 267nm under chromatographic conditions, however, as per reference/innovator's product dissolution method/parameters, the detection wavelength (HPLC/UV) given as 255 nm.	Firm has stated that it is their in-house method and is validated.
5.		The flow rate in analytical method of drug product given as 1ml/min however, in method validation protocol for the drug product the flow rate given as 0.8ml/min.	Firm has stated that it is a typographic error and has been corrected to 0.8ml/min.
6.		As per various documents such as CoA of APIs from substance manufacturer and drug product manufacturer, import invoice, AD (I & E) clearance certificate, product development data, trial batch manufacturing record and separate stability summary data sheets for Sacubitril sodium and Valsartan by the drug substance manufacturer reflect that Sacubitril sodium and Valsartan used as separate materials, while the innovator product is designed as a combination of sacubitril and valsartan in a co-crystal, is a salt complex comprising LCZ696 (Sacubitril/Valsartan anionic moieties), sodium cations, and water molecules. Please justify how the applied formulation is in line with innovator's product.	**The firm has stated that they have developed product 'Estresto tablet' with claims as Sacubitril/Valsartan 24mg/26 mg, Sacubitril/Valsartan 49mg/51mg and Sacubitril/Valsartan 97mg/103 mg.** **This happened only because of availability of Raw materials at the time of development which was the peak era of Covid-19 and there were lot of issues in importing raw materials.** **Now their R&D team has started product development using Sacubitril valsartan complex, its trial batch is under development please** **They will also share the initial data as it will be charged on stability** **Form 6 of Sacubitril valsartan complex is also provided.**
7.		Most recent GMP compliance inspection report conducted within last three years.	Firm has submitted GMP certificate valid till 03.07.2024

Decision of 324th RB 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.

Remarks of Evaluator: The firm has submitted reply in compliance to decision of 324th meeting of RB but they will require more time to submit stability data of batches manufactured from Sacubitril valsartan complex. The firm has submitted initial data in which product is placed on stability in July 2023.

Decision of 330th meeting: Keeping in view the request of the firm, the Registration Board further extended

time for submission of shortcomings within a period of 6 months of publication of minutes of instant meeting.

Case No. 5: Form-5 Deferred Cases

457.	Name and address of manufacturer/ Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name + Dosage Form + Strength	Brethease 400mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….400mcg
	Diary No. Date of R & I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective beta2–adrenergic agonist
	Type of Form	Form 5.
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Not confirmed
	Me-too status	Combivair 400mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Remarks of the Evaluator	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: Confirmation of approval of formulation by the stringent regulatory agencies. Confirmation of API in ultramicronized form.
	Remarks of the Evaluator	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: *―In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."*
	Decision of 289th meeting of RB	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.
	Remarks of the Evaluator	The firm vide letter No. nil dated 13.06.2023 has submitted a revised formulation along with fee of Rs. 30,000/-. The revised formulation is; <u>Each Capsule Contains;</u> Budesonide…….400mcg Formoterol Fumarate…….12mcg

		(Innovator's Specifications) For reference of RRA approval, firm has provided information of Symbicort Turbohaler 400/12 Inhalation Powder MHRA approved. **The reference product is a multi-dose dry powder inhaler, whereas reference product is a capsule to be loaded in a DPI device.** The firm couldn't provide proper evidence of RRA approval of applied formulation.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
458.	Name and address of manufacturer/ Applicant	**M/s Bio-Mark Pharmaceuticals.** 527-Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	**DIVAL Suspension 250mg/5ml**
	Composition	Each 5ml contains: Sodium valproate eq to valproic acid…250mg
	Diary No. Date of R & I & fee	Diary No: 6176, 14/06/2017, Rs: 20,000/-
	Pharmacological Group	Anti-epileptic drug.
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	60ml, 120ml/ As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEPAKENE (valproic acid) oral solution by M/s AbbVie Inc, USFDA approved.
	Me-too status	Epilax Syrup 250mg/5ml by M/s Vision Pharmaceuticals (Reg#037571)
	GMP status	NEW LICENCE.
	Remarks of the Evaluator	Firm has claimed Innovator"s specifications but product monograph is available in USP.
	Decision of 272nd meeting of registration board.	Deferred for evidence of approval of formulation in suspension dosage form in Reference Regulatory Authorities.
	Remarks of the Evaluator Decision of 289th meeting of RB Remarks of the Evaluator	The firm vide letter N. DRA/035/2023 dated nil has submitted following new formulation; Dival Syrup 250mg/5ml Each 5ml contains; Sodium Valproate eq to Valproic Acid…250mg The firm has not submitted any fee for the changes and have also not mentioned specifications of the finished product.
	Decision: Approved with Innovator's specifications as per following label claim: **Dival Syrup 250mg/5ml** **Each 5ml contains;** **Sodium Valproate eq to Valproic Acid…250mg** • **The firm shall submit fee for correction/pre-approval change in product composition and label as per SRO496(I)/2023 dated 17.04.2023, before issuance of registration letter.**	
459.	Name and address of manufacturer/ Applicant	**M/s Bio-Mark Pharmaceuticals.** 527-Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	MENTINE Oral syrup

	Composition	Each 5 ml Contains: Memantine Hydrochloride…….10mg
	Diary No. Date of R & I & fee	Dy. No.6181 dated 14-06-2017; Rs.20,000/- dated 13-06- 2017. **Duplicate Dossier** Dy. No 10014 dated 20-04-2022
	Pharmacological Group	Glutamate NDMA receptor Antagonist
	Type of Form	Form-5
	Finished product Specification	Innovator‟s specifications
	Pack size & Demanded Price	1*120ml, As per DPC.
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Mantin Syrup by M/s Pharmasol (Pvt) Ltd (Reg# 089890)
	GMP status	GMP certificate was issued on 19-05-2020 on the basis of inspection conducted on 13-02-2020
	Remarks of the Evaluator	Firm has claimed Innovator‟s specifications but product monograph is available in USP.
	Decision of 272nd meeting of registration board.	Deferred for evidence of approval of formulation in suspension dosage form in Reference Regulatory Authorities.
	Remarks of the Evaluator	evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 321st meeting of RB	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
	Remarks of the Evaluator	The firm vide letter No. DRA/028/2023 dated nil has submitted following evidence of RRA approval; Memantine Clonmel 10mg/ml Oral Solution HPRA Ireland approved. The firm initially applied for 10mg/5ml strength, now in reply firm has mentioned strength of 10mg/ml but have not submitted revised Form-5 nor the requisite fee. Neither firm has submitted Me-too reference as per revised label.
	Decision: Approved with Innovator's specifications as per following label claim: **Each ml contains;** **Memantine Hydrochloride…….10mg** **The firm shall submit fee for correction/pre-approval change in product composition and label as per SRO496(I)/2023 dated 17.04.2023, before issuance of registration letter.**	
460.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt. Ltd Karachi.
	Brand Name + Dosage Form + Strength	Osmin-D Suspension
	Composition	Each 5ml of Suspension contains: Vitamin D…400 IU Ossein Mineral Complex….400 mg
	Diary No. Date of R & I & fee	Diary No: 2749, 15/12/2016, Rs. 20,000/-

	Pharmacological Group	Vitamin + Mineral
	Type of Form	Form-5
	Finished product Specification	Mfg. Specs.
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	International availability not mentioned.
	Me-too status	Osnate-D Suspension by M/s. AGP Ltd., Karachi.
	GMP status	GMP inspection conducted on 21-02-2019, concluded with the following remarks: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator	□ International availability not confirmed. □ Evidence of atomic absorption spectrophotometer confirmed Firm has claimed in house specs but not provided the following documents in the light of decision of 267th RB meeting Product and formulation development data Manufacturing method development and process validation Analytical method development and validation against innovator's analytical method and innovator's product Comparative pharmaceutical equivalence against innovator's product including comparative dissolution profiling □ Stability data of the product for accelerated and real time period against innovator's product as a reference
	Decision of 269th meeting of registration board.	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and Minutes of 296th Meeting of Registration Board | 2190 detailed composition of ossein mineral complex.
	Remarks of the Evaluator	□ Firm provide the evidence of Me-Too product Osnate-D Suspension registered in the name of M/s. AGP Ltd., Karachi (Reg. No. 070854) □ Complete composition of ossein mineral complex is as under: Ossein Mineral Complex Corresponds to: Calcium…85.59 mg

		Phosphorus…39.61 mg Residual mineral salts…12 mg Collagen…107.95mg Other proteins…32 mg Trace Elements…Fl, Mg, Fe, Ni, Cu
	Decision of 296th meeting of RB	**Deferred for confirmation of availability of Atomic Absorption Spectrophotometer for testing of these products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 11.04.2023 has submitted qualification report of atomic absorption. RRA reference is available as approved by ANSM of France.
	Decision: Approved with Innovator's specifcations as per following label claim: **Each 5ml of Suspension contains:** **Vitamin D…400 IU** **Ossein Mineral Complex** **Corresponds to:** **Calcium…85.59 mg** **Phosphorus…39.61 mg** **Residual mineral salts…12 mg** **Collagen…107.95mg** **Other proteins…32 mg** **Trace Elements…Fl, Mg, Fe, Ni, Cu** **Firm shal submit fee of Rs. 7,500 for pre-approval change/correction in drug product specifications, as per SRO 496(I)/2023 dated 17.04.2023.**	
461.	Name and address of manufacturer/ Applicant	M/s Maxitech Pharma Pvt. Ltd Karachi.
	Brand Name + Dosage Form + Strength	Osmin Suspension
	Composition	Each 5ml of Suspension contains: Ossein Mineral Complex……..250 mg
	Diary No. Date of R & I & fee	Diary No: 2748, 15/12/2016, Rs. 20,000/-
	Pharmacological Group	Vitamin + Mineral
	Type of Form	Form-5
	Finished product Specification	Mfg. Specs.
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	International availability not mentioned.
	Me-too status	Osmin Suspension by M/s Himont Pharmaceuticals.
	GMP status	GMP inspection conducted on 21-02-2019, concluded with the following remarks: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator	□ International availability not confirmed. □ Evidence of atomic absorption spectrophotometer confirmed Firm has claimed in house specs but not provided the

		following documents in the light of decision of 267th RB meeting Product and formulation development data Manufacturing method development and process validation Analytical method development and validation against innovator's analytical method and innovator's product Comparative pharmaceutical equivalence against innovator's product including comparative dissolution profiling □ Stability data of the product for accelerated and real time period against innovator's product as a reference
	Decision of 269th meeting of registration board.	Registration Board in its 269th meeting decided as under: Minutes of 296th Meeting of Registration Board | 2191 Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and detailed composition of ossein mineral complex.
	Remarks of the Evaluator	□ Firm provide the evidence of Me-Too product Ossogin Suspension registered in the name of M/s. Himont Pharmaceuticals (Reg.no.031858) □ Firm provide the complete composition of ossein mineral complex which is as under: Ossein Mineral Complex Corresponds to: Calcium….53.5 mg Phosphorus…24.75 mg Residual Mineral Salts….7.5 mg Collagen….67.46 mg Other proteins….20mg Trace elements…. (Fl, Mg, Fe, Zn, Cu & Ni)
	Decision of 296th meeting of RB	**Deferred for confirmation of availability of Atomic Absorption Spectrophotometer for testing of these products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 11.04.2023 has submitted qualification report of atomic absorption. Firm has not submitted evidence of similar product approval in RRA which was required as per decision of 269th meeting of the Registration Board.
	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 further decided that the applicant shall submit the response within 1 month after publication of the minutes, .	
462.	Name and address of manufacturer/ Applicant	M/s. Sigma Pharma International (Pvt.) Ltd. Plot No. E-50, North Western Industrial Zone, Bin Qasim, Karachi (DML No. 000804) Tablet (General) Section.

	Brand Name + Dosage Form + Strength	NOVOMIT 10mg/10mg Delayed Release Tablet
	Composition	Each delayed release film coated tablet contains; Doxylamine succinate (USP)…..10mg Pyridoxine HCl (USP)……10mg
	Diary No. Date of R & I & fee	Dy. No. 25245 dated 19.02.2017. Fee paid Rs. 20,000/- vide Slip No. 0741983 dated 14-12-2017, endorsed on 19.12.2017. <u>Duplicate dossier:</u> Dy. No. 37507 dated 22.12.2022
	Pharmacological Group	Aminoalkyl ethers, doxylamine, combinations. ATC Code: R06AA59
	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	Xonvea 10 mg/10 mg gastro-resistant tablets (doxylamine succinate and pyridoxine hydrochloride) - PL 16853/0147 MHRA Approved.
	Me-too status	Nausidox 10mg/10mg Tablet. Reg. No. 076292 M/s OBS Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 06.07.2022. GMP status is good. GMP certificate valid till 05.07.2024 is submitted.
	Remarks of the Evaluator	-
	Decision of 326th RB meeting.	**Deferred for evidence of bi-layer tablet manufacturing facility.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 27.05.2023 has submitted that their applied product is not bilayer so they do not need a bilayer tableting machine. It is further added that products approved by MHRA and USFDA are also not bilayer. As per products approved by RRA, it can be a single tablet that is delayed release.
	Decision: Approved.	
463.	Name and address of manufacturer/ Applicant	M/s Ethical Loboratories Pvt Ltd, 14 KM, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	OLO 0.1% eye drop solution
	Composition	Each ml contains: Olopatadine HCL…1mg
	Diary No. Date of R & I & fee	Dy. No. 3456; 25.01.2019 PKR. 20,000/-; 25.01.2019 PKR. 20,000/-; 07.05.2020
	Pharmacological Group	Other antiallergics
	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	Pataday twice daily relief / Patanol (olopatadine hydrochloride ophthalmic solution) 0.1%. USFDA approved.

	Me-too status	Ogate 0.1% Ophthalmic Solution. Reg. No. 75915.
	GMP status	The firm was inspected on 21.11.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator	• The firm revised the dosage form in line with the reference product with submission of Rs. 20000/- fee. The fee challan has not been endorsed by the Division of Budget and accounts. • Undertaking at the end of Form 5 is missing.
	Decision of 295th RB meeting.	Deferred for following: (M-295th) • Submission of fee for revision of formulation after getting endorsement from Budget and Account Division. • Submission of undertaking of Form 5.
	Remarks of the Evaluator	The firm submitted the required undertaking and copy of the challan (not been endorsed by the Division of Budget and accounts).
	Decision of 313th meeting:	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Remarks of the Evaluator	Submission by the firm: The firm has submitted copy of last inspection report dated 08-03-2022. The panel recommended the renewal of DML. Eye drops section (Non-Steroidal) approved.
	Decision of 322nd meeting	Registration Board was apprised that the firm had requested change of strength of the applied formulation from 0.1% to 0.2% Ophthalmic solution. The Board discussed that since both of the strengths are approved in reference regulatory authorities, therefore the Board did not accede to the request of firm.
	Remarks of the Evaluator	The vide letter No. nil dated 02.062023 has stated that they never requested for change of formulation from 0.1% to 0.2%, they had only revised it as per innovator. The label requested by firm is reproduced below; Each ml of solution contains; Olopatadine (as hydrochloride)…… 1 mg
	Decision: Approved with following label claim; **Each ml of solution contains;** **Olopatadine (as hydrochloride)…… 1 mg**	
464.	Name and address of manufacturer/ Applicant	M/s Gillman Pharmaceuticals. 41/2-A, Phase I & II, Industrial Estate, Hattar, Pakistan By M/s Aulton Pharmaceuticals.Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Keto 30mg/1ml Injection
	Composition	Each 1ml Amber Glass Ampoule Contains: Ketorolac tromethamine…30mg
	Diary No. Date of R & I & fee	Dy.No 41506 dated 07-12-2018 **Rs.20,000/-**

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5"s (1ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Tekac Injection of M/s Sami
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of the Evaluator	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. Justification on scientific grounds for addition of 5% overage in master formulation.
	Decision of 295th RB meeting.	**Deferred for the following:** Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. Justification on scientific grounds for addition of 5% overage in master formulation. Remaining fee for contract manufacturing Updated GMP status of the applicant firm from QA&LT Division.
	Remarks of the Evaluator	The firm vide letter No. nil dated 23.06.2023 has stated ampoules will be terminally sterilized Type of glass used is USP type I. There is no overage in product, it was actually potency adjustment based on assay of drug substance. The reply of firm is acceptable, but initial fee mentioned in 295th meeting is Rs. 20,000/- for contract it should have been Rs. 50,000/- Updated GMP status is also not submitted.
	Decision: Approved with manufacturing outline as per innovator drug product. Registration letter will be issued upon submission of following: • **Differential fee of Rs. 30,000/- for application of contract manufacturing.** • **Latest GMP inspection report of drug product manufacturer conducted within last three years.**	
465.	Name and address of manufacturer/ Applicant	M/s Gillman Pharmaceuticals. 41/2-A, Phase I & II, Industrial Estate, Hattar, Pakistan By M/s Aulton Pharmaceuticals.Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Summer-D 1ml Liquid Injection
	Composition	Each 1ml Amber Glass Ampoule Contains: Cholecalciferol…5mg
	Diary No. Date of R & I & fee	Dy.No 41703 dated 07-12-2018 Rs.50,000/-

	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5"s (1ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Saf-D injection 5mg of Saaaf Pharmaceuticals,
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of the Evaluator	□ Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. □ Justification on scientific grounds for addition of 30% overage in master formulation.
	Decision of 295th RB meeting.	**Deferred for the following:** **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** □ **Justification on scientific grounds for addition of 30% overage in master formulation.** □ **Updated GMP status of the applicant firm from QA&LT Division.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 23.06.2023 has stated that type of glass used is USP type I. There is no overage in product, it was actually potency adjustment based on assay of drug substance. Updated GMP status is not submitted.
	Decision: Approved with innovator's specifications. The firm shall submit fee for correction/pre-approval change in product specifications as per SRO496(I)/2023 dated 17.04.2023 and latest GMP inspection report of manufacturer before issuance of registration letter.	
466.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Liquid injection ampoule (general) Section
	Brand Name + Dosage Form + Strength	PTNOL 40mg+0.4mg Injection
	Composition	Each injection contains; Phloroglucnol ……....40mg Trimethylphloroglucinol …..0.4mg
	Diary No. Date of R & I & fee	Dy. No. 16269 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782567 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	Other drugs for functional gastrointestinal disorders. ATC Code: A03AX12
	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	Spasfon Solution for injection in ampoule ANSM France Approved.
	Me-too status	Spasfon Injection Reg. No. 018530

		M/s Himont Oharma Lahore.
	GMP status	Last inspection conducted on 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. Volume of injection needs to be defined and also whether it will be an ampoule or vial.
	Decision of 326th RB	**Deferred for following;** **i. Submission of details whether product is ampoule or vial along with its volume.** **ii. Reference of finished product specifications.** iii. **Latest GMP inspection report/ certificate.**
	Remarks of the Evaluator	The firm vide letter No. LVN/DRAP=PE&R/23(3) dated nil has stated as under; i. The product is in Glass Ampoule of 4ml ii. Volume of injection is 4ml iii. Reference of Finished product specifications is Innovator's Specifications. The firm has not submitted fee for above revisions.
	Decision: Approved with Innovator's specifications as per following label claim: **Each 4ml ampoule contains;** **Phloroglucnol ……....40mg** **Trimethylphloroglucinol …..0.4mg** **The firm shall submit full fee of registration for correction/pre-approval change in product composition and label as per SRO496(I)/2023 dated 17.04.2023 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.**	

Agenda of Evaluator PEC-X

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

a. New Cases

	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Fen-50% WSP
	Composition	Each gram contains: Florfenicol…500mg
	Diary No. Date of R& I & fee	Dy.No 20048 dated 16-07-2021 Rs.30,000/- dated 15-07-2021 (slip No. 6810249672)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Naflor Powder of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 049513)
	GMP status	The firm was inspected on 29-10-2018 with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.

	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on 29-10-2018. Shortcomings: • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
468.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Cin Powder
	Composition	Each gram contains: **Neomycin Sulphate**…60mg **Colistin Sulphate**…10mg **Chlortetracycline HCl**…200mg **Spectinomycin Sulphate**…20mg
	Diary No. Date of R& I & fee	Dy.No 20049 dated 16-07-2021 Rs.30,000/- dated 15-07-2021 (slip No. 1066563781)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Streptochlor Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080738)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on 29-10-2018. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
469.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Bate W/S Powder
	Composition	Each gram contains: Amprolium HCl…200mg Ethopabate…20mg
	Diary No. Date of R& I & fee	Dy.No 19759 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 1795357743)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 25000gm ; Decontrolled
	Me-too status	Coxivet Water Soluble Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur (Reg. No.094490)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been

		discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
470.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Cetamol Powder
	Composition	Each gram contains: Vitamin C…50mg **Paracetamol**…200mg Potassium Carbonate…125mg Sodium Bicarbonate…125mg Vitamin E…125mg
	Diary No. Date of R& I & fee	Dy.No 19758 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 091565212)
	Pharmacological Group	Analgesic, Antipyretic, Antioxidant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Paracet Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad (Reg. No. 079826)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
471.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal-Fos W/S Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 19766 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 3591705670)
	Pharmacological Group	Antibacterial, Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled

	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 078240)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium…200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
472.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Flocin-60 W/S Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 19768 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 2366399994)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Ampronil-50 Oral Powder of M/s Westmont Pharmaceutical Industry, Gujar Khan, Distt. Rawalpindi (Reg. No. 063747)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
473.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form +	Wal Flocin-30 W/S Powder

	Strength	
	Composition	Each gram contains: Oxytetracycline HCl…150mg Florfenicol…150mg
	Diary No. Date of R& I & fee	Dy.No 19767 dated 14-07-2021 Rs.30,000/- dated 14-07-2021 (slip No. 7385444368)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Oxy-Floro Water Soluble Powder of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080726)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
474.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Oxy Wal-950 Powder
	Composition	Each gram contains: Oxytetracycline HCl…950mg
	Diary No. Date of R& I & fee	Dy.No 19754 dated 14-07-2021 Rs.30,000/- dated 14-07-2021 (slip No. 423227285736)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Eter Oxytetracycline-95 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No.109842)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
475.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Metha Wal Water Soluble Powder

	Composition	Each gram contains: Methenamine…950mg Vitamin B1…8mg Vitamin B2…9.2mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 19753 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 9469849664)
	Pharmacological Group	Diuretic, Antiseptic, Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Urimin Water Soluble Powder of M/s Attabak Pharmaceutical Industries, Islamabad (Reg. No. 034527)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **clarification regarding solubility of instant formulation** • **latest GMP inspection report conducted within the period of last three years** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
476.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal CTC-20 W/S Powder
	Composition	Each gram contains: Chlortetracycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 19761 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 631994174951)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Claratin Water Soluble Powder of M/s Attabak Pharmaceutical Industries, Islamabad (Reg. No. 049782)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
477.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.

	Brand Name +Dosage Form + Strength	Wal Lin 4.4% Powder
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 19762 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 7526812042)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Lincomin-44 Powder of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 078370)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
478.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Ammar Wal 1% Powder
	Composition	Each gram contains: **Amantadine HCl**…10mg
	Diary No. Date of R& I & fee	Dy.No 19757 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 68477338)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Amantabak 10% Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No.075697)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Registration Board deferred the case forfurther delibeation and directed PE&R Division to present working paper on international regulatory status of "Amantadine Drug for Veterinary use", in upcoming Board meeting.	
479.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Tysin 10% Premix

	Composition	Each gram contains: Tylosin Phosphate…100mg
	Diary No. Date of R& I & fee	Dy.No 19765 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 71661413388)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Lincomiks 10 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113518)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
480.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Mycin W/S Powder
	Composition	Each gram contains: Florfenicol…150mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 19763 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 895851839249)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Neo Flor Water Soluble Powder of M/s Farm Aid Group, Haripur. (Reg. No. 087961)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
481.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form +	Tiamu Wal Powder

	Strength	
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…450mg
	Diary No. Date of R& I & fee	Dy.No 19755 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 58229763)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Tiamubak 45% Oral Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 048170)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
482.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Stonis-550 W/S Powder
	Composition	Each gram contains: Oxytetracycline HCl…3mg Florfenicol…1mg Neomycin Sulphate…1.5mg
	Diary No. Date of R& I & fee	Dy.No 19751 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 956924200)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Ofencin Oral Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 097869)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
483.	Name and address of manufacturer /	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small

	Applicant	Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Racol-60 W/S Powder
	Composition	Each gram contains: Colistin Sulphate…6,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 19750 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 79343093075)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Neflorex 60 Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113529)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
484.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Spira Wal Powder
	Composition	Each gram contains: Lincomycin HCl…50mg Spectinomycin HCl…75mg Spiramycin Adipitate…25mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 19756 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 740102526)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Spiralinc-B Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 079716)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished	

	product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
485.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Diarro Wal Powder
	Composition	Each gm contains: Neomycin sulphate…33.33mg Streptomycin sulphate…33.33mg Sulphaguanidine…0.33gm Kaolin……0.33gm Pectin…….33.33mg Bismuth Subnitrate…0.167gm Vitamin A…….6666.67 I.U
	Diary No. Date of R& I & fee	Dy.No 19752 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 628911632061)
	Pharmacological Group	Antibacterial, Anti diarrheal, Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	12gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Diarroban Powder of M/s Star Labs, Lahore. (Reg. No. 026438)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
486.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Gest Powder
	Composition	Each gram contains: Propionic Acid Calcium…250mg Propionic Acid Sodium…400mg Acetanilide…150mg Magnesium Oxide…125mg Iron II Sulphate…0.4mg Zince sulphate...0.1mg Magnesium Sulphate…0.2mg Copper Sulphate…0.45mg Cobalt Sulphate…0.4mg Sodium Molybdate…0.1mg Sodium Chloride…20mg
	Diary No. Date of R& I & fee	Dy.No 19764 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 3899363984)
	Pharmacological Group	Digestive supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm,

		25000gm ; Decontrolled
	Me-too status	Anigest Powder of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073906)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **testing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant testing facility for minerals i.e., Atomic absorption spectrophotometer.**	
487.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Grow W/S Powder
	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…1mg Vitamin B3…6.25mg Copper Sulphate…0.25mg Magnesium Sulphate…25mg Calcium Chloride…23mg Zinc Sulphate…2.17mg Maganese Sulphate…10mg Potassium Iodide…0.5mg Sodium Selenite…0.01mg DCP (Phosphorous)…150mg Sodium Chloride…120mg Vitamin B6...4mg
	Diary No. Date of R& I & fee	Dy.No 19760 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 266251072927)
	Pharmacological Group	Multivitamins and minerals supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 058842)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

		• Confirmation of relevant **testing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** **Confirmation of relevant testing facility for minerals i.e., Atomic absorption spectrophotometer.**	
488.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ketogen Injection 100ml
	Composition	Each ml contains: **Ketoprofen…**100mg
	Diary No. Date of R& I & fee	Dy.No 18474 dated 01-07-2021 Rs.30,000/- dated 28-06-2021 (slip No. 2916250106)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No.113398)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of Injectable (General) Veterinary section by CLB
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
489.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Tilcos-25 Oral Liquid
	Composition	Each ml Contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 20172 dated 19-07-2021 Rs.30,000/- dated 19-07-2021 (slip No. 2406299309)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Motil Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113537)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved.The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **Fee of Rs. 30,000/- for correction/pre-approval change in formulation (salt form), and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
490.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Primec Super Injection 10ml

	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 20425 dated 27-07-2021 Rs.30,000/- dated 07-07-2021 (slip No. 75176219429)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Selmec Injection (10ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore (Reg. No. 071087)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
491.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Primec Super Injection 50ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 18629 dated 02-07-2021 Rs.30,000/- dated 24-06-2021 (slip No. 70904660958)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ivermec 2% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111547)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit the latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
492.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Primec Super Injection 250ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 20424 dated 27-07-2021 Rs.30,000/- dated 07-07-2021 (slip No. 03648779839)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Confirmation of relevant manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
493.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxyway 5 Injection 250ml
	Composition	Each ml contains: Oxytetracycline HCl 53.91mg eq. to Oxytetracycline ……50mg
	Diary No. Date of R& I & fee	Dy.No 18627 dated 02-07-2021 Rs.30,000/- dated 24-06-2021 (slip No. 75961978247)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Confirmation of relevant manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
494.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Ectomec 10 Injection 250ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 18628 dated 02-07-2021 Rs.30,000/- dated 24-06-2021 (slip No. 57149996568)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Doramec-DMG Injection (250ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 043544)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

		• Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
495.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Allevia 20% Injection 50ml
	Composition	Each ml contains: Sodium Iodide…200mg
	Diary No. Date of R& I & fee	Dy.No 21420 dated 05-08-2021 Rs.30,000/- dated 29-07-2021 (slip No. 7327494652)
	Pharmacological Group	Ionic compound
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies** • **Confirmation of relevant manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
496.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Allevia 20% Injection 100ml
	Composition	Each ml contains: Sodium Iodide…200mg
	Diary No. Date of R& I & fee	Dy.No 21421 dated 05-08-2021 Rs.30,000/- dated 29-07-2021 (slip No. 50847449403)
	Pharmacological Group	Ionic compound
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies** • **Confirmation of relevant manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
497.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 20432 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 70534384404)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
498.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection 20ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 20431 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 82678962247)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017

		• The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
499.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection 100ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 20433 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 77703107862)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
500.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Enisol-10 Injection 10ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 20428 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No.30214461)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Enflox-10% Injection (10ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112210)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No.82386235066) for change of title of the firm.
	Decision: Approved.	
501.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Enisol-10 Injection 100ml
	Composition	Each ml contains: Enrofloxacin…100mg

	Diary No. Date of R& I & fee	Dy.No 20430 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No.14734011547)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Enflox-10% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112213)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No.48831372810) for change of title of the firm.
	Decision: Approved.	
502.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Enisol-10 Injection 50ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 20429 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No.703448758)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Enflox-10% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No.74123025548) for change of title of the firm.
	Decision: Approved.	
503.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Oxymax Injection 50ml
	Composition	Each ml Contains: Oxytetracycline Dihydrate eq. to Oxytetracycline…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 20426 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No.204885083)
	Pharmacological Group	Antibiotic/ anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Mine Injection (50ml) of M/s. Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111570)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.

	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No.98089578) for change of title of the firm. • Correction in formulation (label claim in line with reference product) is required
	Decision: Approved with following label claim: **Each ml contains:** **Oxytetracycline Dihydrate eq. to Oxytetracycline…300mg** **Flunixin as Meglumine…20mg**	
504.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Marbocin Injecion 50ml
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 20427 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No.6266343225)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Marbo-Vetz 10% Injection (50ml) of M/s. Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 099431)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No.25838199284) for change of title of the firm.
	Decision: Approved.	
505.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Tylobar-100% Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…1000mg
	Diary No. Date of R& I & fee	Dy.No 20171 dated 19-07-2021 Rs.30,000/- dated 09-07-2021 (slip No.10962887283)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Tyflox Oral Powder of M/s ICI Pakistan Limited, Life Sciences, Lahore (Reg. No. 099364)
	GMP status	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product).

	Decision: Approved with following label claim: **Each gram contains:** **Tylosin as Tartrate…1000mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation (salt form), and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.before issuance of registration letter.**	
506.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (10 IU/ml) 500ml
	Composition	Each ml Contains: Oxytocin…10 IU
	Diary No. Date of R& I & fee	Dy.No 27701 dated 06-10-2021 Rs.30,000/- dated 23-09-2021 (slip No. 861034407386)
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**500ml**: Decontrolled
	Me-too status	Oxytovetz Injection (500ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 111471)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide conversion of Oxytocin from IU to grams • Confirmation of relevant manufacturing facility i.e. **Injectable Hormone (Veterinary) (LVP)** section
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility i.e. Injectable Hormone (Veterinary) (LVP) section** • **conversion of Oxytocin from IU to grams.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
507.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (5 IU/ml) 500ml
	Composition	Each ml Contains: Oxytocin…5 IU
	Diary No. Date of R& I & fee	Dy.No 27699 dated 06-10-2021 Rs.30,000/- dated 23-09-2021 (slip No. 5433809555)
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide conversion of Oxytocin from IU to grams • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of relevant manufacturing facility i.e. **Injectable Hormone (Veterinary) (LVP)** section
	Decision: Deferred for following: • **conversion of Oxytocin from IU to grams**	

	• **evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** • **confirmation of relevant manufacturing facility i.e. Injectable Hormone (Veterinary) (LVP) section.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
508.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Leucole S Injection 50ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 22620 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 9109408338)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Adicin Injection (50ml) of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 109801)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
509.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Leucole S Injection 100ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 22615 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 69581870255)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Piram Injection (100ml) of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 062144)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
510.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Leucole S Injection 10ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 22614 dated 17-08-2021 Rs.30,000/- dated 09-07-2021

		(slip No. 765351604398)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Lispiracin Injection (10ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 069602)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
511.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (20 IU/ml) 500ml
	Composition	Each ml Contains: Oxytocin…20 IU
	Diary No. Date of R& I & fee	Dy.No 27700 dated 06-10-2021 Rs.30,000/- dated 23-09-2021 (slip No. 157958565706)
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**500ml**: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Registration Board in its 313th meeting, considered and endorsed the decision of Expert Working Group on Veterinary Drugs** *The Expert Working Group on Veterinary Drugs deliberate the case and decided to allow for granting multidose vials for Oxytocin as per following details:* • *Oxytocin .... 10 UI upto 500ml as per Spanish authority approval or any pack size available in any other RRA.* • ***Oxytocin .... 20 UI upto 50ml as per Australian Pesticides and Veterinary medicine Authority approval or any pack size available in any other RRA.***
	Decision: Deferred for submission of fill volume as per recommendations of the Expert Working Group on Veterinary Drugs, presented in 313th meeting of Registration Board.	
512.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection 10ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 22609 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 77983104)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (10ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106694)

	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
513.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 22604 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 10792384591)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (50ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106695)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
514.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection 100ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 22605 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 718116033117)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (100ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106696)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
515.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Marfocin Injection 50ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 22608 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 96427930)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Marbo-Vetz 10% Injection (50ml) Of M/s VETZ Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 099431)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
516.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Marfocin Injection 20ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 22606 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 70110386409)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Marbo-Vetz 10% Injection (20ml) Of M/s VETZ Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 099430)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
517.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Marfocin Injection 100ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 22607 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 3742617210)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Marbo-Vetz 10% Injection (100ml) Of M/s VETZ Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 099432)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
518.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Istal Injection 20ml

	Composition	Each ml contains: **Aceclofenac**…25mg
	Diary No. Date of R& I & fee	Dy.No 22599 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 79358945)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Aceclovetz Injection (20ml) of M/s VETZ Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 088160)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to Ministry of Food Security & Research for opinion regarding therapeutic requirement of applied veterinary drug, keeping in view safety & efficacy parameters.	
519.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Istal Injection 50ml
	Composition	Each ml contains: **Aceclofenac**…25mg
	Diary No. Date of R& I & fee	Dy.No 22613 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 0011250561)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Aklonac Injection (50ml) of M/s Manhattan Pharma, Karachi. (Reg. No. 106765)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to Ministry of Food Security & Research for opinion regarding therapeutic requirement of applied veterinary drug, keeping in view safety & efficacy parameters.	
520.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Istal Injection 100ml
	Composition	Each ml contains: **Aceclofenac**…25mg
	Diary No. Date of R& I & fee	Dy.No 22600 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 591448067924)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.

	Decision: Referred to Ministry of Food Security & Research for opinion regarding therapeutic requirement of applied veterinary drug, keeping in view safety & efficacy parameters.	
521.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isxine Injection 10ml
	Composition	Each ml contains: Flunixine Maglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 22601 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 63250434590)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Floonix Injection (10ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 112246)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Flunixine as Maglumine…50mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
522.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isxine Injection 100ml
	Composition	Each ml contains: Flunixine Maglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 22603 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 319960379171)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Floonix Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 112255)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Flunixine as Maglumine…50mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	

523.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isxine Injection 50ml
	Composition	Each ml contains: Flunixine Maglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 22602 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 5130295215)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Floonix Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 112247)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Flunixine as Maglumine…50mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
524.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Injection 50ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 22610 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 0567760383)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Vitamall Injection (50ml) of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 113632)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
525.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Injection 10ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin D3…40,000 IU

		Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 22611 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 777872872243)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Vital-3 Injection (10ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049635)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
526.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Injection 100ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 22612 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 1640330792)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Pro Vade Injection (100ml) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113608)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
527.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 10ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 22617 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 6768206298)
	Pharmacological Group	Multivitamin
	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 strength and pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.

	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
528.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 100ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 22618 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 646015370135)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and apck size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
529.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection 50ml
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…80,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 22619 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 59220361316)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too

		status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
530.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isbectin-T Oral Liquid
	Composition	Each ml contains: Albendazole…100mg Triclabendazole…120mg Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 22616 dated 17-08-2021 Rs.30,000/- dated 09-07-2021 (slip No. 898886931)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,250ml,500ml: Decontrolled
	Me-too status	Triverzole Oral Drench of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 109985)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Syrup (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. The firm shall submit fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
531.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Atoras Injection 100ml
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 21974 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 20416728742)
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml; N/A
	Me-too status	Atrofin Injection (100ml) of M/s A&K Pharmaceutical, Faisalabad. (Reg. No. 102102)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
532.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Meparas Injection 50ml
	Composition	Each ml contains: **Mepyramine Maleate**…50mg

	Diary No. Date of R& I & fee	Dy.No 21972 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 8549203524)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	Meprax Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 112258)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. • **Target species:** i. Cattle and horses ii. Sheep **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
533.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fluximin Injection 50ml
	Composition	Each ml Contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 21976 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 690436359340)
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	FM-50 Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No.111550)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product).
	Decision: Approved with following label claim: **Each ml contains:** **Flunixin as Maglumine…50mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
534.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Rasquon Injection 20ml

	Composition	Each ml Contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 21979 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 81742077545)
	Pharmacological Group	Anti-protozoal
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	20ml; N/A
	Me-too status	Empilex Injection (20ml) of M/s Manhattan Pharma, Karachi. (Reg. No. 109090)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
535.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Heparas Injection 50ml
	Composition	Each ml Contains: Phenoxy-2 Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 21978 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 6784878018)
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	Bio-Hepa Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112182)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
536.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tyloras Injection 100ml
	Composition	Each ml Contains: Tylosin Tartrate…200mg
	Diary No. Date of R& I & fee	Dy.No 21977 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 487832281004)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; N/A

	Me-too status	Tylosin 20% Solution for Injection (100ml) of M/s Chakwal Pharma International, Lahore. (Reg. No. 111212)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • The firm shall submit fee Rs. 30,000/- for correction in formulation (label claim in line with reference product).
	Decision: Approved with following label claim: **Each ml Contains:** **Tylosin as Tartrate…200mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
537.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Gentosin Injection 100ml
	Composition	Each ml contains: Tylosin as Tartrate…100mg Gentamycin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 21975 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 84611691)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; N/A
	Me-too status	Tylogent Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059108)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
538.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Dermaras-25 Injection 50ml
	Composition	Each ml Contains: Pheniramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 21973 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 3780931269)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	Ann-Vil Injection (50ml) of M/s Venus Pharma, Lahaore (Reg.

		No.035158)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
539.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	TG-150 Liquid Injection 100ml
	Composition	Each ml Contains: Tylosin Tartrate…100mg Gentamycin…50mg
	Diary No. Date of R& I & fee	Dy.No 21685 dated 09-08-2021 Rs.30,000/- dated 06-08-2021 (slip No. 94333830013)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tylogent Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059108)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml Contains:** **Tylosin as Tartrate…100mg** **Gentamycin…50mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years, and fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
540.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Brics RTU Injection 10ml
	Composition	Each ml contains: Ceftiofur as HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 18910 dated 06-07-2021 Rs.30,000/- dated 23-06-2021 (slip No. 74086201075)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Jexinel Injection (10ml) of M/s International Pharma Labs

		Lahore (Reg. No.053979)
	GMP status	Inspection conducted on **16-01-2020** concluded fair level of GMP compliance in veterinary sections.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • 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: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
541.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	El-Flostin Solution
	Composition	Each ml Contains: Florfenicol…230mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 18911 dated 06-07-2021 Rs.30,000/- dated 23-06-2021 (slip No. 2504483965)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000ml and 5000ml: Decontrolled
	Me-too status	Flatirox Oral Solution of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh (Reg. No. 112361)
	GMP status	Inspection conducted on **16-01-2020** concluded fair level of GMP compliance in veterinary sections.
	Remarks of the Evaluator [X]	**Oral Liquid (G) Veterinary** section confirmed vide panel inspection dated 22-08-2022 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Conversion of Colistin Sulphate from MIU to grams
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years.** • **conversion of Colistin Sulphate from MIU to grams.** • **fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
542.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Enrocol Oral Solution 100ml
	Composition	Each ml Contains: Enrofloxacin…100mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 22922 dated 23-08-2021 Rs.30,000/- dated 29-07-2021 (slip No. 692841977)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	ET-Enrocamallin Oral Liquid of M/s Eterna Pharma (Pvt) Ltd.,Mirpur, AJK (Reg. No. 112147)

	GMP status	Inspection conducted on **16-01-2020** concluded fair level of GMP compliance in veterinary sections.
	Remarks of the Evaluator [X]	**Oral Liquid (G) Veterinary** section confirmed vide panel inspection dated 22-08-2022 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Conversion of Colistin Sulphate from MIU to grams
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years.** • **conversion of Colistin Sulphate from MIU to grams.** • **fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
543.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Diarrocina Powder
	Composition	Each gram Contains: Neomycin sulphate…33.33mg Streptomycin sulphate…33.33mg Sulphaguanidine…0.33gm Kaolin…0.33gm Pectin…33.33mg Bismuth Subnitrate…0.167gm Vitamin A Acetate…6666.67 I.U
	Diary No. Date of R& I & fee	Dy.No 24547 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 79451330)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	12gm: Decontrolled
	Me-too status	Diarroban Powder of M/s Star Labs Lahore (Reg. No. 026438)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Conversion of Vitamin A Acetate from IU to grams
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **Conversion of Vitamin A Acetate from IU to grams.** • **fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
544.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Clomet Suspension
	Composition	Each ml contains: Closantel…50mg Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 24538 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 44684944172)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	500ml and 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **latest GMP inspection report conducted within the period of last three years.** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The applicant shall submit the response within 1 month after publication of the minutes, .**	
545.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Feverceena Oral Solution
	Composition	Each ml Contains: Meloxicam…7.50mg **Paracetamol**…10mg
	Diary No. Date of R& I & fee	Dy.No 24546 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 869217749)
	Pharmacological Group	Antirheumatic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	120ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
546.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Piperacena Suspension
	Composition	Each ml contains: Piperazine…10mg
	Diary No. Date of R& I & fee	Dy.No 24537 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 3900451398)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	

	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The applicant shall submit the response within 1 month after publication of the minutes, .**	
547.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Fendaceena Suspension
	Composition	Each ml Contains: Fenbendazole…150mg
	Diary No. Date of R& I & fee	Dy.No 24541 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No.8609770263)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	1000ml: Decontrolled
	Me-too status	Fenbak 15 Suspension of M/s Attabak Pharmaceuticals, Plot # 5c, I-10/3, Industrial Area, Islamabad.(Reg. No. 062181)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
548.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Avesantal Suspension
	Composition	Each ml contains: Closantel as Sodium Dihydrate…50mg
	Diary No. Date of R& I & fee	Dy.No 24540 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 90258150)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	1000ml: Decontrolled
	Me-too status	Clant Oral Suspension of M/s Elko Organization (Private) Ltd., Karachi. (Reg. No. 075649)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
549.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Sulphacina Suspension
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 24539 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 14876558732)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml and 200ml: Decontrolled
	Me-too status	NES-Bromine ET Oral Suspension of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113514)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
550.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Deworcena Suspension
	Composition	Each ml contains: Triclabendazole…85mg Oxfendazole…22.65mg
	Diary No. Date of R& I & fee	Dy.No 24549 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 6911223688)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Hitverm Drench of M/s Manhattan Pharma, Karachi. (Reg. No. 106767)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
551.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Avifen Plus Suspension

	Composition	Each ml contains: Fenbendazole…25mg Selenium Sulphide…0.40mg Cobalt Sulphate…0.94mg
	Diary No. Date of R& I & fee	Dy.No 24545 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 636927857)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 500ml, and 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. • The firm has submitted list of equipments for confirmation of testing facility (HPLC, FTIR, Flame photometer, UV spectrophotometer) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **latest GMP inspection report conducted within the period of last three years.** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
552.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Avizol Granules
	Composition	Each gram contains: Albendazole…200mg
	Diary No. Date of R& I & fee	Dy.No 24548 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 5642010294)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm: Decontrolled
	Me-too status	Alzo-20 Powder of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. (Reg. No. 092171)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
553.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form +	Cennagest Powder

	Strength	
	Composition	Each gram contains: Propionic Acid Calcium…250mg Propionic Acid Sodium…400mg Acetanilide…150mg Magnesium Oxide…125mg Iron II Sulphate…0.40mg Zinc Sulphate...0.10mg Magnesium Sulphate…0.20mg Copper Sulphate…0.45mg Cobalt Sulphate…0.40mg Sodium Molybdate…0.10mg Sodium Chloride…20mg
	Diary No. Date of R& I & fee	Dy.No 24542 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 90486083)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm: Decontrolled
	Me-too status	Evegest Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 093833)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. • The firm has submitted list of equipments for confirmation of testing facility (HPLC, FTIR, Flame photometer, UV spectrophotometer) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
554.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Triclacina Suspension
	Composition	Each ml contains: Triclabendazole…120mg Albendazole…100mg Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 24543 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 38525948118)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, and 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).

		• **Ivermectin …2gm** is mentioned on cover letter while **Ivermectin …0.2gm /100ml** is mentioned in label claim on Form-5; clarification regarding applied strength is required. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Clarification regarding applied strength since varied composition si mentione in coveing letter and submitted Form 5.** • **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, .**	
555.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Trimectin Suspension
	Composition	Each 100ml Contains: Triclabendazole…5g Ivermectin…100mg
	Diary No. Date of R& I & fee	Dy.No 24544 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 798417062682)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, and 1000ml: Decontrolled
	Me-too status	Trimall Oral Suspension of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 112226)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
556.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Kamas Off 2Km, Multalib Road, Near Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Mili Calfosfocin Oral Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…50mg Fructose 1,6 Diphosphate…180mg Sodium Phosphate…150mg Magnesium Phosphate…100mg Sodium Chloride q.s.…1000mg
	Diary No. Date of R& I & fee	Dy.No 28436 dated 15-10-2021 Rs.30,000/- dated 14-10-2021 (slip No. 3877364599)
	Pharmacological Group	Antibiotics-Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm and 5000gm: Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator [X]	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium…200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride q.s.…1000mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
557.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Kamas Off 2Km, Multalib Road, Near Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Mili Alben 10% Drench
	Composition	Each ml Contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 28434 dated 15-10-2021 Rs.30,000/- dated 14-10-2021 (slip No. 890469735418)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml and 1000ml: Decontrolled
	Me-too status	Albatop-10% Drench of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078334)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator [X]	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Predex Injection 10ml and 50ml
	Composition	Each ml Contains: **Prednisolone Acetate**…7.5mg **Dexamethasone as Sodium Phosphate**…2.5mg
	Diary No. Date of R& I & fee	Dy.No 24722 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 09534344)
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10ml and 50ml: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** by the Central Licensing Board. • Revise Form-5 along with its enclosures since Predex injection (**Prednisolone Acetate…7.5mg/ml and Dexamethasone as Sodium Phosphate…2.5mg/ml)** is mentioned on cover letter while Clarification regarding the applied formulation and demanded pack size is required • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 10ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: **i. Me too Status.** **ii. Confirmation of facility for Injecatble Steroids (Veterinary)**	
559.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceftin Injection 50ml
	Composition	Each ml Contains: Ceftiofur as HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 24725 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 829114329)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Excefur Injection (50ml) of M/s S.J. & G Fazul Ellahie (Pvt) Limited., Karachi. (Reg. No. 063704)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** by the Central Licensing Board.
	Decision: Deferred for confirmation of relevant manufacturing facility. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.	
560.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceftin Injection 10ml
	Composition	Each ml Contains: Ceftiofur as HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 24724 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 55279213)
	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	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** by the Central Licensing Board. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied 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,**	
561.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ectocide Injection 100ml
	Composition	Each ml contains: Deltamethrin…25mg
	Diary No. Date of R& I & fee	Dy.No 27293 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 25327212506)
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied dosage form and pack size**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied 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, .	
562.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxivet Oral Liquid
	Composition	Each ml contains: Oxolinic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 27294 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 243308625)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000ml: Decontrolled
	Me-too status	Eter Vet Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 109229)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated

		03-08-2021
	Remarks of the Evaluator [X]	• **Oral Liquid section (General) (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.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
563.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Masti-Nil Oral Liquid
	1Composition	Each ml contains: Calcium Chloride…8mg Ammonium Chloride…50mg Zinc Sulphate…0.025mg Selenium…0.10mg
	Diary No. Date of R& I & fee	Dy.No 28224 dated 13-10-2021 Rs.30,000/- dated 24-09-2021 (slip No.89227140060)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	240ml, 450ml, and 1000ml: Decontrolled
	Me-too status	**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 Liquid section (General) (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. • The firm has submitted list of equipments for confirmation of testing facility (atomic absorption spectrophotometer). **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **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, .**	
564.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Formatic Acids Oral Liquid
	Composition	Each ml contains: Formic Acid…350mg Propionic Acid…120mg Citric Acid…10mg Lactic Acid…5mg Copper Sulphate…18mg
	Diary No. Date of R& I & fee	Dy.No 27295 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No.74775391847)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml, 1000ml, 5000ml, and 30000ml: Decontrolled
	Me-too status	**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 Liquid section (General) (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. • The firm has submitted list of equipments for confirmation of testing facility (atomic absorption spectrophotometer). **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **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, .**	
565.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Calciphos Oral Liquid
	Composition	Each ml contains: Phosphorus as Pentoxide…110mg Calcium as Calcium Chloride…15mg Sodium as Sodium Chloride…15mg Magnesium as Magnesium Sulphate…22mg Manganese as Manganese Sulphate…2.5mg Zinc as Zinc Sulphate...2.2mg Iron as Ferric Chloride...1.5mg Copper Gluconate...0.49mg
	Diary No. Date of R& I & fee	Dy.No 27296 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No.33254677097)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml, 1000ml, and 5000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Liquid section (General) (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. • The firm has submitted list of equipments for confirmation of testing facility (atomic absorption spectrophotometer). **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **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, .**	
566.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Calcimax Infusion 300ml

	Composition	Each ml contains: Calcium Gluconate…197.5mg Calcium D Sachharate…10mg Magnesium Hypophosphite…50mg Magnesium Chloride…10mg Boric Acid…42.5mg Dextrose…200mg
	Diary No. Date of R& I & fee	Dy.No 24719 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 83153839)
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	300ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• The firm has submitted list of equipments for confirmation of testing facility (atomic absorption spectrophotometer). **Shortcomings:** • Confirmation of **relevant manufacturing facility** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied 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, .**	
567.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mulitpro Injection
	Composition	Each 100ml contains: L-Carnitine…5mg Thioctic Acid...0.20mg Pyridoxine HCl...0.15mg Cyanocobalamin...0.03mg DL-Acetylmethionine...20mg L-Arginine...2.40mg L-Ornithine...1.20mg L-Citruline...1.20mg L-Lysine...0.50mg Glycine...1.50mg Taurine...1.50mg Aspartic Acid...1.50mg Glutamic Acid...1.50mg Fructose...50mg Sorbitol...80mg
	Diary No. Date of R& I & fee	Dy.No 27040 dated 30-09-2021 Rs.20,000/- dated 19-11-2020 & Rs.10,000/- dated 24-09-2021 (slip No. 4609565809)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021

	Remarks of the Evaluator [X]	• The firm has submitted list of equipments for confirmation of testing facility (HPLC). **Shortcomings:** • Confirmation of **relevant manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility** • **Choice of only one pack size** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied 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, .**	
568.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Megavit Injection 100ml
	Composition	Each ml contains: Sodium Selenate…0.5mg Vitamin E…70mg Vitamin B12…100mcg Vitamin B1…20mg Adenosine-5-Phosphoric Acid…5mg Sorbitol…50mg
	Diary No. Date of R& I & fee	Dy.No 24723 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 037467695)
	Pharmacological Group	Supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Selevit Injectable Solution of M/s. Prix Pharma Lahore 023495 **(composition and pack size could not be confirmed)**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size as applied 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, .	
569.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Energizer Infusion 250ml

	Composition	Each 100ml Contains: Caffeine…3.5mg Sodium Salicylate…3.5mg **Novaminsulfon**…40mg Nicotinamide…0.3mg Calcium Gluconate…100mg Magnesium Gluconate…10mg Boric Acid…10mg Sorbitol…200mg Soidum Alpha-Oxybenzylphosphonic Acid…5mg Methyl Parahydroxybenzoate…0.7mg
	Diary No. Date of R& I & fee	Dy.No 24721 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 22726082596)
	Pharmacological Group	Supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision: Disposed off the instant application on the recommendation of the Expert Working Group on Veterinary Drugs since veterinary drugs containing Novaminsulfon are associated with serious adverse effects like agranulocytosis.	
570.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bromo Menthol Water Soluble Powder
	Composition	Each gram contains: Bromhexine HCl…20mg Menthol…4mg
	Diary No. Date of R& I & fee	Dy.No 27299 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 286992136234)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Z-B Menthol Water Soluble Powder of M/s Zoic International, Lahore. (Reg. No. 099415)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
571.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Super Cool Water Soluble Powder
	Composition	Each gram contains: **Vitamin C**…200mg **Acetyl Salicylic Acid**…67mg Calcium Carbonate…50mg Sodium Chloride…40mg Magnesium Sulphate…40mg Sodium Citrate…0.7mg
	Diary No. Date of R& I & fee	Dy.No 27300 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 8424971818)

	Pharmacological Group	Antipyretic, Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Coolant Powder of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 081721)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
572.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neskep Oral Powder
	Composition	Each gm Contains: Neomycin Sulphate…33.33mg Streptomycin Sulphate…33.33mg Sulfaguanidine…0.33gm Kaolin…0.33gm Pectin…33.33mg Bismuth Subnitrate…0.167gm Vitamin A Acetate…6666.67 IU
	Diary No. Date of R& I & fee	Dy.No 29157 dated 26-10-2021 Rs.20,000/- dated 19-11-2020 & Rs.10,000/- dated 24-09-2021 (slip No. 808816799)
	Pharmacological Group	Antibacterial, Antidiarrheal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 1000gm: Decontrolled
	Me-too status	Dyro-X Powder of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088096)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
573.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Para-Electro C Water Soluble Powder
	Composition	Each gram contains: **Paracetamol**…200mg Vitamin C…50mg Potassium Carbonate…125mg Sodium Bicarbonate…125mg Vitamin E…12.5mg
	Diary No. Date of R& I & fee	Dy.No 27298 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 87676242855)
	Pharmacological Group	Antipyretic, Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Peravit ST-20 Powder of M/s Vetec Laboratories, Rawalpindi. (Reg. No. 097973)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
574.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Electro-C Water Soluble Powder
	Composition	Each gram Contains: **Paracetamol**…20mg Ascorbic Acid…200mg Calcium Carbonate…45mg Magnesium Sulphate…35mg Potassium Chloride…40mg
	Diary No. Date of R& I & fee	Dy.No 27297 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 40561715804)
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
575.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Zoster Oral Suspension
	Composition	Each ml contains: Triclabendazole…85mg Oxfendazole…22.65mg
	Diary No. Date of R& I & fee	Dy.No 27289 dated 04-10-2021 Rs.30,000/- dated 27-09-2021 (slip No. 0943303893)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Twozole Drench of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 099063)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Oral Liquid General Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
576.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Wormec DS Injection
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 27290 dated 04-10-2021 Rs.30,000/- dated 27-09-2021 (slip No. 510178981)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml, 50ml: Decontrolled
	Me-too status	Ivermec 2% Injection (10ml; Reg. No. 111546) and (50ml; Reg. No. 111547) of M/s Grand Pharma (Pvt) Ltd., Islamabad.
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 10ml 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.
	Decision: Approved. Firm shall select only one pack size before issuance of registration letter.	
577.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Strox-34% Injection
	Composition	Each ml contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 29422 dated 28-10-2021 Rs.30,000/- dated 25-10-2021 (slip No. 22381961583)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml: Decontrolled
	Me-too status	Nitroxl Forte Injection (10ml; Reg. No. 106697) and (50ml; Reg. No. 106698) of M/s Mediexcel Pharmaceuticals, Islamabad.
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 10ml 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.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Choice of only one pack size.**	
578.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Astrowan Injection
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 29423 dated 28-10-2021 Rs.30,000/- dated 25-10-2021 (slip No. 4528170785)
	Pharmacological Group	Belladonna alkaloids, tertiary amine
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled

	Me-too status	Atopin Injection (10ml, 25ml, 50ml and 100ml) of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 062122)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 100ml 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.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Choice of only one pack size.**	
579.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Demotin Solution for Injection
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 29425 dated 28-10-2021 Rs.30,000/- dated 25-10-2021 (slip No. 7796447960)
	Pharmacological Group	Avermectin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml: Decontrolled
	Me-too status	Dectron Liquid Injection (10ml; Reg. No. 087093) and (50ml; Reg. No. 087095) of M/s ICI Pakistan Limited, Life Sciences, Lahore.
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 10ml and 50ml 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.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Choice of only one pack size.**	
580.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Metavit-Max Injection
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…50Mcg Taurine…37.3mg Nicotinamide…23mg DL Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 29424 dated 28-10-2021 Rs.30,000/- dated 25-10-2021

		(slip No. 48572491554)
	Pharmacological Group	Mineral supplements
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Fospho-AV Injection (50ml; Reg. No. 088084) and (100ml; Reg. No. 099370) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore.
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. • The firm has submitted list of equipments for confirmation of testing facility (FTIR nicolet 380) **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 100ml 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.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Choice of only one pack size.**	
581.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Cefur DC Intramammary Suspension (10ml syringe)
	Composition	Each ml contains: Ceftiofur as HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 27291 dated 04-10-2021 Rs.30,000/- dated 27-09-2021 (slip No. 443695010194)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	12 x 10ml plastic syringes: Decontrolled
	Me-too status	Spectramast DC Sterile Suspension (10ml) of M/s Ghazi Brothers, Karachi (Reg. No. 092190)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	Approval of **Liquid injection section (veterinary) (Cephalosporin**) confirmed vide letter No.F. 2-10/93-Lic (Vol-I) dated 10-03-2022
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
582.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Vivonex DC Intramammary Suspension
	Composition	Each ml contains: Rifaximin…20mg
	Diary No. Date of R& I & fee	Dy.No 27292 dated 04-10-2021 Rs.30,000/- dated 27-09-2021 (slip No. 35177194284)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	12 x 5ml syringes: Decontrolled
	Me-too status	Fatroximin D.C Intramammary Ointment of M/s Prix Pharmaceutica, Lahore. (Reg. No. 095647)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
583.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Floroxy-M Forte Oral Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 26397 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.7173519642)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Ampronil-50 Oral Powder of M/s Westmont Pharmaceutical Industry, Gujar Khan, Distt. Rawalpindi (Reg. No. 063747)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
584.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Lincomag Oral Powder
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 26400 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.449529034097)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Lincobar-44 Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 088636)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in	

	finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
585.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Linconex-100 Oral W/S Powder
	Composition	Each gram contains: Lincomycin HCl…100mg Colistin Sulphate…800,000 IU
	Diary No. Date of R& I & fee	Dy.No 26410 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.84600497358)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Z-Lincolis Water Soluble Powder of M/s Zoic International, Lahore. (Reg. No. 080941)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
586.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Phosfomax-M Oral Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 26407 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.3733087015)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, and 5000gm; Decontrolled
	Me-too status	Fosomax Oral Powder of M/s Biogen Pharma, Rawat (Reg. No. 063808)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium…200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg**	

	Magnesium Sulphate…100mg **Firm shall submit fee of Rs.30000/- for correction/pre-approval change in formulation (salt form) and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
587.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Ampicox 30 Oral W/S Powder
	Composition	Each gram contains: Amprolium HCl…300mg Sulphaquinoxaline Sodium…200mg Vitamin K3…6mg
	Diary No. Date of R& I & fee	Dy.No 26404 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.6937473165)
	Pharmacological Group	Anticoccidal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Amral-SK Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 112237)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Deferred for solubility of formulation. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.	
588.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Le-Mune Oral Powder
	Composition	Each gram Contains: Lysozyme…220mg Vitamin E 50 SD…5mg
	Diary No. Date of R& I & fee	Dy.No 26409 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.340303522)
	Pharmacological Group	Immunostimulator/Antimicrobial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm and 5000gm; Decontrolled
	Me-too status	Hylise Water Soluble Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112256)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
589.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Urinoflush Oral W/S Powder
	Composition	Each gram contains: Frusemide…20mg Magnesium Sulphate…35mg Maganese Sulphate…1mg

		Potassium Chloride…0.400mg Sodium Chloride…35mg Calcium Carbonate…45mg
	Diary No. Date of R& I & fee	Dy.No 26408 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.107084953151)
	Pharmacological Group	Combination of minerals and diuretic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1000gm, and 5000gm; Decontrolled
	Me-too status	Neyphralyte Powder of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071072)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction in formulation (salt form of furosemide) and change in finished product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated07-05-2021 before issuance of registration letter.	
590.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	M-Flox BC Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.50 MIU Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 26403 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.3945112648)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, and 5000ml; Decontrolled
	Me-too status	EG Supertonic Solution of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 074071)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
591.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	AG Flox-M Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…40mg Guaiphenesin…100mg
	Diary No. Date of R& I & fee	Dy.No 26399 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.46822541559)
	Pharmacological Group	Antibacterial, expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Amino GE 2400 Oral Liquid of M/s Kayans Pharmaceuticals,

		Rawat, Rawalpindi (Reg. No. 111346)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
592.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	M-Brom Plus Oral Solution
	Composition	Each ml contains: Bromhexine HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 26402 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.505257971686)
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml, 2500ml and 5000ml; Decontrolled
	Me-too status	Bromit 5% Oral Solution of M/s Wimits Pharmaceuticals, Lahore. (Reg. No.112386)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
593.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Normin-AG Oral Liquid
	Composition	Each ml contains: **Norfloxacin**…200mg Aminophylline…80mg Guaifenesin…200mg
	Diary No. Date of R& I & fee	Dy.No 26401 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.98562844748)
	Pharmacological Group	Antibacterial, expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, and 5000ml; Decontrolled
	Me-too status	NOR + AG Solution of M/s Biogen Pharma Rawat (Reg. No. 058968)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Disposed off the instant application on the recommendation of Expert Working Group on Veterinary Drugs due to potential of AMR and in the best public health interest.	
594.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form +	Majizaan Drench

	Strength	
	Composition	Each ml contains: Oxyclozanide…60mg Levamisole HCl…30mg
	Diary No. Date of R& I & fee	Dy.No 26406 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.21545535451)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 450ml, and 1000ml; Decontrolled
	Me-too status	Nawazan DS Suspension of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 101445)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
595.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Majitone Oral Suspension
	Composition	Each ml contains: **Silymarin**…21mg Vitamin E…15mg
	Diary No. Date of R& I & fee	Dy.No 26405 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.861675734)
	Pharmacological Group	Hepatoprotective, Antioxidant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Liver Fit Oral Suspension of M/s Westmont Pharmaceutical Industry, Distt. Rawalpindi (Reg. No. 063743)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved.	
596.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Majizole Drench
	Composition	Each ml contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 26398 dated 23-09-2021 Rs.30,000/- dated 20-09-2021 (slip No.16689462636)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 500ml, and 1000ml; Decontrolled
	Me-too status	Bendol 10 Suspension of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113512)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP

		compliance.
	Remarks of the Evaluator [X]	**Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
597.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	E-Sel Grow Oral Liquid
	Composition	Each ml contains: Vitamin C…40mg Vitamin E…200mg Selenium as Sodium Selenite…25mg
	Diary No. Date of R& I & fee	Dy.No 25525 dated 14-09-2021 Rs.30,000/- dated 10-09-2021 (slip No.3215668345)
	Pharmacological Group	Vitamin and mineral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml and 1000ml; Decontrolled
	Me-too status	Soluvit E Plus Liquid of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 057046)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Veterinary Oral Liquid (General)** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 • The firm has submitted list of equipments for confirmation of testing facility. **Shortcomings:** • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Approved.	
598.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Noxin Oral Solution
	Composition	Each ml contains: **Norfloxacin** HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 25522 dated 14-09-2021 Rs.30,000/- dated 10-09-2021 (slip No.606605462)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml and 1000ml; Decontrolled
	Me-too status	Nor-Oxime Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad (Reg. No. 080137)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	**Veterinary Oral Liquid (General)** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 **Shortcomings:** • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Disposed off the instant application on the recommendation of Expert Working Group on Veterinary Drugs due to potential of AMR and in the best public health interest.	
599.	Name and address of manufacturer /	M/s Lucky Core Industries Limited, 45-KM, off

	Applicant	Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Tylofosfin Oral Powder
	Composition	Each gram contains: Calcium Fosfomycin…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 25523 dated 14-09-2021 Rs.30,000/- dated 10-09-2021 (slip No.854280656)
	Pharmacological Group	Antibiotic/ Mineral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	FAS-FO 73 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113592)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	**Oral Dry Powder (General) Veterinary** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 **Shortcomings:** • The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No. 96708637494) for change of title of the firm. • Correction in formulation (salt form) in line with reference formulation is required.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg**	
600.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Vita-Poul Oral Powder
	Composition	Each gram contains: Vitamin A…20,000 IU Vitamin D3…2000 IU Vitamin E…6mg Vitamin K3…5mg
	Diary No. Date of R& I & fee	Dy.No 25524 dated 14-09-2021 Rs.30,000/- dated 10-09-2021 (slip No.46579541912)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Kaaz-ADEK Powder of M/s English Pharma, Lahore (Reg. No. 028510)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	**Oral Dry Powder (General) Veterinary** section confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 18-03-2021 **Shortcomings:**

		• The firm has submitted revised form-5 with its new title along with fee Rs. 30,000/- (slip No. 2858070878) for change of title of the firm.
	Decision: Approved.	
601.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobi Oxfn Powder
	Composition	Each gram contains: Oxytetracycline HCl…300mg Florfenicol…100mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 26350 dated 22-09-2021 Rs.30,000/- dated 22-09-2021 (slip No.967088793554)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Stonis Powder of M/s Nawal Pharmaceuticals, Taxila. (Reg. No. 097977)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
602.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobi Ksulp Powder
	Composition	Each gram contains: Sulphachlorpyridazine Sodium…333.3mg Vitamin K3…30mg
	Diary No. Date of R& I & fee	Dy.No 25521 dated 14-09-2021 Rs.30,000/- dated 14-09-2021 (slip No.72549656)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,250gm, 500gm, 1000gm; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.

	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
603.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobifos-Forte Oral Powder
	Composition	Each gram contains: Fosfomycin Calcium …200mg Tylosin Tartrate…50mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg Sodium Chloride QS…1000mg
	Diary No. Date of R& I & fee	Dy.No 24844 dated 08-09-2021 Rs.30,000/- dated 08-09-2021 (slip No.694663696876)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm; Decontrolled
	Me-too status	Fosbac Plus-T Powder of M/s Tec-Man International, Rawalpindi (Reg. No. 039968)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **Sodium Chloride QS…1000mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years alongwith fee of Rs.30000/- for correction/pre-approval change in formulation (salt form) and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	

	before issuance of registration letter.	
604.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobificoc Powder
	Composition	Each gram contains: **Sulphadimerazine**…100mg **Sulphadiazine**…60mg **Sulphathiazole**…40mg **Trimethoprim**…40mg
	Diary No. Date of R& I & fee	Dy.No 24843 dated 08-09-2021 Rs.30,000/- dated 08-09-2021 (slip No.1611471729)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm; Decontrolled
	Me-too status	TS-30 Powder of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 074002)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
605.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobixol Liquid
	Composition	Each ml contains: Oxolinic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 24842 dated 08-09-2021 Rs.30,000/- dated 08-09-2021 (slip No. 24464208128)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Eter Vet Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 109229)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.**
	Remarks of the Evaluator [X]	Approval of **Veterinary Oral Liquid (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
606.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Meprafar Injection
	Composition	Each ml contains: **Mepyramine Maleate**…50mg
	Diary No. Date of R& I & fee	Dy.No 28968 dated 22-10-2021 Rs.30,000/- dated 15-10-2021 (slip No. 676552239431)
	Pharmacological Group	Antihistamine/ Anti-allergic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	**10ml, 30ml**; Decontrolled
	Me-too status	Elramine Injection (10ml, 30ml) of M/s Elko Organisation (Pvt) Ltd Karachi (Reg. No. 018458)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 10ml and 30ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Title of the firm mentioned on DML is "***M/s Izfaar Pharmaceutical Industries***" while "***M/s Izfaar Pharmaceutical Pvt. Ltd."*** is mentioned on form-5 and fee challan; clarify.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Choice of only one pack size.** • **Clarification regarding title of the firm since on DML "*M/s Izfaar Pharmaceutical Industries*" while "*M/s Izfaar Pharmaceutical Pvt. Ltd."* is mentioned on form-5 and fee challan.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
607.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Maxofar Injection
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 28969 dated 22-10-2021 Rs.30,000/- dated 15-10-2021 (slip No. 72927892)
	Pharmacological Group	Antipyretic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	**10ml, 20ml, 50ml**; Decontrolled
	Me-too status	Fluxim-5% Injection (10ml: Reg. No. 109941; 20ml:109942; and 50ml: 109943) of M/s Univet Pharmaceuticals, Rawalpindi.
	GMP status	

	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Title of the firm mentioned on DML is "***M/s Izfaar Pharmaceutical Industries***" while "***M/s Izfaar Pharmaceutical Pvt. Ltd."*** is mentioned on form-5 and fee challan; clarify.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Choice of only one pack size.** • **Revised form-5 along with fee of Rs.30000/- for correction in formulation (salt form) in line with reference product, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Clarification regarding title of the firm since on DML "*M/s Izfaar Pharmaceutical Industries*" while "*M/s Izfaar Pharmaceutical Pvt. Ltd."* is mentioned on form-5 and fee challan.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
608.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Sulfa-Far Injection 100ml
	Composition	Each ml Contains: Sulphadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 28970 dated 22-10-2021 Rs.30,000/- dated 15-10-2021 (slip No. 45299206)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Sulpharas Injection (100ml) of M/s RAS Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 109954)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Address of the firm mentioned on DML is "***542/A-B, Sundar Industrial Estate, Lahore***" while "***542-A, Sundar Industrial Estate, Lahore"*** is mentioned on form-5. Moreover, title of the firm mentioned on DML and form-5 is "***M/s Izfaar Pharmaceutical Industries***" while "***M/s Izfaar Pharmaceutical Pvt. Ltd."*** is mentioned on fee challan; clarify.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Choice of only one pack size.** • **Clarification regarding title and address of the firm since address of the firm mentioned on DML is "*542/A-B, Sundar Industrial Estate, Lahore*" while "*542-A, Sundar Industrial Estate,***	

	***Lahore"* is mentioned on form-5. Moreover, title of the firm mentioned on DML and form-5 is "*M/s Izfaar Pharmaceutical Industries*" while "*M/s Izfaar Pharmaceutical Pvt. Ltd."* is mentioned on fee challan.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
609.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Trioxysol Oral Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 29004 dated 25-10-2021 Rs.30,000/- dated 20-10-2021 (slip No. 29990313691)
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Stenop Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089846)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Oral Powder (General) Veterinary section** confirmed vide cGMP certificate based upon evaluation conducted on 24-01-2023 and 25-01-2023
	Decision: Approved.	
610.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amino-Vita 250ml Injection
	Composition	Each ml contains: L-Carnitine HCl 6.133mg Eq. to L-Carnitine…5mg Thioctic Acid...0.20mg Pyridoxine HCl...0.15mg Cyanocobalamin...0.03mg D L-Acetylmethionine...20mg L-Arginine...2.40mg L-Ornithine HCl 1.532mg Eq. to L-Ornithine...1.20mg L-Citrulline...1.20mg L-Lysine HCl 0.625mg Eq. to L-Lysine...0.50mg Glycine...1.50mg Taurine...1.50mg Aspartic Acid...1.50mg Glutamic Acid...1.50mg Fructose...50mg Sorbitol...80mg
	Diary No. Date of R& I & fee	Dy.No 23706 dated 30-08-2021 Rs.30,000/- dated 23-08-2021 (slip No. 12207413635)
	Pharmacological Group	Vitamins & other micronutrients
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	250ml vial; Decontrolled
	Me-too status	Multimino-V Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 058712)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.

	Remarks of the Evaluator [x]	• **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • The firm has submitted list of equipments for confirmation of testing facility. **Shortcomings:** • Confirmation of relevant manufacturing facility i.e. **Liquid injectable LVP (veterinary)**
	Decision: Deferred for confirmation of relevant manufacturing facility. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .	
611.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Pregnasure Injection 2.5ml
	Composition	Each ml contains: Buserelin Acetate…0.004mg
	Diary No. Date of R& I & fee	Dy.No 24720 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 5663217879)
	Pharmacological Group	LHRH agonist
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	2.5ml; Decontrolled
	Me-too status	Buserovet Injection (2.5ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 109960)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [x]	**Shortcomings:** • Approval of **Veterinary Liquid vials injection (Hormone)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in label claim in line with reference formulation, finished product specifications and typographic error in brand and generic name on cover letter as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility.** • **fee of Rs. 30,000/- for correction/pre-approval change in label claim in line with reference formulation, finished product specifications and typographic error in brand and generic name on cover letter as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
612.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Pregtin Injection 10ml
	Composition	Each ml contains: Progesterone…25mg
	Diary No. Date of R& I & fee	Dy.No 24718 dated 07-09-2021 Rs.30,000/- dated 02-09-2021 (slip No. 7249572276)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled

	Me-too status	I-Proges Injection (10ml) of M/s International Pharma Labs. Lahore. (Reg. No. 074758)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Veterinary Liquid vials injection (Hormone)** 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: Deferred for confirmation of relevant manufacturing facility. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .	

b. Deferred Cases

613.	Name and address of manufacturer / Applicant	M/s D-Maarson Pharmaceuticals, Plot No. 17, St SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ivoran Plus Injection 10ml
	Composition	Each 100ml Contains: Ivermectin…1gm Vitamin A…2500,000 IU Vitamin D3…3,75,000 IU Vitamin E…2.5gm
	Diary No. Date of R& I & fee	Dy.No 24955 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
	Pharmacological Group	Anthelmintic/ Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Mectin Plus Injection (10ml) of M/s Breeze Pharma Islamabad (Reg. No. 059142)
	GMP status	
	Remarks of the Evaluator [X]	• 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. • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Vitamin A and vitamin D3 from IU to grams.
	Decision of 324th meeting: Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid Injection (Veterinary) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form-5, within six months.	
	Updated status: Liquid Vial Injectable General (Veterinary) section confirmed vide letter No. F. 6-3/2014-Lic (M-234) dated 24-03-2014.	
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **conversion of Vitamin A and vitamin D3 from IU to grams.** • **fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
614.	Name and address of manufacturer / Applicant	M/s D-Maarson Pharmaceuticals, Plot No. 17, St SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ivoran Plus Injection 50ml
	Composition	Each 100ml Contains: Ivermectin…1gm Vitamin A…2500,000 IU

		Vitamin D3…3,75,000 IU Vitamin E…2.5gm
	Diary No. Date of R& I & fee	Dy.No 24956 dated 25-11-2019 Rs.20,000/- dated 25-11-2019
	Pharmacological Group	Anthelmintic/ Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Mectin Plus Injection (50ml) of M/s Breeze Pharma Islamabad (Reg. No. 059142)
	GMP status	
	Remarks of the Evaluator [X]	• 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. • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Vitamin A and vitamin D3 from IU to grams.
	Decision of 324th meeting: Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid Injection (Veterinary) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form-5, within six months.	
	Updated status: Liquid Vial Injectable General (Veterinary) section confirmed vide letter No. F. 6-3/2014-Lic (M-234) dated 24-03-2014.	
	Decision: Approved. The firm shall submit the following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **conversion of Vitamin A and vitamin D3 from IU to grams.** • **fee of Rs. 7500/- for correction/pre-approval change in finished product 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 Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Albofyl D Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…55MIU Bromhexine HCl…0.5mg
	Diary No. Date of R& I & fee	Dy. No 33143 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 300ml, 500ml, 1000ml: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm **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 323rd 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.	
	Updated status: The firm has now revised the formulation as mentioned below: **Each 100ml Contains:** **Enrofloxacin…10gm**	

	Colistin Sulphate…55MIU **Bromhexine HCl…0.5gm** ➢ **Metoo status:** En-C Raft Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi. (Reg. No. 078251) The firm has submitted fee Rs. 30,000/- for revision of label claim via deposit slip no 405866381230	
	Decision: Approved with following label claim: **Each 100ml Contains:** **Enrofloxacin…10gm** **Colistin Sulphate…55MIU** **Bromhexine HCl…0.5gm**	
616.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Toldibar Injection
	Composition	Each 100ml contains: Toldimfos Sodium…20gm Vitamin B-12…5mg
	Diary No. Date of R& I & fee	Dy.No 15018 dated 20-08-2019 Rs.20,000/- dated 19-08-2019
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Tonovit Injetion (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 033253)
	GMP status	
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • 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 324th meeting: Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid Injection (Veterinary) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months.	
	Updated status: Liquid Injection (General) Veterinary section confirmed vide letter No. F. 1-11/2010-Lic (Vol-I) dated 14-09-2017.	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
617.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Sulfa-L Bolus
	Composition	Each Bolus Contains: Sulphadimidine…350mg
	Diary No. Date of R& I & fee	Dy.No 17170 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50s: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded

		satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Bolus section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings**: • Clarification of salt form • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 326th meeting: Deferred for following: • Clarification of salt form • 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 now revised the formulation as mentioned below: **Each Bolus Contains:** **Sulphadimidine HCl…350mg** ➢ **Metoo status:** Sulf-B Bolus of M/s International Pharma Labs. Lahore. (Reg. No. 073930) The firm **has Not** submitted fee Rs. 30,000/- for revision of label claim.	
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for correction/pre-approval change in label claim in line with reference formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
618.	Name and address of manufacturer / Applicant	M/s Epoch Pharmaceuticals, Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ketolin Injection Vet I/M, S/C
	Composition	Each ml injection contains: Oxytetracycline as HCl…….200mg **Ketoprofen**……30mg
	Diary No. Date of R& I & fee	Dy.No.3474 dated 22-01-2019; Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti- infective/ NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml, 100ml & Decontrolled
	Me-too status	Keto- Oxy La Injection M/s International Pharma Labs, Defence Road, Lahore 094412
	GMP status	Last GMP inspection was conducted on 28-09-2020 And the report concludes: "In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board.
	Remarks of the Evaluator	• GMP status is not compliant.
	Decision of 297th 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	
	Updated status: The firm has submitted cGMP certificate dated 20-12-2022 based on inspection conducted on 21-11-2022	

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
619.	Name and address of manufacturer / Applicant	M/s Epoch Pharmaceuticals, Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Trimisole Suspension
	Composition	Each ml Suspension Contains: Triclabendazole……120mg Levamisole HCl……75mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 11417 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 1000ml; Decontrolled
	Me-too status	Flukazole Suspension 19.5% by M/s S.J. & G. Fazul Ellahie (Reg#048297)
	GMP status	The firm was inspected on 28-09-2020 and conclusion of inspection was: In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/ Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board
	Remarks of the Evaluator	• The firm submitted letter No. F. 2-1/94-Lic (Vol. I) dated 14th September 2006 issued by Secretary Central Licensing Board confirming the presence of Veterinary oral. However, it does not confirm whether it is oral liquid or oral powder • The firm submitted complete manufacturing outline
	Decision of 308th meeting: Deferred for following: • Updated status of GMP of the firm from QA & LT division • Evidence of required manufacturing facility / section from licensing division	
	Updated status: The firm has submitted the following: • cGMP certificate dated 20-12-2022 based on inspection conducted on 21-11-2022 • Oral liquid (General) Veterinary section confirmed vide letter No. F. 2-1/94-Lic (Vol-III) dated 10-06-2022	
	Decision: Approved. The firm shall submit fee Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
620.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clomectin Pour on Liquid
	Composition	Each ml Contains: Ivermectin…5mg Closental as Sodium…200mg
	Diary No. Date of R& I & fee	Dy.No 5139 dated 20-03-2020 Rs.20,000/- dated 20-03-2020
	Pharmacological Group	Endectocide (Anthelmintic and ectoparasitic)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter, 20Liter: Decontrolled
	Me-too status	Could not be confirmed in the applied strength and dosage form
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of approval of **Topical Liquid (General)** section. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	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.	
	Updated status: The firm has now revised the brand name and formulation as mentioned below: **Clomectin Oral Liquid** **Each ml Contains:** **Ivermectin…10mg** **Closental as Sodium…125mg** **Demanded pack sizes:** 50ml, 100ml, 200ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 20000ml • **Metoo status:** Iver-Par Oral Liquid of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No.062036) • The firm has submitted fee Rs. 30,000/- vide challan No. 35250379958 for revision of label claim. • **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal	
	Decision: Approved with change in brand name, as per innovator's specifications and with following label claim: **Clomectin Oral Liquid** **Each ml Contains:** **Ivermectin…10mg** **Closental as Sodium…125mg**	
621.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clomisol Injection
	Composition	Each ml Contains: Levamisol as HCl…100mg Closental Sodium Di-Hydrate…5mg
	Diary No. Date of R& I & fee	Dy.No 31453 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**10ml, 20ml, 50ml, 100ml, 450ml, 500ml**: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple

		pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • 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 324th 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: The firm has now revised the formulation as mentioned below: **Each ml Contains:** **Levamisol as base…100mg** **Closental …50mg** **Demanded pack size:** 100ml **Metoo status:** Closole Injection (100ml) of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.062158) • The firm has **NOT** submitted fee Rs. 30,000/- for revision of label claim.	
	Decision: Approved with 100ml pack size, as per innovator's specifications and with following label claim: **Each ml contains:** **Levamisol as base…100mg** **Closental …50mg** **Firm shall submit fee Rs. 30,000/- for correction/pre-approval change in label claim in line with reference formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
622.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Butavit Injection
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…50mcg
	Diary No. Date of R& I & fee	Dy.No 21494 dated 21-10-2019 Rs.20,000/- dated 18-10-2019
	Pharmacological Group	Phosphorus supplement/ Viatmin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Carosil Injectable Solution **(100ml)** of M/s Huzaifa International, Sargodha. (Reg. No. 074046) **Could not be confirmed in the applied fill volume/ pack size**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcoming:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the applied fill volume/pack size** alongwith registration number, brand name and name of firm.
	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.	
	Updated status: The firm has now revised the **demanded pack size to 50ml**	

	Metoo status: Phosvit Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088081) • The firm has **NOT** submitted fee Rs. 30,000/- for revision of pack size.	
	Decision: Approved with 50ml pack size. Firm shall submit fee Rs. 30,000/- for correction/pre-approval change of pack size and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
623.	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	G-Mox Plus Injection 100ml
	Composition	Each ml Contains: Amoxicillin as Trihydrate…150mg Gentamicin As Sulphate…40mg
	Diary No. Date of R& I & fee	Dy.No 3199 dated 02-03-2020 Rs.20,000/- dated 02-03-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	A Gent 150/40 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113606)
	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]	**Shortcomings:** • **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 324th meeting: Deferred for submission of evidence of approval of required manufacturing facility i.e., Liquid Injection (Veterinary) section from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months.	
	• **Updated status: Penicillin Area (Liquid Injection) Veterinary** section confirmed routine GMP inspection report based on evaluation conducted dated 20-12-2022.	
	Decision: Approved. The firm shall submit fee Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

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

a. New DML /section

I. M/s Poulvet Pharmaceuticals (Pvt) Ltd, Multan.

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 (General) I (Veterinary)**
2. **Oral Powder (General) II (Veterinary)**
3. **Oral Liquid/ Drench (General) (Veterinary)**

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

Section	No. of Products applied	No. of Molecules applied
Oral Powder (General) I (Veterinary)	22	10

Oral Powder (General) I (Veterinary) (22 Products/ 10 Molecules)		
624.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	P.Entadine 10 WSP
	Composition	Each gram contains: **Amantadine HCl**…100mg
	Diary No. Date of R& I & fee	Dy.No 14660 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 1252961726)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Amancin-10 Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi (Reg. No. 112234)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Registration Board deferred the case forfurther delibeation and directed PE&R Division to present working paper on international regulatory status of "Amantadine Drug for Veterinary use", in upcoming Board meeting.	
625.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	P.Entadine 98 WSP
	Composition	Each gram contains: **Amantadine HCl**…980mg
	Diary No. Date of R& I & fee	Dy.No 14654 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 581489383)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Registration Board deferred the case forfurther delibeation and directed PE&R Division to present working paper on international regulatory status of "Amantadine Drug for Veterinary use", in upcoming Board meeting.	
626.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Chlor-20 Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 14658 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 70443323421)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Cyclo-Mix 20 of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113527)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
627.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Chlor-25 Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline HCl…250mg
	Diary No. Date of R& I & fee	Dy.No 14656 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 25932412632)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Amseclor-25% Oral Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 112282)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
628.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Frusa Lex WSP
	Composition	Each gram contains: Furosemide…20mg Potassium Chloride…4mg Calcium Carbonate…45mg Magnesium Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 14659 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 1565023677)
	Pharmacological Group	Diuretic/ Electrolytes
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Biofurose Water Soluble Powder of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 111220)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction in formulation (salt form of furosemide), as per notification No.F.7-11/2012-B&A/DRAP dated07-05-2021 before issuance of registration letter.	
629.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Linco Poul-4.4 Powder
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 14641 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 93276376899)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Lincos-P Oral Powder of M/s. A&K Pharmaceuticals, Faisalabad (Reg. No. 049667)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
630.	Name and address of manufacturer /	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal,

	Applicant	25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Linco Poul-11 Powder
	Composition	Each gram contains: Lincomycin HCl…110mg
	Diary No. Date of R& I & fee	Dy.No 14645 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 696562158019)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Eline 11 Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 111529)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
631.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Linco Poul-40 Powder
	Composition	Each gram contains: Lincomycin HCl…400mg
	Diary No. Date of R& I & fee	Dy.No 14640 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 257654900)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Z-Linco-40 Water Soluble Powder of M/s. Zoic International, Lahore (Reg. No. 090658)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated07-05-2021 before issuance of registration letter.	
632.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	PSL-100 Water Soluble Powder
	Composition	Each gram contains: Lincomycin HCl…222mg Spectinomycin HCl…444.7mg
	Diary No. Date of R& I & fee	Dy.No 14647 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 0390234849)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Bio-Spin Powder of M/s. Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 112171)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:**

		• Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated07-05-2021 before issuance of registration letter.	
633.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Neo Poul-70 Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…700mg
	Diary No. Date of R& I & fee	Dy.No 14669 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 3308367104)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Neoritis-70 Powder of M/s. Neotech Pharmaceuticals (Pvt) Ltd. Kamoke (Reg. No. 111420)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
634.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Neo Poul-72 Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…720mg
	Diary No. Date of R& I & fee	Dy.No 14670 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 69288409686)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Neo-70 Water Soluble Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.113522)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
635.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Neo Poul-100 Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…1000mg
	Diary No. Date of R& I & fee	Dy.No 14667 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 092542933)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Neorox-100 Water Soluble Powder of M/s. Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No.

		111294)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
636.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Amp-30 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 14653 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 58141303)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Roxaprol Water Soluble Powder of M/s. Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No.111284)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
637.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Amp-60 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…600mg
	Diary No. Date of R& I & fee	Dy.No 14651 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 950151957100)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Kryprolium Oral Powder of M/s. Krypton Pharma (Pvt) Ltd., Faisalabad (Reg. No. 113424)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
638.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Amp-90 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…900mg
	Diary No. Date of R& I & fee	Dy.No 14652 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 01722464150)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Pentaprol 90 Powder of M/s. Neotech Pharmaceuticals (Pvt) Ltd. Kamoke (Reg. No. 111416)
	GMP status	New DML
	Remarks of the Evaluator [X]	

	Decision: Approved.	
639.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Doxs-20 Water Soluble Powder
	Composition	Each gram contains: Doxycycline Hyclate…200mg
	Diary No. Date of R& I & fee	Dy.No 14663 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 32416516)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Eter Doxycycline -20 Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.109847)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
640.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Doxs-50 Water Soluble Powder
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 14674 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 6187042492)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Dox Reena 50% Water Soluble Powder of M/s. Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111574)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
641.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Doxs-80 Water Soluble Powder
	Composition	Each gram contains: Doxycycline Hyclate…800mg
	Diary No. Date of R& I & fee	Dy.No 14648 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 2165283095)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Eter Doxycycline -80 Water Soluble Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.109849)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
642.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Poultin-48 Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate…4,800,000 IU
	Diary No. Date of R& I & fee	Dy.No 14671 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 27744839792)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Coli Skill-48 Powder of M/s. Bioskils Pharmaceuticals, Sadhoke, District Gujranwala (Reg. No.113508)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
643.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poultin-50 Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate…5,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 14672 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 8174851150)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Colicid Water Soluble Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.113525)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
644.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poultin-60 Water Soluble Powder
	Composition	Each gram contains: Colistin Sulphate…6,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 14673 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 82703865)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Neflorex 60 Water Soluble Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113529)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
645.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul CNC Water Soluble Powder

	Composition	Each gram contains: Neomycin Sulphate…70mg Colistin Sulphate…4mg Chlortetracycline…80mg
	Diary No. Date of R& I & fee	Dy.No 14650 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 526451523)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	SB Neocotin Soluble Powder of M/s. SB Pharma, Islamabad. (Reg. No. 109882)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** Firm shall submit fee of Rs.30000/- for correction in formulation (salt form of Chlortetracycline), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction in formulation (salt form of Chlortetracycline), as per notification No.F.7-11/2012-B&A/DRAP dated07-05-2021 before issuance of registration letter.	

Case no. 03 Registration applications of import cases

a. New Cases (Veterinary)

646.	Name and address of Applicant	M/s Mian Traders, Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Mian Traders Address: Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan Validity: 22-01-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet), King Abdullah II, Ibn Al-Hussein Industrial Zone, Sahab, Amman, Jordan Street 16, Building 401
	Name and address of marketing authorization holder	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet),P.O Box 202, Amman 11512 Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 19012 Dated 07-07-2021
	Fee including differential fee	Rs : 150,000 Dated 05-07-2021 (slip N0. 62298092001)
	Brand Name +Dosage Form + Strength	Spectra Flor Solution
	Composition	Each ml contains: Florfenicol…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1000ml
	International availability	N/A
	Me-too status	Technoflor-10 Liquid of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke. (Reg. No. 111444)
	Detail of certificates attached	• Originally legalized CoPP No. 011225 dated 26.11.2020 certified by Ministry of Agriculture, Veterinary Department

		Jordan, confirms GMP status of the manufacturer as well as free sale status of the applied product in country of origin. • Letter of authorization/ distribution agreement between the MAH and the applicant is **not provided.**
	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. ➢ ***Same formulation of the same MAH has also been applied by M/s Aves Care, Faisalabad.*** (Considered and deferred in 324th meeting of the Registration Board***).*** **Letter of authorization/ distribution agreement between the MAH and the applicant has not been provided by both the firms.** **Shortcomings:** • Provide copy of valid DSL • Provide valid notarized original letter of authorization (LOA)/ distribution agreement • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
647.	Name and address of Applicant	M/s Mian Traders, Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Mian Traders Address: Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan Validity: 22-01-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet), King Abdullah II, Ibn Al-Hussein Industrial Zone, Sahab, Amman, Jordan Street 16, Building 401
	Name and address of marketing authorization holder	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet),P.O Box 202, Amman 11512 Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 19010 Dated 07-07-2021
	Fee including differential fee	Rs : 150,000 Dated 05-07-2021 (slip N0. 3517477914)
	Brand Name +Dosage Form + Strength	Spectra Col Forte Powder
	Composition	Each gram contains: Colistin as Sulphate…6,000,000 IU
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	500gm, 1000gm
	International availability	N/A
	Me-too status	Neflorex 60 Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113529)
	Detail of certificates attached	• Originally legalized CoPP No. 011223 dated 26.11.2020 certified by Ministry of Agriculture, Veterinary Department

		Jordan, confirms GMP status of the manufacturer as well as free sale status of the applied product in country of origin. • Letter of authorization/ distribution agreement between the MAH and the applicant is **not provided.**
	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 valid notarized original letter of authorization (LOA)/ distribution agreement • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
648.	Name and address of Applicant	M/s Mian Traders, Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Mian Traders Address: Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan Validity: 22-01-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet), King Abdullah II, Ibn Al-Hussein Industrial Zone, Sahab, Amman, Jordan Street 16, Building 401
	Name and address of marketing authorization holder	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet),P.O Box 202, Amman 11512 Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 19011 Dated 07-07-2021
	Fee including differential fee	Rs: 150,000 Dated 05-07-2021 (slip N0. 6726172802)
	Brand Name +Dosage Form + Strength	Spectra Tilcosin Solution
	Composition	Each ml contains: Tilmicosin as Phosphate…250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	240ml, 960ml
	International availability	N/A
	Me-too status	Kptil Oral 25% Oral Liquid of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113415)
	Detail of certificates attached	• Originally legalized CoPP No. 011224 dated 26.11.2020 certified by Ministry of Agriculture, Veterinary Department Jordan, confirms GMP status of the manufacturer as well as free sale status of the applied product in country of origin. • Letter of authorization/ distribution agreement between the MAH and the applicant is **not provided.**

	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 valid notarized original letter of authorization (LOA)/ distribution agreement • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	

649.	Name and address of Applicant	M/s Mian Traders, Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Mian Traders Address: Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan Validity: 22-01-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet), King Abdullah II, Ibn Al-Hussein Industrial Zone, Sahab, Amman, Jordan Street 16, Building 401
	Name and address of marketing authorization holder	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet),P.O Box 202, Amman 11512 Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 19013 Dated 07-07-2021
	Fee including differential fee	Rs: 150,000 Dated 05-07-2021 (slip N0. 95761503061)
	Brand Name +Dosage Form + Strength	Spectra Brom D.S Solution
	Composition	Each ml contains: Bromhexine HCl…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Mucolytic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	500ml, 1000ml
	International availability	N/A
	Me-too status	Vet Brom 1% Oral Liquid of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 113490)
	Detail of certificates attached	• Originally legalized CoPP No. 011230 dated 26.11.2020 certified by Ministry of Agriculture, Veterinary Department Jordan, confirms GMP status of the manufacturer as well as free sale status of the applied product in country of origin. • Letter of authorization/ distribution agreement between the MAH and the applicant is **not provided.**
	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:** • Provide copy of valid DSL • Provide valid notarized original letter of authorization (LOA)/ distribution agreement

	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
650.	Name and address of Applicant	M/s Mian Traders, Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Mian Traders Address: Railway Road Morre Eimenabad, Gujranwala, Punjab, Pakistan Validity: 22-01-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet), King Abdullah II, Ibn Al-Hussein Industrial Zone, Sahab, Amman, Jordan Street 16, Building 401
	Name and address of marketing authorization holder	M/s Al-Mutawwaj Veterinary Pharmaceutical Industries (Spectra Vet),P.O Box 202, Amman 11512 Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 19009 Dated 07-07-2021
	Fee including differential fee	Rs: 150,000 Dated 05-07-2021 (slip N0. 3060154986)
	Brand Name +Dosage Form + Strength	Spectra Dox Forte Powder
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	500gm, 1000gm
	International availability	N/A
	Me-too status	Farmadox 50 Oral Powder of M/s ZS Biotech, Lahore. (Reg. No. 113635)
	Detail of certificates attached	• Originally legalized CoPP No. 011225 dated 26.11.2020 certified by Ministry of Agriculture, Veterinary Department Jordan, confirms GMP status of the manufacturer as well as free sale status of the applied product in country of origin. • Letter of authorization/ distribution agreement between the MAH and the applicant is **not provided.**
	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 valid notarized original letter of authorization (LOA)/ distribution agreement. • The official monograph of the applied formulation exists in USP 44-NF 39 which states that "***Doxycycline for Oral Suspension contains the equivalent of NLT 90.0% and NMT 125.0% of the labeled amount of doxycycline (C22H24N2O8) when constituted as directed."*** • The firm shall submit fee Rs. 150,000/- for revision of formulation in line with pharmacopoeia and correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **fee Rs. 150,000/- for revision of formulation in line with pharmacopoeia and correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
651.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24091 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 965127188165)
	Brand Name +Dosage Form + Strength	Oksimed Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100gm, 250gm, 500gm, 1000gm and 5000gm
	International availability	N/A
	Me-too status	Oxyveto-50 S Soluble Powder of M/s Orient Traders International, Karachi. (Reg. No. 049545)
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted **scanned copy is expired now but valid upon submission.**

		• Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • **Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg** is mentioned on Form 5A while **Oxytetracycline HCl…500mg** is mentioned on FSC; clarification regarding the applied formulation is required. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding the applied formulation since Oxytetracycline HCl Eq. to Oxytetracycline Base…500mg is mentioned on Form 5A while Oxytetracycline HCl…500mg is mentioned on FSC** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
652.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Idol Ilac Dolum San. Ve Tic.A.S. Davutpasa Cad. Cebealibey Sok. No: 20 34010 Zeytinburnu/Istanbul
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24086 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 4197476974)
	Brand Name +Dosage Form + Strength	Tilotarmed 20% Solution for Injection
	Composition	Each ml Contains: Tylosin Tartrate Eq. to Tylosin Base…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A

	Me-too status	Tylox-20 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113562)
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S0212/2020 dated 16.03.2020 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Tilomed-E 30% Solution for Injection)** Validity: 17-07-2022 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted scanned copy is **expired now but valid upon submission.** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
653.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Idol Ilac Dolum San. Ve Tic.A.S. Davutpasa Cad. Cebealibey Sok. No: 20 34010 Zeytinburnu/Istanbul
	Name and address of marketing authorization holder	Medicavet Tarim Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. Itosb Tuzla Organize San. Bolgesi Eski Ankara Asfalti 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A

	Diary No. & Date of R& I	Dy.No 24088 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 9580364966)
	Brand Name +Dosage Form + Strength	Tilomed-E 30% Solution for Injection
	Composition	Each ml contains: Tilmicosin Phosphate Eq. to Tilmicosin Base…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Mico Sol Injection (100ml) of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 080150)
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Originally legalized GMP certificate No. GMP/TR/V/YI/S0212/2020 dated 16.03.2020 certified by Ministry of Agriculture and Forestry Turkey. Validity: 17-07-2022 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
654.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial

		Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24089 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 476694961)
	Brand Name +Dosage Form + Strength	Medicatay Water Soluble granules
	Composition	Each gram Contains: Tylosin Tartrate Eq. to Tylosin Base…1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	22gm, 55gm, 110gm, 100gm, 500gm, 550gm, 1000gm, 1100gm
	International availability	N/A
	Me-too status	Tylo Tartrate-100 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113430)
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Originally legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement**	

	• **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
655.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24087 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 43956898)
	Brand Name +Dosage Form + Strength	Tilomed 30% Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate Eq. to Tilmicosin Base…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	70 x 250ml, 50 x 500ml, 10 x 1000ml bottles, 3 x 5000ml drum
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy.

		• Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage 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: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **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.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
656.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24093 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 5459799264)
	Brand Name +Dosage Form + Strength	Mediquinol 20% Oral Solution
	Composition	Each ml contains: Enrofloxacin…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml
	International availability	N/A
	Me-too status	Bovicin-20 Oral Solution of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.112149)
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control

		Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
657.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24092 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 5344055462)
	Brand Name +Dosage Form + Strength	NS-Med 50% Oral Solution Powder

	Composition	Each gram Contains: Neomycin Sulphate 715mg Eq. to Neomycin Base…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	20gm, 100gm, 500gm, 1000gm, 2500gm
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage 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: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **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.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
658.	Name and address of Applicant	M/s Unicare Enterprises, Commercial-6, Block A, Kazimabad, Model Colony, Karachi-75100, Pakistan
	Detail of Drug Sale License	Name: M/s Unicare Enterprises Address: Plot No. 587/1-B, Srtreet No. 3 Punjab Small Industrial

		Estate, Nalka Kohala Sargodha Road Faisalabad. Validity: 10-04-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name and address of marketing authorization holder	Medicavet Tarim ve Hayvancilik Ilac ve Kimya San. Tic. Ltd. Sti. ITOSB Eski Ankara Asfalti 34959 12. Cad. No: 1 Tepeoren Tuzla/Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24090 Dated 01-09-2021
	Fee including differential fee	Rs: 150,000 Dated 24-08-2021 (slip N0. 39669651)
	Brand Name +Dosage Form + Strength	Tetraklor Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline Base…600mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	20gm, 100gm, 500gm, 1000gm, 2500gm
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	• Originally legalized FSC certified by Ministry of Agriculture and Forestry, General Directorate of Food and Control Republic of Turkey free sale status of the applied product in country of origin. • Scanned copy of legalized GMP certificate No. GMP/TR/V/YI/S00137/2019 dated 27.03.2019 certified by Ministry of Agriculture and Forestry Turkey. **(Originally legalized in Medicatay Water Soluble granules dossier)** Validity: 31-12-2021 • Scanned copy of sole and exclusive distribution letter, dated 16-10-2019, between the MAH and the applicant.
	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 valid legalized original GMP certificate, since the already submitted is **expired now but valid upon submission** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement, since the already submitted is scanned copy. • Address of the firm mentioned on DSL is "***Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.***" while "***Commercial-6, Block A, Kazimabad, Model Colony, Karachi"*** is mentioned on form-5A, clarify. • In the finished product label the Urdu version of the following namely; (i) Name of drug and (ii) dosage is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • **Chlortetracycline Base…600mg/gram** is mentioned on Form 5A while **Chlortetracycline HCl…600mg/gram** is mentioned on FSC; clarification regarding the applied formulation 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.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **clarification regarding address of the applicant mentioned on DSL, since "*Plot No. 587/1-B, Street No. 3 Punjab Small Industrial Estate, Nalka Kohala Sargodha Road Faisalabad.*" Is mentioned on DSL while "*Commercial-6, Block A, Kazimabad, Model Colony, Karachi* is mentioned on form-5A** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** • **clarification regarding the applied formulation since Chlortetracycline Base…600mg/gram is mentioned on Form 5A while Chlortetracycline HCl…600mg/gram is mentioned on FSC** • **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, .**	
659.	Name and address of Applicant	M/s Aves Care, Office Address: P-74, Street No. 3, Rehman town, Satiana Road, Faisalabad. Warehouse Address: P-68, Street No. 3, Rehman Town, Satiana Road, Faisalabad, Pakistan
	Detail of Drug Sale License	**Not Provided**
	Name and address of manufacturer	M/s Cenavisa S.L. Cami Pedra Estela, s/n 43205 Reus, Spain
	Name and address of marketing authorization holder	M/s Cenavisa S.L. Cami Pedra Estela, s/n 43205 Reus, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24717 Dated 07-09-2021
	Fee including differential fee	Rs : 1,50,000 Dated 02-09-2021 (slip No. 9111732823)
	Brand Name +Dosage Form + Strength	Doxycen 500 powder
	Composition	Each gram contains: Doxycycline (Hyclate)…500mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm, 2000gm
	International availability	N/A
	Me-too status	Farmadox 50 Oral Powder of M/s. ZS Biotech, Lahore. (Reg. No. 113635)
	Detail of certificates attached	➢ Original legalized Certificate of Pharmaceutical Product Certificate No. 2021/272 Issued on 25-03-2021, Certified by Spanish agency of Medicines and Medical Devices, Spain. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturer. ➢ Sole agency certificate between MAH and the applicant is **not provided.**
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months real time stability study data of 03 batches according to zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL

		• Provide notarized original valid Letter of Authorization/ Sole agency certificate. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
660.	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 24711 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 86671310068)
	Brand Name +Dosage Form + Strength	Actionis Suspension for Injection
	Composition	Each ml Contains: Ceftiofur as Ceftiofur HCl…50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	Calicef 50mg Suspension for Injection **(100ml)** of M/s Orient Animal Health (Pvt) Ltd., Karachi. (Reg. No. 108996)
	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 06 months accelerated and 24 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. • 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 registration number, brand name and name of firm.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **legalized original valid CoPP** • **confirmation of dedicated manufacturing facility** • **choice of only one pack size** • **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, .**	
661.	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 24714 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 3126078138)
	Brand Name +Dosage Form + Strength	Amoxoil Retard Suspension for Injection
	Composition	Each ml contains: Amoxicillin as Amoxicillin Trihydrate…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	Amocillin 15% Injection **(100ml)** of M/s Eterna Pharma (Pvt) Ltd.,Mirpur, AJK (Reg. No. 113596)
	Detail of certificates attached	➢ Scanned copy of CoPP dated 22-01-2021 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 in **Actionis Suspension for Injection dossier**; valid for 5 years
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 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. • 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 registration number, brand name and name of firm.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **legalized original valid CoPP** • **confirmation of dedicated manufacturing facility** • **choice of only one pack size** • **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, .**	
662.	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 registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
663.	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 24715 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No.23252367362)
	Brand Name +Dosage Form + Strength	Exabiopen Suspension for Injection
	Composition	Each ml contains: Benzyl Penicillin (Procaine)…200,000 IU Dihydrostreptomycin sulfate…250mg
	Finished Product Specification	Inhouse

	Pharmacological Group	Antibacterial
	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 legalized 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 registration number, brand name and name of firm.
	Decision: 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** • **confirmation of dedicated manufacturing facility** • **choice of only one pack size** • **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, .**	
664.	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: 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** • **confirmation of dedicated manufacturing facility** • **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, .**	
665.	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 24713 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No.8633785976)
	Brand Name +Dosage Form + Strength	Enroxina Solution for Oral Administration
	Composition	Each ml contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml, 1000ml, and 5000ml
	International availability	N/A
	Me-too status	Hipralona / Enro-S Oral Solution of M/s Aims Traders Karachi (Reg. No. 017080)
	Detail of certificates attached	➢ **Unattested photocopy** of CoPP No. 207/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.
	Decision: 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** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
666.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035

	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25220 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.5456745503)
	Brand Name +Dosage Form + Strength	Flumine Plus 8% Injection 100ml
	Composition	Each ml contains: Flunixin Meglumine…80mg
	Finished Product Specification	USP specifications
	Pharmacological Group	NSAID
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042901 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time 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 • Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **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.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes,**	
667.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035

	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25222 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.047892117)
	Brand Name +Dosage Form + Strength	Neogent 10% Injection
	Composition	Each ml contains: Gentamycin Sulphate…100mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Genster 10 Injection (100ml) of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 111395)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042908 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time 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 • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **Attested copy of valid DSL** • **Notarized copy valid Letter of Authorization/ Sole agency certificate.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
668.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25229 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.9085466559)
	Brand Name +Dosage Form + Strength	Solo-P 50ml Injection

	Composition	Each ml contains: **Prednisolone**…10mg Chlorpheniramine Maleate…4mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Bacteriostatic/ antihistamine
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Chlorprem 14 Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 113496)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042904 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time 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 • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
669.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25228 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.040060899785)
	Brand Name +Dosage Form + Strength	N-Flor 30 Injection 50ml
	Composition	Each ml contains: Florfenicol…300mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	G-Flor 30% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd.,

		Islamabad (Reg. No.111548)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042913 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time 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 • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
670.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25226 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.98635031)
	Brand Name +Dosage Form + Strength	Trizole 100ml Injection
	Composition	Each ml contains: Sulfadiazine…200mg Trimethoprim…40mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Kerry T.S Injection (100ml) of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 088829)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042902 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer

		Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time 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 • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
671.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25225 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.40463491104)
	Brand Name +Dosage Form + Strength	Dimipro Plus 2.36gm Granules for Injection
	Composition	Per Unit contains: Diminazene Aceturate…1.05g Vitamin B6…5mg Vitamin B12…1mg **Antipyrine** add to 2.36g
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	2.36gm bag
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042911 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction 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: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
672.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25219 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.7002853833)
	Brand Name +Dosage Form + Strength	Neomec Super 100ml Injection
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antiparasitic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Iver-Soun Injection (100ml) of M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 109793)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042907 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
673.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25221 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.82541926272)
	Brand Name +Dosage Form + Strength	Neomec-DS 100ml Injection
	Composition	Each ml contains: Ivermectin…40mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antiparasitic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042905 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction 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: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **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** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
674.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25218 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.19448977213)
	Brand Name +Dosage Form + Strength	Neoflox-20 50ml Injection
	Composition	Each ml contains: Enrofloxacin…200mg
	Finished Product Specification	CVP specifications
	Pharmacological Group	Bacteriostatic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Enflox-20% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112216)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042906 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
675.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25217 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.114907453336)
	Brand Name +Dosage Form + Strength	Tonophos-B 100ml Injection
	Composition	Each ml contains: Tonophosphan…124.4mg Vitamin B12…0.05mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Nutritional supplements
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	New Dechaphosphan Injection (100ml) of M/s Atzan Pharmaceuticals, Sargodha. (Reg. No. 039972)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042903 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL

		• notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
676.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25223 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.2331535224)
	Brand Name +Dosage Form + Strength	Neo AD3E 100ml Injection
	Composition	Each ml contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Nutrients
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Trivetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079285)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042909 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii)

		Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
677.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25224 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.07196659530)
	Brand Name +Dosage Form + Strength	Oligovit-M 100ml Injection
	Composition	Each ml contains: Vitamin A, Retinol Palmitate…15,000 IU Vitamin D3, Cholecalciferol...7500 IU Vitamin E, Tocopherol Acetate...20mg Thiamine HCl...10mg Riboflavine Sodium Phosphate...5mg Pyridoxine HCl...3mg Cyanocobalamin...60mcg D-Panthenol...25mg Nicotinamide...50mg Folic Acid...150mg Biotin...125mg **Amino Acids...12mg** Water for Injection...1ml
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Vitamin supplements
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042910 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:**

		• copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Specify which amino acids are included in the formulation and accordingly, 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: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** • **Specify which amino acids are included in the formulation and accordingly, provide 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, .**	
678.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25227 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.5613671777)
	Brand Name +Dosage Form + Strength	Neovital Fort 250ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.425mg L-Cysteine HCl...0.02mg L-Histidine HCl...0.02mg L-Isoleucine...0.525mg L-Leucine HCl...0.6mg L-Methionine...0.525mg L-Threonine...0.35mg L-Tryptophan...0.175mg L-Phenylalanine...0.35mg L-Valine...0.525mg L-Lysine HCl...0.525mg Monosodium Glutamate...0.08mg Riboflavin...0.05mg D-Pantothenol ...0.1mg Pyridoxine HCl...0.1mg Nicotinamide...3mg Thiamine HCl...0.1mg Glucose...50mg

		Calcium Chloride...2mg Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate...7.5mg Water for Injection...1ml
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Vitamin supplements
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	250ml
	International availability	N/A
	Me-too status	Enersel Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 112275)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042912 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
679.	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 : 28429 Dated 15-10-2021
	Fee including differential fee	Rs : 150,000 Dated 20-09-2021(Slip No. 843490248510)
	Brand Name +Dosage Form + Strength	Alfamec 1% Solution for Injection
	Composition	Each ml contains: Ivermectin…10mg

	Finished Product Specification	BP specifications
	Pharmacological Group	Antiparasitic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	500ml
	International availability	Not applicable
	Me-too status	Mac Rold 1% Liquid Injection (500ml) of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 106818)
	Detail of certificates attached	➢ **Photocopy of embassy attested COPP** BD/2017/No. of Certificate 247607 dated **13-06-2017** 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 100 mL registered, reg. No. 103795 dossier submission date 17-11-2017.)** ➢ Photocopy of letter of exclusive sole distributor/ authorization dated: 05-05-2017
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide copy of valid DSL • Provide legalized original valid CoPP since already **submitted copy** is **expired now but valid upon submission.** • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already **submitted copy** is **expired now but valid upon submission.** • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.
	Decision: Deferred for following: • **copy of valid DSL** • **legalized original valid CoPP** • **notarized original valid Letter of Authorization/ Sole agency certificate** • **06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
680.	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 : 28428 Dated 15-10-2021
	Fee including differential fee	Rs : 150,000 Dated 20-09-2021(Slip No. 8520380570)
	Brand Name +Dosage Form + Strength	Lincomycin-Spectinomycin 5/10 Solution for Injection
	Composition	Each ml contains: Lincomycin as HCl…50mg

		Spectinomycin as HCl…100mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Antibiotics
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Not applicable
	Me-too status	Spectral Injection (100ml) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi (Reg. No. 113610)
	Detail of certificates attached	➢ **Scanned copy of embassy attested COPP** BD/2017/No. of Certificate 247613 dated 15-06-2017 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. 103796 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.**
	Decision: Deferred for following: • **copy of valid DSL** • **legalized original valid CoPP** • **notarized original valid Letter of Authorization/ Sole agency certificate** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
681.	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: 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, .**	
682.	Name and address of Applicant	M/s Orion Group, P-97, Usman Block, Muslim Town No.1, Near Lasani Pully, Sargodha Road, Faisalabad
	Detail of Drug Sale License	M/s Orion Group, Address: 97 Commercial Area, Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad Validity: 22/01/2023 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s S.P. Veterinaria, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O Box 60, 43330, RIUDOMS (Tarragona) Spain.
	Name and address of marketing authorization holder	M/s S.P. Veterinaria, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O Box 60, 43330, RIUDOMS (Tarragona) Spain.

	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 28722 Dated 20-10-2021
	Fee including differential fee	Rs : 150,000 Dated 15-10-2021 (slip No. 4656654522)
	Brand Name +Dosage Form + Strength	Floxavex 100mg/ml Solution for Injection
	Composition	Each ml Contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	N/A
	Me-too status	Enro-Pro 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd Mirpur, AJK (Reg. No.113561)
	Detail of certificates attached	➢ Original legalized COPP dated 13-07-2021 issued by Spanish Agency for Medicines and Health Products confirms free sale status of the product in exporting country as well as GMP status of the manufacturer ➢ Distribution agreement between PLH and the applicant is **not provided.**
	Remarks of the Evaluator [x]	**Shortcomings:** • Provide valid copy of DSL • Notarized original sole agency/distribution agreement between PLH and Applicant • Provide accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **notarized original valid Letter of Authorization/ Sole agency certificate** • **06 month accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
683.	Name and address of Applicant	M/s Orion Group, P-97, Usman Block, Muslim Town No.1, Near Lasani Pully, Sargodha Road, Faisalabad
	Detail of Drug Sale License	M/s Orion Group, Address: 97 Commercial Area, Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad Validity: 22/01/2023 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s O.L. Kar-AgroZooVet -Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name and address of marketing authorization holder	M/s O.L. Kar-AgroZooVet-Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name of exporting country	Ukraine
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 25413 Dated 13-09-2021

	Fee including differential fee	Rs : 150,000 Dated 27-08-2021 (slip No.9292114099)
	Brand Name +Dosage Form + Strength	Mastiline Intramammary syringe tube for livestock
	Composition	Each 1gm Contains: Cloxacillin Sodium Salt…2000 mg Amoxicillin Trihydrate…750mg Glycerin…200mg Sodium Carboxymethyl Cellulose…140mg Benzil Alcohol…500mg Distilled Water…9335mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	5gm syringe tube
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of FSC No. PK00500S 30/1 dated 29-01-2020 Validity: **29-01-2021** ➢ Scanned copy of GMP certificate 602-1121-16/3654 of 25-05-2018, certified by the state service of Ukraine on Food safety and Consumer protection Ukraine. ➢ Scanned copy of Distribution agreement between PLH and the applicant dated 01-12-2019**.**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide original legalized valid FSC, since the already submitted FSC is **expired even upon submission**. • Provide original legalized valid GMP certificate, since the already submitted is scanned copy • Notarized original sole agency/distribution agreement between PLH and Applicant since the already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility** • Provide accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction 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: Deferred for following: • **copy of valid DSL** • **original legalized valid FSC** • **original legalized valid relevant GMP certificate** • **notarized original valid Letter of Authorization/ Sole agency certificate** • **confirmation of dedicated manufacturing facility** • **06 month accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life.** • **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** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
684.	Name and address of Applicant	M/s Orion Group, P-97, Usman Block, Muslim Town No.1, Near

		Lasani Pully, Sargodha Road, Faisalabad
	Detail of Drug Sale License	M/s Orion Group, Address: 97 Commercial Area, Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad Validity: 22/01/2023 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s O.L. Kar-AgroZooVet -Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name and address of marketing authorization holder	M/s O.L. Kar-AgroZooVet-Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name of exporting country	Ukraine
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 25412 Dated 13-09-2021
	Fee including differential fee	Rs : 150,000 Dated 31-07-2021 (slip No. 3543254018)
	Brand Name +Dosage Form + Strength	Mastilong Forte Combined antimicrobial Intramammary syringe tube for livestock
	Composition	1 Syringe (8g) Tube Contains: Tetracycline HCl…200mg Neomycin Sulphate…250mg Bacitracin…200 IU **Prednisolone**…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic/ steroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	8gm syringe tube
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of FSC No. PK00500S 28/1 dated 29-01-2020 Validity: **28-01-2021** ➢ Scanned copy of GMP certificate 602-1121-16/3654 of 25-05-2018, certified by the state service of Ukraine on Food safety and Consumer protection Ukraine. ➢ Scanned copy of Distribution agreement between PLH and the applicant dated 01-12-2019**.**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide original legalized valid FSC, since the already submitted FSC is **expired even upon submission**. • Provide original legalized valid GMP certificate, since the **scope of already submitted GMP does not cover hormones** • Notarized original sole agency/distribution agreement between PLH and Applicant since the already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility** • Provide accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction 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: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in	

	view safety, efficacy and quality parameters.	
685.	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: Deferred for following: • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **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.** **The Board further decided that the applicant shall submit the response within 1 month after**	

	publication of the minutes, .	
686.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: **29-06-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Yuanzheng Pharmaceutical Co., Ltd. China No.16 Liuyuan Road, Chang' an District, Shijiazhuang City Hebei Province.
	Name and address of marketing authorization holder	M/s Hebei Yuanzheng Pharmaceutical Co., Ltd. China No.16 Liuyuan Road, Chang' an District, Shijiazhuang City Hebei Province.
	Name of exporting country	Peoples Rpublic of China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1057 Dated 28-09-2016
	Fee including differential fee	Rs : 1,00,000 Dated 28-09-2016
	Brand Name +Dosage Form + Strength	Velenium Oral Solution
	Composition	Each ml contains: Vitamin E.....100mg Sodium Selenite.....0.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Vitamin and minerals
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	500ml, 1000ml
	International availability	N/A
	Me-too status	Z-Selovit-E Ol Oral Liquid of M/s Zoic International, Lahore. (Reg. No. 090663)
	Detail of certificates attached	• Legalized original COPP No. 2014 J.S.P.Z.W.M.Z. No. 8541 dated 17-10-2014 issued by Ministry of Agriculture of People's Republic of China confirms GMP status of the manufacturer and free sale status of the applied product in exporting country. • Legalized original LOA No. 2014 J.S.P.Z.W.M.Z. No. 8538 dated 17-10-2014
	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:** • copy of valid DSL • Legalized original COPP sole agency/distribution agreement/LOA 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.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original CoPP** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
687.	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 Better Pharma Co., Ltd., Betagro Tower (North Park), 323 Vibhavadi Rangsit Road, Laksi, Bankok, 10210, Thailand
	Name and address of marketing authorization holder	M/s Better Pharma Co., Ltd., Betagro Tower (North Park), 323 Vibhavadi Rangsit Road, Laksi, Bankok, 10210, Thailand
	Name of exporting country	Thailand
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17501 Dated 23-06-2021 with Master File Bearing Dy No. 17499 Having All Original Legalised Documents
	Fee including differential fee	Rs : 1,50,000 Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Tylin Oral Powder
	Composition	Each gram contains: Tylosin as Tylosin Phosphate…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20Kg
	International availability	N/A
	Me-too status	**TYLOSIN-100 Powder of M/s. VETERINARY FARMS AIDS SHEIKHPURA, 012981 1KG**
	Detail of certificates attached	• Scanned copy of legalized FSC dated 28-05-2020 issued by the Food and Drug Administration, Ministry of Public Health, Thailand confirms free sale status of the product in country of origin. Validity: **27-05-2022** • Original legalized GMP certificate dated 28-11-2017 issued by the Food and Drug Administration, Ministry of Public Health Thailand confirms GMP status of the manufacturing site. Validity: **27-11-2021** • Original legalized distribution agreement made on 01-12-2020 between the applicant and product license holder is provided. Validity: **31-12-2024**
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Submit legalized original valid FSC, since the already submitted scanned copy is ***expired now but valid upon submission.*** • Submit legalized original valid GMP certificate since the already submitted is ***expired now but valid upon submission.***
	Decision: Approved. Firm shall submit the following before issuance of registration letter: • **legalized original valid FSC** • **legalized original valid GMP certificate of the manufacturer** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
688.	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 15262 Dated 02-06-2021
	Fee including differential fee	Rs : 1,50,000 Dated 28-05-2021
	Brand Name +Dosage Form + Strength	Farmaxilin 50 Powder
	Composition	Each gram contains: Amoxicillin (as Amoxicillin trihydrate)…500mg
	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	Amocillin 50% Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.112326)
	Detail of certificates attached	• Scanned copy of FSC dated 02-05-2018 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. **(Does not cover the scope of penicillin production line.)** • 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 scanned copy is ***expired now but valid upon submission.*** • Submit legalized original valid relevant GMP certificate; covering the scope of **penicillin production lines.** • Confirmation of dedicated/self contained manufacturing facility • Provide notarized original valid distribution agreement between product license holder and distributor, since already submitted photocopy is **expired now but valid upon submission.**
	Decision: Deferred for following: • **legalized original valid FSC** • **legalized original valid GMP certificate covering the scope of penicillin production lines.** • **confirmation of dedicated/self contained manufacturing facility**	

	• **valid notarized copy of letter of authorization (LOA)/ distribution agreement** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
689.	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: Deferred for following: • **legalized original valid FSC** • **legalized original valid GMP certificate.**	

	• **valid notarized copy of 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, .**	
690.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11001 Dated 09-04-2021
	Fee including differential fee	Rs : 100,000 Dated 09-04-2021
	Brand Name +Dosage Form + Strength	Para-Sone Water Soluble Powder
	Composition	Each gram contains: **Paracetamol**…45 mg Bromhexine HCl…2mg Prednisolone…0.1mg
	Finished Product Specification	Inhouse
	Pharmacological Group	NSAID/ Mucolytic/ Corticosteroid
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **(scope does not cover steroid manufacturing lines)** **Validity: 5 Years** • Copy of Free sale certificate No. 618/2019/QLT-CFS dated 17-06-2019 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 2 Years** ➢ Copy of agency agreement concluded on 17-10-2020 between the applicant and PLH
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC), since already submitted are copies. • Provide valid legalized original relevant GMP certificate since the scope of already submitted copy does not cover **steroid manufacturing lines.** • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
691.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11002 Dated 09-04-2021
	Fee including differential fee	Rs : 100,000 Dated 09-04-2021
	Brand Name +Dosage Form + Strength	Doxycyclin Soluble Powder
	Composition	Each 100g Contains: Doxycycline Hyclate…80g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	100gm
	International availability	N/A
	Me-too status	Eter Doxycycline -80 Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 109849)
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** ➢ Copy of agency agreement concluded on 17-10-2020 between the applicant and PLH
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Provide valid copy of DSL • Provide valid notarized original letter of authorization (LOA)/ sole agency certificate since already submitted is copy. • Provide valid legalized original Free sale certificate (FSC) • Provide valid legalized original GMP certificate since already submitted copy is **expired now but valid upon submission**. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **valid legalized original FSC** • **valid legalized original GMP certificate** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986** **The Board further decided that the applicant shall submit the response within 1 month after**	

	publication of the minutes, .	
692.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11784 Dated 20-04-2021
	Fee including differential fee	Rs : 100,000 Dated 20-04-2021
	Brand Name +Dosage Form + Strength	Tylofos Powder for Oral Solution
	Composition	Each gm contains: Fosfomycin Sodium…200mg Tylosin Tartrate…50mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 607/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC 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: Deferred for following: • **valid legalized original GMP certificate** • **valid legalized original FSC** • **valid notarized copy of 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, .**	
693.	Name and address of Applicant	M/s Orient Traders International, CM-10, Block A, Kazimabad, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Traders International Address: CM-10, Block A, Kazimabad, Model Colony, Karachi Validity: 26-01-2024 Status: Drug License By Way of Wholesale (Form No.07).
	Name and address of manufacturer	M/s Laboratoires Biove, 3 Rue de, Lorraine, F-62510 Arques, France (Manufacturing, Quality control and primary packaging) M/s V.M.D. N. V. Hoge Mauw 900 B-2370 Arendonk-Belgium (Batch release and secondary packaging in EU)
	Name and address of marketing authorization holder	M/s V.M.D. N. V. Hoge Mauw 900 B-2370 Arendonk-Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6206 Dated 04-06-2021
	Fee including differential fee	Rs : 1,50,000 Dated 01-06-2021
	Brand Name +Dosage Form + Strength	Tulinovet 100mg/ml Injectable Solution
	Composition	Each ml contains: Tulathromycin…100mg
	Finished Product Specification	Ph. Eur
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	N/A
	Pack size	100ml vial
	International availability	N/A
	Me-too status	Thrust Injection (100ml) of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 080930)
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 02/21/154788 Issued on 18/02/2021, Certified by *European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands.* The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. ▪ Original notarized declaration of sole agent dated 12-06-2023, validity 3 years, is given.
	Remarks of the Evaluator [X]	➢ 06 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. ➢ The official monograph of the applied formulation **does not exist in any available edition of pharmacopoeia.**
	Decision: Approved. Fim shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
694.	Name and address of Applicant	M/s Orion Group, P-97, Usman Block, Muslim Town No.1, Near Lasani Pully, Sargodha Road, Faisalabad
	Detail of Drug Sale License	Name: M/s Orion Group, Address: 97 Commercial area Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad Validity: **22-01-2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s S.P. Veterinaria, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O Box 60, 43330, RIUDOMS

		(Tarragona) Spain.
	Name and address of marketing authorization holder	M/s Cenavisa S.A. Cami Pedra Estela, s/n 43205 Reus (Tarragona) Spain.
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17936 Dated 28-06-2021
	Fee including differential fee	Rs : 150,000 Dated 25-06-2021
	Brand Name +Dosage Form + Strength	15-Amox Injectable Suspension
	Composition	Each ml Contains: Amoxicillin (Trihydrate)…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Amocillin 15% Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113596)
	Detail of certificates attached	➢ Originally legalized COPP No. 2021/203 dated 04-03-2021 issued by Spanish Agency for Medicines and Health Products confirms free sale status of the product in exporting. ➢ Originally legalized GMP certificate No. ES/103HV/18** dated 09-06-2020 issued by the Spanish Agency for Medicines and Health Products. **(scope covers β- lactam antibiotics production lines)** **Validity: 20-07-2021** ➢ Originally legalized distribution agreement dated 05-06-2019 between the manufacturer and the applicant
	Remarks of the Evaluator [x]	Provided 06months accelerated and **12months** real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide Original legalized valid relevant GMP certificate, covering the scope of **penicillin production lines;** since the already submitted copy of GMP certificate is **expired now but valid upon submission**. • Provide Original notarized valid distribution agreement/ power of attorney between the Marketing Authorization Holder and the applicant • Provide real time stability studies data of three batches as per zone IV-A conditions **upto claimed shelf life.** • Confirmation of **dedicated manufacturing facility** • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **copy of valid DSL** • **valid legalized original GMP certificate covering the scope of penicillin production lines** • **valid notarized copy of letter of authorization (LOA)/ distribution agreement** • **real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life** • **confirmation of dedicated manufacturing facility** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	

	• **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
695.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17939 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Actimisin AK Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate…250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24months
	Demanded Price	Decontrolled
	Pack size	480ml
	International availability	N/A
	Me-too status	Kptil Oral 25% Oral Liquid of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113415)
	Detail of certificates attached	▪ Originally legalized COPP No. 09.11.2006-17/004 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 08-11-2021** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 24months real time stability studies data of three batches as per zone IV-A conditions. • Initially the firm has applied for **Tilmicosin Phosphate…250mg/ml** on Form 5A while **Tilmicosin as Phosphate…250mg/ml** in COPP and FSC is mentioned. Upon clarification of applied formulation the firm has revised formulation to below mentioned label claim as per COPP and FSC. However, the fim **has not submitted fee for revision of label claim.** **Shortcomings:**

		• Provide original legalized valid COPP and GMP certificate since the already submitted **are expired now but valid upon submission.**
	Decision: Approved with following label claim: **Each ml contains:** **Tilmicosin as Phosphate…250mg** **Firm shall submit following before issuance of registration letter:** • **original legalized valid COPP and GMP certificate** • **Fee Rs. 150,000/- for correction/pre-approval change in formulation (salt form) and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
696.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17941 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Actimisin Solution for Injection
	Composition	Each ml contains: Tilmicosin …300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Micobak Injection (100ml) of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062148)
	Detail of certificates attached	▪ Originally legalized COPP No. 12.04.2005-14/0058 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 11-04-2025** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. • The official monograph of the applied formulation **exists in USP**

		Shortcomings: • Provide original legalized valid GMP certificate since the already submitted **is expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before the issuance of registration letter.	
697.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17938 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Ultramec 2% Solution for Injection 50ml
	Composition	Each ml Contains: Ivermectin…20mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Endoctosit
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Ivermec 2% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Rawat. (Reg. No. 111547)
	Detail of certificates attached	▪ Originally legalized COPP No. 11.11.2005-015/0021 dated 07-12-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 10-11-2025** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid GMP certificate since the already submitted **is expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per	

	notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before the issuance of registration letter.	
698.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17944 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Fenerol Solution for Injection (100ml)
	Composition	Each ml Contains: Florfenicol…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Florfenicen Injectable Solution (100ml) of M/s Mustafa Brothers, Faisalabad (Reg. No. 103910)
	Detail of certificates attached	▪ Originally legalized COPP No. 05.03.2007-17/086 dated 07-12-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 04-03-2022** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid COPP and GMP certificate since the already submitted **are expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before the issuance of registration letter.	
699.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan

	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17942 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Enrolen 10% Solution for Injection (100ml)
	Composition	Each ml Contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Enro-Pro 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113561)
	Detail of certificates attached	▪ Originally legalized COPP No. 02.04.1997-08/0805 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 01-04-2022** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid COPP and GMP certificate since the already submitted are **expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit following before issuance of registration letter: • **Original legalized valid COPP.** • **Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
700.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan

		Validity: 15-03-2028. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17940 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Enrolen 20% Oral Solution
	Composition	Each ml Contains: Enrofloxacin…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1000ml
	International availability	N/A
	Me-too status	Bovicin-20 Oral Solution of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 112149)
	Detail of certificates attached	▪ Originally legalized COPP No. 28.11.2005-15/032 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 27-11-2025** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 24months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid GMP certificate since the already submitted **is expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before the issuance of registration letter.	
701.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey

	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17945 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Gantapan 15% Solution for Injection
	Composition	Each ml Contains: Gentamicin as Sulphate…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Gantasin-15% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 112221)
	Detail of certificates attached	▪ Originally legalized COPP No. 08.03.2005-14/0045 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 07-03-2025** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [x]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid GMP certificate since the already submitted **is expired now but valid upon submission.**
	Decision: Approved as per policy for inspection of manufacturer abroad. Firm shall submit Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before the issuance of registration letter.	
702.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey

	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17946 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Megasil LA Suspension for Injection
	Composition	Each ml Contains: Amoxicillin as (Trihydrate)…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Amocillin 15% Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.113596)
	Detail of certificates attached	▪ Originally legalized COPP No. 26.09.2008-20/0057 dated 17-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 25-09-2023** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid relevant GMP certificate since the already submitted **is expired now but valid upon submission.** • Confirmation of **dedicated penicillin manufacturing facility.**
	Decision: Deferred for following: • **Original legalized valid relevant GMP certificate** • **Confirmation of dedicated penicillin manufacturing facility.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
703.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey

	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17947 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Neozid Powder for Oral Solution
	Composition	Each gram contains: Neomycin as Sulphate…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	72 months
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	▪ Originally legalized COPP No. 22.03.2002-11/1023 dated 07-12-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 21-03-2022** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06-month accelerated and **48-month** real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid CoPP and GMP certificate since the already submitted are **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. • Provide real time stability studies data of three batches as per zone IV-A conditions **upto claimed shelf life.**
	Decision: Deferred for following: • **Original legalized valid COPP and relevant GMP certificate** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
704.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).

	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17943 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Buparvon Solution for Injection
	Composition	Each ml Contains: Buparvaquone…50mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Eter Bupra Injection (50ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 109843)
	Detail of certificates attached	▪ Originally legalized COPP No. 07.06.2005-014/0076 dated 07-12-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 06-06-2025** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid GMP certificate since the already submitted **is expired now but valid upon submission.**
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Original legalized valid GMP certificate** • **Fee Rs. 7,500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
705.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey

	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17937 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Fenerol 30% Oral Solution
	Composition	Each ml Contains: Florfenicol…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1000ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	▪ Originally legalized COPP No. 13.04.2009-21/019 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 12-04-2024** ▪ Original legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Original legalized distribution agreement dated 28-09-2020 between the MAH and the applicant. **Validity: 5 years**
	Remarks of the Evaluator [X]	Provided 06months accelerated and 24months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Provide original legalized valid GMP certificate since the already submitted **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: Deferred for following: • **Original legalized valid GMP certificate** • **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, .**	
706.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	**Legible copy not provided**
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11656 Dated 21-04-2021

	Fee including differential fee	Rs : 100,000 Dated 06-04-2021
	Brand Name +Dosage Form + Strength	Amoxiqas Oral Powder for Use in Drinking Water
	Composition	Each gram contains: Amoxicillin Trihydrate 700mg Eq. to Amoxicillin…610mg
	Finished Product Specification	Ph Eur specifications
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	**CIMAvet, Spain approved** with brand name AMOXIDIAN
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original legalized COPP dated 31-01-2019 issued by Spanish agency of Medicines and Health products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of legalized sole distributor agreement dated 28-02-2019 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Impurity E rises at 3rd and 6th month time point in accelerated stability study.** **Shortcomings:** • Provide legible **copy of valid DSL** • Provide original notarized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Confirmation of **dedicated penicillin manufacturing facility.**
	Decision: Deferred for following: • **legible copy of valid DSL** • **original notarized valid Power of attorney/sole distributor agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **confirmation of dedicated penicillin manufacturing facility.** • **accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
707.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	**Legible copy not provided**
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11657 Dated 21-04-2021
	Fee including differential fee	Rs : 100,000 Dated 06-04-2021
	Brand Name +Dosage Form + Strength	Megluvet Solution for Injection
	Composition	Each ml Contains:

		Flunixin (Meglumine)…50mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Anti-inflammatory non-steroidal
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Floonix Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112255)
	Detail of certificates attached	➢ Original legalized COPP dated 16-02-2021 issued by Spanish agency of Medicines and Health products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of sole distributor agreement dated 21-01-2021 between applicant and MAH for the applied product.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide legible **copy of valid DSL** • Provide original notarized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following: • **legible copy of valid DSL** • **original notarized/appostile valid Power of attorney/sole distributor agreement** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	

b. Deferred cases

i. Veterinary

708.	Name and address of Applicant	M/s Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan.
	Detail of Drug Sale License	Name: M/s Huzaifa International Address: Commercial Area, Aziz Bhatti Town, Sargodha. Validity: **20-11-2019** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Komipharm International Co., Ltd. 17 Gyeongje-ro, Siheung-Si, Gyeonggi-Do, South Korea
	Name and address of marketing authorization holder	M/s Komipharm International Co., Ltd. 17 Gyeongje-ro, Siheung-Si, Gyeonggi-Do, South Korea
	Name of exporting country	The Republic of Korea (South Korea)
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32616 Dated 08-12-2020
	Fee including differential fee	Rs : 100,000 Dated 08-12-2020
	Brand Name +Dosage Form + Strength	Komidocarb Injection
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-parasitic
	Shelf life	3 years

	Demanded Price	Decontrolled
	Pack size	**10ml, 20ml, 50ml, 100ml**
	International availability	N/A
	Me-too status	Durazol Injection (10ml, 20ml, 50ml, 100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 078204)
	Detail of certificates attached	➢ Originally legalized FSC certificate No. M2010391 issued by the Animal and plant Quarantine Agency, republic of Korea DOES NOT CONFIRM free sale status of the product in exporting country. ➢ Original legalized GMP certificate dated 06-04-2020 issued by the Animal and plant Quarantine Agency, republic of Korea ➢ Scanned copy of authorization letter dated 06-10-2020 between PLH and Applicant
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Provide originally legalized FSC since the already submitted FSC states that *the applied product is registered and permitted to be freely sold in* ***overseas markets***. • In the finished product label the Urdu version of the following namely; (i) dosage; and (ii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following • valid copy of DSL • originally legalized Free Sale Certificate • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: i. Copy of DSL valid till 20-11-2023. ii. Original legalized FSC # M2301188 dated 18-05-2023 issued by the Animal and plant Quarantine Agency, republic of Korea confirms the free sale status in country of origin. iii. Label in accordance with The Drugs (Labeling and Packing) Rules, 1986 fro pack size of **10ml**.	
	Decision: Approved with 10ml pack size. Firm shall submit fee Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
709.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18339 Dated 27-07-2020

	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Ceftiofur S Suspension for Injection
	Composition	Each 100ml Contains: Ceftiofur HCl…5gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Ceptifi Veterinary Injectable Suspension (100ml) of M/s Al-Asar Enterprises, Multan. (Reg. No. 094479)
	Detail of certificates attached	➢ Originally, Legalized FSC No. 1211/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the **scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection)** **Issued on:** 02-06-2017 **Validity**: 5 years • Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy **is expired now but valid upon submission.**
	Decision of 326th meeting: Deferred for following • confirmation of dedicated manufacturing facility • original valid legalized relevant GMP certificate	
	Updated status: i. Firm has submitted that a letter of confirmation form APA UNITED NANOTECHNOLOGY CO., LTD, stating that in Vietnam, the Ministry of Agriculture & Rural Development, Department of Animals Health only certify two production lines of Beta-Lactam and Non Beta-Lactam. Their product belongs to Beta-Lactam line. ii. Firm has also submitted that AL-ASAR ENTERPRISES (PAKISTAN) MULTAN is distributor of VEMEDIM ANIMAL HEALTH VIETNAM, they register one of suspension product namely VIME-AMOX 15% LA having DRAP Registration No. 094478 and Cepti Veterinary Injectable Suspension Reg. No. 094479 with same GMP. It is therefore requested to please consider our case to register our products.	
	Decision: Deferred for clarification rearding the international practices for manufacturing of beta lactam anitibiotics.	
710.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.

	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18331 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Amox Gen S Suspension
	Composition	Each 100ml contains: Amoxicillin Trihydrate…15gm Gentamycin Sulphate…4gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Pro-Mox Injection (100ml) of M/s Prix Pharmaceutica, Lahore. (Reg. No.102203)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1214/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection) **Issued on:** 02-06-2017 **Validity**: 5 years • Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy is expired now but valid upon submission.

	Decision of 326th meeting: Deferred for following • confirmation of dedicated manufacturing facility • original valid legalized relevant GMP certificate	
	Updated status: i. Firm has submitted that a letter of confirmation form APA UNITED NANOTECHNOLOGY CO., LTD, stating that in Vietnam, the Ministry of Agriculture & Rural Development, Department of Animals Health only certify two production lines of Beta-Lactam and Non Beta-Lactam. Their product belongs to Beta-Lactam line. ii. Firm has also submitted that AL-ASAR ENTERPRISES (PAKISTAN) MULTAN is distributor of VEMEDIM ANIMAL HEALTH VIETNAM, they register one of suspension product namely VIME-AMOX 15% LA having DRAP Registration No. 094478 and Cepti Veterinary Injectable Suspension Reg. No. 094479 with same GMP. It is therefore requested to please consider our case to register our products.	
	Decision: Deferred for clarification rearding the international practices for manufacturing of beta lactam anitibiotics.	
711.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18334 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Clorprostinex Injection
	Composition	Each ml Contains: Cloprostenol Sodium 26.3mg Eq. To Cloprostenol…25mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Prostaglandin
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	N/A
	Me-too status	Ovuprost Injection (20ml) of M/s Ghazi Brothers, Karachi. (Reg. No.099427)
	Detail of certificates attached	• Originally Legalized FSC No. 459/2020/QLT-CFS dated 15-05-2020 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam; its **scope does not cover manufacturing operations of injectable Hormone.**

		Issued on: 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide legalized original valid relevant GMP certificate since the scope of already submitted copy does not cover manufacturing operations of **injectable Hormone.** • Provide original valid Legalized FSC since already submitted is **expired now but valid upon submission**
	Decision of 326th meeting: Deferred for following • confirmation of relevant manufacturing facility • original valid legalized relevant GMP certificate • original valid Legalized FSC	
	Updated status: i. Firm has submitted that a letter of confirmation form APA UNITED NANOTECHNOLOGY CO., LTD, stating that in Vietnam, the Ministry of Agriculture & Rural Development, Department of Animals Health only certify two production lines of Beta-Lactam and Non Beta-Lactam. Their product belongs to Non Beta-Lactam line.	
	Decision: Deferred for following • **Clarification rearding the international practices for manufacturing of beta lactam anitibiotics.** • **Valid Legalized FSC and GMP certficate**	
712.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18333 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Amox 15S Suspension
	Composition	Each 100ml contains: Amoxicillin Trihydrate…15gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years

	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Sinomox LA Suspension for Injection (100ml) of M/s Ghazi Brothers, Karachi. (Reg. No. 106781)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1216/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection) **Issued on:** 02-06-2017 **Validity**: 5 years • Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy is expired now but valid upon submission.
	Decision of 326th meeting: Deferred for following • confirmation of relevant manufacturing facility • original valid legalized relevant GMP certificate	
	Updated status: i. Firm has submitted that a letter of confirmation form APA UNITED NANOTECHNOLOGY CO., LTD, stating that in Vietnam, the Ministry of Agriculture & Rural Development, Department of Animals Health only certify two production lines of Beta-Lactam and Non Beta-Lactam. Their product belongs to Beta-Lactam line. ii. Firm has also submitted that AL-ASAR ENTERPRISES (PAKISTAN) MULTAN is distributor of VEMEDIM ANIMAL HEALTH VIETNAM, they register one of suspension product namely VIME-AMOX 15% LA having DRAP Registration No. 094478 and Cepti Veterinary Injectable Suspension Reg. No. 094479 with same GMP. It is therefore requested to please consider our case to register our products.	
	Decision: Deferred for clarification rearding the international practices for manufacturing of beta lactam anitibiotics.	

Agenda of Evaluator PEC-XI

Case No. 1: Registration applications of Human Drugs on form 5F (New DML):
M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
The Central Licensing Board 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 three sections to **M/s Pinnacle Biotech (Pvt.) Ltd.,** Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi under Drug Manufacturing License No. 000939 by way of Formulation vide approval letter No. F. 2-10/2011-Lic(Vol-I) dated 13th September 2021. The Drug Manufacturing License No. 000939 by way of

formulation is hereby issued w.e.f. 13-09-2021.

S No.	Name of Sections
1.	Tablet (General)
2.	Capsule (General)
3.	Sachet (General)
4.	Research & Development Laboratory

Following applications have been submitted for registration by the firm.

713.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued on 21-10-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 2986 dated 01-02-2023
	Details of fee submitted	Rs.30,000/- dated 18-01-2023 (Deposit slip#4595632206)
	The proposed proprietary name / brand name	**Azijet 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Azithromycin Dihydrate equivalent to azithromycin……500mg
	Pharmacotherapeutic Group of (API)	Tablet
	Pharmaceutical form of applied drug	Macrolide Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZITHROMAX 500mg film-coated tablets, USFDA Approved.
	For generic drugs (me-too status)	Zetro 500mg Tablet by M/s Getz Pharma (Reg#53120)
	Name and address of API manufacturer.	M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, 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, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data as per zone IV-A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: C0802-201909002, C0802-201909001, C0802-201909003
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Azomax 500mg tablet by M/s GSK Consumer Healthcare Pakistan Limited (mfgr) / Novartis Pharma (MAH) by performing quality tests (Identification, average weight, disintegration time, uniformity of dosage units, dissolution, assay) CDP has been performed against the product Azomax 500mg tablet by M/s Sandoz in Phosphate buffer (pH 4.5), Phosphate buffer (pH 6.0) & Phosphate Buffer (pH 7.5). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China
API Lot No.	C0802-202111007
Description of Pack (Container closure system)	Alu-alu Blister strip 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-057	T-056	T-053
Batch Size	1500 Tab	1500 Tab	1500 Tab
Manufacturing Date	19-05-2022	19-05-2022	17-05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
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.	The firm has submitted written confirmation for active substance exported to EU to M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China issued by Hubei Medical Products Administration valid upto 1st June 2025. The certificate confirms that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. Firm has submitted copy of DML (E20200125) in name of M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China issued by Hubei Drug Administration valid upto 28th September 2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Justification is required for setting assay specification of drug substance on "dried basis instead of anhydrous basis" by drug product manufacturer with reference to recommendations of USP monograph. • Submitted analytical method verification report declares the details for "Azithromycin 500mg tablets".	• The firm submitted that in specification and testing method Assay limits is 94.5% to 103.0% that is same as per USP monograph and mentioned in analytical raw data report and Certificate of Analysis. The firm submitted that rectification of dried basis has been made and Fees has been submitted against typographical error having challan No. 888753469724 of Rs.7500/- • The firm submitted that Azijet is a suggested brand name and Azithromycin is a generic. We have performed the verification on Azijet 500mg tablet and there is no difference in product "Azijet" and "Azithromycin".

3.2.P.1	• You have used dibasic phosphate anhydrous in your formulation instead of dibasic calcium phosphate anhydrous clarify?	We have use Dicalcium phosphate anhydrous. It is same as dibasic calcium phosphate anhydrous having same (CAS NO: 7757-93-9), against GRN: RM2122 COA of material is submitted
3.2.P.2	• Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product • Selection of dissolution media (phosphate buffer pH 4.5, pH 6, pH 7.5) in CDP studies shall be justified with reference to applicable guidelines • Clarification is required as the submitted details show that the reference product against which pharmaceutical equivalence and CDP studies is performed is from two different supplier	• Image/picture/ snap shot of innovator/reference/comparator pack is submitted. • The firm submitted that for stability testing, the dissolution media pH 6.0 phosphate buffer is used that is recommended by USP. While for CDP 3 different pH dissolution media used that is 0.1M phosphate buffer, pH 4.5, 0.1M phosphate buffer pH 6.0 and 0.1M phosphate buffer pH 7.5. Reference of selection of this 3 pH is "Clinical Pharmacology and biopharmaceutics review application number 50-784". CDP has been performed with reference to this guideline. • Pharmaceutical equivalence and CDP performed against same reference product that is Azomax 500mg tablet. Details are provided. Azomax 500mg tablet Manufactured for: Novartis Pharma (Pakistan) Limited By M/s GSK Consumer Healthcare Pakistan Limited Jamshoro Sandoz a Novartis Division
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP. • Justification is required for not including the test for uniformity of dosage unit in finished product specification as recommended by USP	• The firm submitted that dissolution time is 30minutes and is mentioned in analytical testing method and it is now mentioned in specification as well. Revised Specification and testing method is submitted. • The firm submitted that uniformity of dosage unit by weight variation already mentioned in finished product specification and submitted finished product specifications.
3.2.P.8	• Documents for the procurement of API with approval from DRAP is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm has submitted copy of invoice dated 09-12-2021 for import of 04kg of Azithromycin Dihydrate in name of M/s Pinnacle Biotech (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 28-12-2021. Firm has also submitted copy of form 6 dated 28-12-2021 for import of 04kg of Azithromycin Dihydrate in name of M/s Pinnacle Biotech (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 28-12-2021. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Decision: Approved. Registration letter will be issued after submission of CDP studies in three physiological medias (i.e. 0.1N HCl pH 1.2, Acetate Buffer pH 4.5 and Phosphate Buffer pH 6.8)

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

714.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued on 21-10-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 2985 dated 01-02-2023
	Details of fee submitted	Rs.30,000/- dated 18-01-2023 (Deposit slip#2697906550)
	The proposed proprietary name / brand name	Azijet 250mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Azithromycin Dihydrate ……250mg
	Pharmacotherapeutic Group of (API)	Capsule
	Pharmaceutical form of applied drug	Macrolide Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZITHROMAX 250 mg Capsule, MHRA Approved.
	For generic drugs (me-too status)	Azomax 250mg Capsule by M/s AGP Limited (Reg#112797)
	Name and address of API manufacturer.	M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, 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, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data as per zone IV-

	(Conditions & duration of Stability studies)	A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: C0802-201909002, C0802-201909001, C0802-201909003
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Azomax 250mg tablet by M/s GSK Consumer Healthcare Pakistan Limited (mfgr) / Novartis Pharma (MAH) by performing quality tests (Identification, average weight, disintegration time, uniformity of dosage units, dissolution, assay) CDP has been performed against the product Azomax 250mg capsule by M/s Sandoz in Phosphate buffer (pH 4.5), Phosphate buffer (pH 6.0) & Phosphate Buffer (pH 7.5). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China		
API Lot No.	C0802-202111007		
Description of Pack (Container closure system)	Alu-alu Blister strip 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-050	T-060	T-061
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	14-05-2022	14-05-2022	21-05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
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.	The firm has submitted written confirmation for active substance exported to EU to M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China issued by Hubei Medical Products Administration valid upto 1st June 2025. The certificate confirms that the manufacturing plant complies with

		requirement of Chinese Good Manufacturing practices. Firm has submitted copy of DML (E20200125) in name of M/s Huangshi Shixing Pharmaceutical Co., Ltd., No. 73 East Jinshan Road, Huangjinshan Development Zone, Huangshi, Hubei, P.R. China issued by Hubei Drug Administration valid upto 28th September 2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Justification is required for not considering the hydrated form in label claim	The firm has revised the label claim as per reference formulation considering the hydrated form along with submission of Rs. 30000/- on deposit slip No#7210225081. The revised label claim is as under: Each Capsule Contains: Azithromycin Dihydrate equivalent to azithromycin……..250mg
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Justification is required for setting assay specification of drug substance on "dried basis instead of anhydrous basis" by drug product manufacturer with reference to recommendations of USP monograph. • Submitted analytical method verification report declares the details for "Azithromycin 500mg tablets".	• The firm submitted that in specification and testing method Assay limits is 94.5% to 103.0% that is same as per USP monograph and mentioned in analytical raw data report and Certificate of Analysis. The firm submitted that rectification of dried basis has been made and Fees has been submitted against typographical error having challan No. 7869667766 of Rs.7500/- • The firm has submitted Azijet is a suggested brand name and Azithromycin is a generic. We have performed the verification on Azijet 250 Capsules and there is no difference in product "Azijet" and "Azithromycin."
3.2.P.1	• Justify the role of purified water used in the applied formulation, clarify?	Purified water is used as a solvent for binder solution preparation.
3.2.P.2	• Finished Pharmaceutical development report for Aziject 500mg tablet is submitted instead of Aziject 250mg capsule, clarify? • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name,	• Finished Pharmaceutical development report for Azijet 250mg Capsules is submitted. Pharmaceutical development report for Aziject 500mg tablet is attached by mistake • Image/picture/ snap shot of innovator/reference/comparator pack is submitted. • The firm submitted that for stability testing, the dissolution media pH 6.0 sodium dihydrogen

	manufacturer, batch# and expiry date of the innovator /reference/comparator product • Selection of dissolution media (phosphate buffer ph 4.5, ph 6, ph 7.5) shall be justified with reference to applicable guidelines • Clarification is required as the submitted details show that the reference product against which pharmaceutical equivalence and CDP studies is performed is from two different supplier	orthophosphate buffer is used that is recommended by BP. While for CDP 3 different pH dissolution media used that is 0.1M phosphate buffer, pH 4.5, 0.1M phosphate buffer pH 6.0 and 0.1M phosphate buffer pH 7.5. Reference of selection of this 3 pH is "Clinical Pharmacology and biopharmaceutics review application number 50-784". CDP has been performed with reference to this guideline. • Pharmaceutical equivalence and CDP performed against same reference product that is Azomax 250mg capsule. Details are provided. Azomax 250mg capsule Manufactured for: Novartis Pharma (Pakistan) Limited By M/s GSK Consumer Healthcare Pakistan Limited Jamshoro Sandoz a Novartis Division
3.2.P.5	• Justification is required for using BP specification for drug product while drug substance is analyzed as per USP monograph by drug substance manufacturer and drug product manufacturer • Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by BP. • In batch analysis in column of quantity 1500 tablets are written instead of capsule, clarify	• The firm submitted that according to USP monograph of Azithromycin Capsule "Amperometric electrochemical detector" is required that we don't have this detector so, we have adopted BP monograph for capsule analysis in which UV detector is used. • The firm submitted that dissolution time is 45minutes and is mentioned in analytical testing method and it is now mentioned in specification as well. Revised Specification and testing method is submitted. • The firm submitted that in Analytical Raw Data 1500 capsules mentioned while in the certificate of analysis it was mistakenly written 1500 tablets. The firm has submitted revised COA. Fees Rs.7500/- has been submitted against typographical error having challan No. 54963436130.
3.2.P.6	• The submitted COA of reference / working standard follow USP specifications while finished drug product follow BP specifications	We have procured one Reference standard that is of USP. So we utilize USP reference standard to standardize the working standard and that same working standard used for finished drug product analysis.
3.2.P.8	• Documents for the procurement of API with approval from DRAP is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm has submitted copy of invoice dated 09-12-2021 for import of 04kg of Azithromycin Dihydrate in name of M/s Pinnacle Biotech (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 28-12-2021. Firm has also submitted copy of form 6 dated 28-12-2021 for import of 04kg of Azithromycin Dihydrate in name of M/s Pinnacle Biotech (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 28-12-2021. • 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:

- **CDP studies in three physiological medias (i.e. 0.1N HCl pH 1.2, Acetate Buffer pH 4.5 and Phosphate Buffer pH 6.8)**
- **Justification for use of USP reference / working standard for analysis of product that follow BP specifications**

- **Analysis of drug substance as per BP monograph by drug product manufacturer**
- **Registration Board further decided that firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change (typo error), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

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

M/s Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat.
The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five sections to M/s, Carer Pharmaceuticals Industries Plot # 27, Main Road, Rawat Industrial Estate, Rawat under Drug Manufacturing License No. 000925 by way of Formulation vide approval letter No. F. 1-32/2016-Lic dated 07th June 2021. The Drug Manufacturing License No. 000925 by way of formulation is hereby issued w.e.f. 18-03-2021.

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

Following applications have been submitted for registration by the firm.

715.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 13767 dated 02-06-2023
	Details of fee submitted	Rs.30,000/- dated 02-06-2023 (Deposit slip#84353931118)
	The proposed proprietary name / brand name	**Caraflox 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Levofloxacin (as Hemihydrate)……..500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVAQUIN 500mg film coated tablets, USFDA approved *Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** Levofloxacin 500mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Leflox 500mg Tablet by M/s Getz Pharma (Reg#26163)
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Economic Development Zone of Sanmen County, Zhejiang 31700, 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, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (DC-0401-1203001, DC-0401-1203002, DC-0401-1203003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against product Leflox 500mg tablet by M/s Getz Pharma by performing quality tests (Identification, uniformity of dosage units, disintegration test, dissolution, assay) CDP has been performed against the product Leflox 500mg tablet by M/s Getz Pharma in 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 method verification studies including Accuracy, precision (repeatability).

STABILITY STUDY DATA	
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Economic Development Zone of Sanmen County, Zhejiang 31700, P.R. China
API Lot No.	DC-004-2112011
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.	T001	T002	T003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	20-11-2022	20-11-2022	20-11-2022
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 Zhejiang East-Asia Pharmaceutical Co., Ltd., Coastal Industrial city, Pubagang town, Sanmen County, Zhejiang China issued by China Food & Drug Administration valid upto 15-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate for import of 05kg Levofloxacin Hemihydrate from M/s Zhejiang East Asia Pharmaceutical Company., Ltd China attested by AD (I&E) DRAP Islamabad dated 11-05-2022.
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 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 Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address mentioned on submitted GMP certificate is different than that given in section 1.6.5	• The firm has submitted copy of DML (License#20000312) of M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Coastal Industrial city, Pubagang town, Sanmen County, Zhejiang China valid upto 07-10-2024 verified from NMPA website. • The firm has corrected address in section 1.6.5 as per DML: M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Coastal Industrial city, Pubagang town, Sanmen County, Zhejiang 317100, P.R., China
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Signed copies of drug substance specifications by drug product manufacturer shall be submitted • Result for specificity test are not submitted in method verification study	• Signed copies of drug substance specifications by drug product manufacturer is submitted • Result for specificity test is submitted in method verification study

	• Test for specific rotation is not performed in batch analysis by drug product manufacturer as recommended by USP	• Firm has submitted revised batch analysis report of drug substance in which Test for specific rotation is performed
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	• The firm submitted that CDP has been performed with comparator pack (Leflox 500mg tablets) due to unavailability of innovator's pack • Image/picture/snapshot of innovator /reference/comparator against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed is submitted
3.2.P.5	• Justification is required for not mentioning the number of USP test used for dissolution study • The rpm used in dissolution study (50rpm) is different than that recommended by USP monograph (75rpm) • Result for specificity test are not submitted in method verification study	• The firm has submitted revised analytical method mentioning USP test 1 for dissolution test. • The firm submitted mentioned was a typing mistake and now rpm used in dissolution study is corrected as per USP monograph (75rpm). • Result for specificity test in method verification study is submitted
3.2.P.8	• The batch size of applied formulation is neither mentioned in batch analysis nor in stability summary sheets clarify? • The submitted UV spectra does not depict the batch number or dosage form of applied formulation	• The firm submitted that batch size is mentioned now in batch analysis report and revised batch analysis report is submitted • The firm submitted that UV spectra was software generated report now batch No. and strength of product added

Decision: Approved:

- **Fee of Rs. 7,500/- for correction/pre-approval change (typo error), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Registration Board directed the QA division to conduct the GMP inpevction during active production.**

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

M/s Pasteur & Fleming Pharma Plot No. P-70-A, Road No. 04, Phase 3, Industrial Estate Hattar, KPK**.** The Central Licensing Board 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 sections to **M/s Pasteur & Fleming Pharma** Plot No. P-70-A, Road No. 04, Phase 3, Industrial Estate Hattar, KPK under Drug Manufacturing License No. 000945 by way of Formulation vide approval letter No. F. 3-1/2017-Lic dated 11th November 2021. The Drug Manufacturing License No. 000945 by way of formulation is hereby issued w.e.f. 10-11-2021.

S No.	Name of Sections
1.	Tablet (Hormone)
2.	Tablet (General)
3.	Capsule (General)
4.	Dry Powder Suspension (General)
5.	Cream/Ointment Section (General)

Following applications have been submitted for registration by the firm.

716.	**Name, address of Applicant / Marketing Authorization Holder**	**Pasteur & Fleming Pharma, Plot # P-70-A, Phase–III, Road No.4, Industrial Estate Hattar KPK.**
	Name, address of Manufacturing site.	Pasteur & Fleming Pharma, Plot # P-70-A, Phase–III,

		Road No.4, Industrial Estate Hattar KPK.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 11-11-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 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	Form-5F Dy.No 11784 dated 15-05-2023
	Details of fee submitted	Rs.30,000/- dated 06-04-2023 (Deposit slip#625437102309)
	The proposed proprietary name / brand name	**Loxit 30mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Duloxetine HCl enteric coated pellets (17%) eq. to Duloxetin……..……30mg
	Pharmacotherapeutic Group of (API)	Selective serotonin and norepinephrine reuptake inhibitors (SSNRIs) Anti-Depressants
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP
	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)	Dulan 30mg capsule by M/s Hilton Pharma (Reg.No#055447)
	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, solubility, physical form, manufacturers, description of manufacturing process and 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 Studies of Drug Substance is submitted. However, Stability Studies of Drug Substance is not

		readable
	Module-III Drug Product:	Firm has submitted data of drug product including 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 study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence studies of their product against the product Dulan capsule 30mg by performing quality tests (Description, Identification, dissolution and Assay).. Firm has submitted CDP results of their product against Dulan capsule 30mg by M/s Hilton Pharma Limited in 0.1N HCl (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 including specificity, precision and accuracy.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle , Kahuta Road Islamabad		
API Lot No.	DXT291		
Description of Pack (Container closure system)	Alu-Alu Blisters packed in bleechboard 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.	T-01	T-02	T-03
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	21-06-2022	21-06-2022	21-06-2022
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.	The firm has submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 31-01-2019 based on inspection conducted on 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for purchase of 01Kg of Duloxetine (HCL) EC pellets 17% from M/s Vision Pharmaceuticals (Pvt.) Ltd., 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 data of stability batches supported by unattested 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)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	Submit valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	The firm has submitted copy of cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.
2.3.R.1	• Justification shall be submitted for the dispensed quantity of Duloxetine (HCl) EC Pellets 17% against the label claim with reference to the potency of Duloxetine (HCl) EC Pellets determined during drug substance analysis by M/s Pasteur & Fleming Pharma.	The firm submitted that actually we had done the calculation in the term of kilogram on the excel sheet the digits were not seen as after the decimal point were rounded off now we have done it again in the term of grams than three digits have been clarified. We have use this formula for dispensed quantity with given potency as 17.15 %. Qty per caps = 100/potency x label claim Loxit Capsules = 100/17.15 * 30= 175mg/ Cap So, Batch Size is = 1500 capsules 175x1500/1000 262.5gm/ Batch
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) performed by the Drug Product manufacturer for drug substance is submitted.
3.2.S.7	• Readable copies of stability data of drug substance 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 18 months. Batches: (DXT250, DXT256, DXT 258)
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	• The firm submitted that at the time of stability study we searched a Cymbalta capsules 30mg lot but couldn't find the innovator product of Loxit 30mg capsules, the innovator's product was not available at market and we got only the Brand Leader since we started this work for saving time brand leader Dulan Capsules 30mg capsules from Hilton Pharma Pvt. Ltd., Karachi having Registration Number.055447, DML # 000136, batch Number. 141104 instead of Innovator, Brand Leader has also done studies according to the innovator's specs that we also considered it appropriate. • Image/picture/snapshot of innovator / comparator pack against which Pharmaceutical

		equivalence/Comparative dissolution profile studies have been performed is submitted
3.2.P.5	• Signed copies of finished product specifications, analytical procedure and method verification studies shall be submitted • Justification shall be submitted for not including the test for uniformity of dosage unit in finished product specifications as recommended by USP • HPLC column details shall be submitted for assay test • The USP test number adopted for dissolution test is not mentioned in product specifications • Unsinged copies of Batch analysis of three batches are submitted	• Signed copies of finished product specifications, analytical procedure and method verification studies is submitted • The firm submitted that in Loxit hard gelatine capsules 30mg (Duloxetine HCl) the ratio of Active pharmaceuticals Ingredient (API) and label claimed of Loxit capsules 30mg is more than 25mg, so uniformity of content cannot be applied here only weight variation will be applied in this case. As per USP monograph the product Containing 25 mg or more of a drug substance or comprises 25% or more (by weight) of one capsule. However uniformity of dosage unit by content uniformity shall be included in specifications • The firm submitted that USP test No#01 is used for dissolution test. • The firm has provided details of HPLC column used for assay test, C8; 4.6X75MM,3.5µm • Singed copies of Batch analysis of three batches are submitted
3.2.P.8	• Unattested and unsigned documents like Raw data sheets, COA, summary data sheets etc. are submitted • Chromatograms for dissolution test are not submitted	• Signed documents like Raw data sheets, COA, summary data sheets etc. are submitted • Chromatograms for dissolution test 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.**

Registration letter will be issued after submission of:

- **Revised finished product specifications including the test for uniformity of dosage unit i.e. content uniformity as per USP monograph**
- **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.**

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

M/s World Biz Pharmaceutical Company Plot#340 Phase-II, Industrial Estate, Multan
The Central Licensing Board 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 one section to **M/s World Biz Pharmaceutical Company** Plot#340 Phase-II, Industrial Estate, Multan under Drug Manufacturing License No. 000942 by way of Formulation vide approval letter No. F. 1-25/2008-Lic dated 17th September 2021. The Drug Manufacturing License No. 0009942 by way of formulation is hereby issued w.e.f. 13-09-2021.

S No.	Name of Sections
6.	Oral Liquid Syrup section (General).

Following applications have been submitted for registration by the firm.

717.	Name, address of Applicant / Marketing Authorization Holder	M/s World Biz Pharmaceutical Company Plot#340 Phase-II, Industrial Estate, Multan
	Name, address of Manufacturing site.	M/s World Biz Pharmaceutical Company Plot#340 Phase-II, Industrial Estate, Multan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 13-09-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 17-09-2021 specifying Oral Liquid Syrup section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 5487 dated 27-02-2023
	Details of fee submitted	Rs.30,000/- dated 22-02-2023 (Deposit slip#460730580)
	The proposed proprietary name / brand name	**MetroBiz Suspension 200mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Metronidazole as benzoate……200mg (B.P Specifications)
	Pharmacotherapeutic Group of (API)	Anti-amoebic and anti-infective
	Pharmaceutical form of applied drug	Oral suspension
	Reference to Finished product specifications	B.P Specifications
	Proposed Pack size	30ml, 60ml, 90ml, 100ml, 120ml,, 450ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Metronidazole 200mg/5ml Oral Suspension by Rosemont Pharma (MHRA Approved)
	For generic drugs (me-too status)	Flygyl Suspension by M/s Sanofi-aventis Pakistan (Reg.No. 001214)
	Name and address of API manufacturer.	M/s Aarti Drugs Limited., Plot No 109 – D Mahendra Industrial Estate 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, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubility, 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. Batches: (MBO/402046, MBO/406279, MBO/410534)
	Module-III Drug Product:	Firm has submitted detail of drug product including its description, composition, Pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of drug Product, specifications, analytical procedures, analytical method verification studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence is established against Citzin syrup by M/s Sanofi Aventis Pakistan by performing quality tests (Identification, pH, deliverable volume and Assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including linearity, range, accuracy, precision, specificity, LOD and LOQ.

STABILITY STUDY DATA

Manufacturer of API	M/s Aarti Drugs Limited., Plot No 109 – D Mahendra Industrial Estate Road No 29, Sion (East), Mumbai - 400 022, INDIA.		
API Lot No.	MBO/12090523		
Description of Pack (Container closure system)	An amber glass bottle containing yellow coloured suspension with characteristic pleasant flavour, labelled sealed with pp. aluminium cap packed in specific unit carton. (60ml)		
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.	RD-MS-001	RD-MS-002	RD-MS-003
Batch Size	500 bottles	500 bottles	500 bottles
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)	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 of M/s Aarti Drugs Limited., Plot No. K-40/41, MIDC, Tarapur, Biosar, Tal-Palghar, Dist Thane 401506 Mahrashtra State, India issued by Food and Drugs Administration Maharashtra State, India valid upto 29th November 2024. 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 request for Loan of raw material to M/s British Pharmaceutticals 23-Km Sheikhupura Road, Lahore dated 11-07-2022. M/s British Pharmaceutticals 23-Km Sheikhupura Road, Lahore has accepted the request for Loan of Raw material dated 12-07-2022. Firm has submitted copy of Agreement for Loan of raw material to M/s British Pharmaceutticals 23-Km Sheikhupura Road, Lahore dated 12-07-2022. Firm has submitted copy of receiving letter addressed to assistant director PE&R dated 14-02-2023 for Borrowing of API, "Metronidazole Benzoate" for product development, R&D and Stability testing. Firm has submitted that the Metronidazole benzoate material of quantity 10Kg was obtained via loan from M/s British Pharmaceuticals Lahore. Copy of Form 3, 7, COA, commercial invoice (invoice# EXP/1750/22-23) dated: 21-09-2022 is submitted. *However the invoice not cleared by AD (I&E) DRAP filed office*
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	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)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for 3 months only.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Address mentioned on GMP certificate is different than that given in section 1.6.5, clarify	The firm submitted that address mentioned on GMP certificate is same as mentioned on the used Lot of API. The firm has revised the address in section 1.6.5 as M/s Aarti Drugs Limited., Plot No. K-40,41, MIDC, Tarapur-Biosar, Tal-Plghar Dist. Thane, India
3.2.S.4	• In contrary to the recommendations of BP monograph justification shall be submitted for not including the tests for loss on drying and sulphated ash in drug substance specification by drug product manufacturer • Justification shall be submitted for not performing the tests for sulphated ash in batch analysis of drug substance by drug product manufacturer	• Firm has submitted revised drug substance specifications and included the tests for loss on drying and sulphated ash • The firm submitted that suphated ash test was performed but skipped in the certificate of analysis typographically and submitted revised certificate of analysis of API.
3.2.P.2	• In section 3.2.P.2 of form 5F details for Cetirizine Hydrochloride syrup is submitted • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	• The firm submitted that this was a typographical error. Revised data in section 3.2.P.2 is submitted • Image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence studies have been performed is submitted. • The firm submitted that comparative product used was Flagyl Suspension 200mg/5ml (120ml) Batch No#AA263 Mfg date; Sep, 2022 Exp date; Aug, 2024

	• The submitted pharmaceutical equivalence reports shows comparison of SetBiz Syrup against Citzin Syrup, clarify	• Revised Pharmaceutical equivalence report performed against Flagyl Suspension 200mg/5ml by M/s Sanofi Aventis Pakistan by performing quality tests (Appearance, Identification, pH, deliverable volume and Assay).
3.2.P.5	• Justification is required as specification for identification test is by HPLC instead IR with reference to recommendations of BP mongraph • Justification is required as tests for antimicrobial preservative content and efficacy of preservative is not included in specification • Method used for standard solution preparation for assay is not as per recommendations of BP monograph, clarify (Dimethylformamide is not used along with methanol for dissolution of standard metronidazole benzoate)	• The firm submitted that identification of the product was performed by the HPLC retention time. HPLC is more precise technique than FTIR. So, that's why in specifications, identification via HPLC is mentioned • Antimicrobial preservative content and efficacy test study was performed and documents are submitted. • The firm submitted that method used for standard solution preparation is same as per recommendation of BP, only Dimethyl formamide was skipped due to non-availability. Once product is registered, we will adopt the same procedure as of BP monograph
3.2.P.8	• Justification is required as batch analysis show pack size of 60ml while BMR shows pack size of 90ml of trial batches • 6th month time point stability study data is not submitted • The submitted commercial invoice is not attested by AD (I&E) DRAP field office	• The firm submitted that pack size use for stability and batch analysis was 90ml. The firm has submitted revised batch analysis report. • Firm has submitted stability study data at 6th month time point • Commercial invoice (invoice# EXP/1750/22-23) dated: 21-09-2022 is submitted. *However the invoice not cleared by AD (I&E) DRAP filed office*

Decision: Keeping in view the remarks of evaluater and the submission of revised information and data with multiple typographic errers as admitted by the firm and not submitting the DRAP office attested invoice for the API used for production of trial batches for stability studies, the board decided to deffer the case for the submission complete dossier with new batches with full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Case No. 05; Registration application of Human drugs on Form 5-F on export facilitation

Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

718.	Name, address of Applicant / Marketing Authorization Holder	M/s Macter International Ltd., F-216, SITE, Karachi-Pakistan.
	Name, address of Manufacturing site.	M/s Macter International Ltd., F-216, SITE, Karachi-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 05-08-2022 based on inspection conducted on 04-08-2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-13/95-Lic (Vol-III) dated 10-12-2019 which specifies injectable section (ceph)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 843 dated 10-01-2023
	Details of fee submitted	Rs.30,000/- dated 10-10-2022 (Deposit slip#387617737581)
	The proposed proprietary name / brand name	**Avicef 2.5gm Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime as Ceftazidime pentahydrate……..…2g Avibactam as avibactam sodium ……0.5g
	Pharmaceutical form of applied drug	Sterile powder for injection
	Pharmacotherapeutic Group of (API)	Ceftazidime belongs to the group of antibiotics called "cephalosporin" Avibactam is "beta-lactamase inhibitor"
	Reference to Finished product specifications	Not submitted
	Proposed Pack size	1's
	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, 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 has been established against the brand that is Avycaz 2.5g Powder for injection by M/s GSK Italy., by performing quality tests (Appearance, identification, average weight, pH, Assay and related substances).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, accuracy, precision, specificity and 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)	25cc Clear glass vial, rubber stopper, flip off seal and leaflet in unit carton (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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB-077-001	21SB-078-002	21SB-079-003
Batch Size	100 Vials	100 Vials	100 Vials
Manufacturing Date	07-09-2021	07-09-2021	07-09-2021
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)	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.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 01-04-2020 for import of 1kg of Avibactam and Ceftazidime sterile (Working standard & Impurities) in name of M/s Macter International Limited. ***However, the invoice is not attested by AD (I&E) DRAP field office.***
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	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.6	• Mention the reference specifications of the finished product	• The firm has mentioned Innovator's specifications for applied product

1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of DML (License#Nei20160028) in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District, Chifeng, China issued by Drug Administration of Nei Monggol China valid upto 27-12-2025.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification is required for not performing the test for content uniformity and pyridine content in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Firm has submitted analytical method validation studies including linearity, accuracy, precision, specificity and robustness performed by the Drug Product manufacturer for drug substance. • Test for content uniformity has been performed by drug product manufacturer and revised reports submitted. *However, test for pyridine content is not 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 firm submitted that sterile water for injection will be provided with applied drug product that is already registered with M/s Macter International
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, pyridine content, uniformity of dosage unit, particulate matter, water content, bacterial endotoxins and sterility)	• Firm has submitted the justification on Pharmaceutical Equivalence included complete testing (Appearance, Identification, Avg. weight, pH, Assay, Related Substance, Any unspecified impurity, Total Impurity) of the drug product Avicef 2.5 g powder for injection and the innovator product recommended by the following guidelines, "Pharmaceutical equivalence – Drug products are considered pharmaceutical equivalents if they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product [1, 2]".Report of pharmaceutical equivalence is submitted. • Also the equivalence relationships between brand name and generic drugs are the following parameters; (API, Dosage form, Dose, Route of Administration, Labeling. • The test parameters stated in query already performed in our in-house testing for finished product.
3.2.P.3	• 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 Macter International Ltd. • Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance	• No justification is submitted for batch size of trial batches against the number of units required for complete testing of drug product during stability study till claimed shelf life • The firm submitted that batch size was determined according to the standard mixture, which is 315.0g for 100vials. The firm further stated that batch was filled according to the potency of API, which was tested by M/s Macter International. • Firm has submitted that content sodium

	are different than that recommended by innovator product	carbonate in premixed drug substance has been corrected and mentioned Certificate of Analysis for drug substance and stated that COA is submitted in dossier.
3.2.P.5	• Justification is required for not including the test for reconstitution time, pyridine content, uniformity of dosage unit and water content in finished product specification by drug product manufacturer as recommended by innovator product review document • Justification is required for not performing the test for reconstitutions time, uniformity of dosage units, pyridine content and water content in batch analysis by drug product manufacturer as recommended by innovator product review document	• Firm submitted that reconstitution time, uniformity of dosage unit and water content tests were already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test performed and mentioned in revised report of the drug substance of Avicef 2.5 g powder for injection. *However results for uniformity of dosage unit is not submitted*
3.2.P.7	• Description of the primary container closure systems including the type of glass shall be submitted	• Clear glass vial 25cc
3.2.P.8	• Justification is required for not performing the test for reconstitutions time, uniformity of dosage units, pyridine content and water content in stability study by drug product manufacturer as recommended by innovator product review document • Submit document for procurement of API with approval from DRAP	• Firm submitted that test for reconstitution time, uniformity of dosage unit and water content were already performed but didn't incorporated in the report and specifications, now mentioned in revised report, while pyridine content test *will be perform in ongoing stability study of the drug substance Avicef 2.5 g powder for injection. However, no revised reports are submitted* • Firm has submitted copy of invoice dated 17-06-2021 for import of 1kg of Avibactam and Ceftazidime sterile (& Impurities) in name of M/s Macter International Limited attested by AD (I&E) DRAP Karachi dated 22-06-2021

Decision: Deferred for submission of following:

- **Justification for not performing the test for pyridine content in batch analysis of drug substance by drug product manufacturer**
- **Justification as pharmaceutical equivalence study report 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, pyridine content, uniformity of dosage unit, particulate matter, water content, bacterial endotoxins and sterility)**
- **Justification for 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 not including the test for reconstitution time, pyridine content, uniformity of dosage unit and water content in finished product specification by drug product manufacturer**
- **Results for uniformity of dosage unit in batch analysis of drug product.**
- **Reports for reconstitution time, uniformity of dosage unit, water content in stability study**
- **Results for pyridine content in ongoing stability study**

Case No. 6: Deferred Registration applications of Human Drugs on form 5F (New DML):
M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi

The Central Licensing Board 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 three sections to **M/s Pinnacle Biotech (Pvt.) Ltd.,** Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi under Drug Manufacturing License No. 000939 by way of Formulation vide approval letter No. F. 2-10/2011-Lic(Vol-I) dated 13th September 2021. The Drug Manufacturing License No. 000939 by way of formulation is hereby issued w.e.f. 13-09-2021.

S No.	Name of Sections
5.	Tablet (General)
6.	Capsule (General)
7.	Sachet (General)
8.	Research & Development Laboratory

Following applications have been submitted for registration by the firm.

719.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1371 dated 16/01/2023
	Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#70103647320)
	The proposed proprietary name / brand name	**Neptune 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin……500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciproxin 500mg film-coated Tablets, MHRA Approved.

	For generic drugs (me-too status)	Ciproxin 500mg Tablet by M/s Bayer Pakistan Private Limited (Reg#107222)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data as per zone IV-A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: 00510011/001/2014, 00510011/002/2014, 00510011/003/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time, uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 500mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore		
API Lot No.	00510011 / 279 / 2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T047	T054	T055
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	16-05-2022	18-05-2022	18-05-2022

Date of Initiation	01-06-2020	01-06-2020	01-06-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore issued on 22-11-2022 based on inspection conducted on 18-11-2022 valid for two years from date of inspection
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 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	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)	Not Submitted

Remarks of Evaluator [XI]:

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

Previous Decision (327th–DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm (10th April 2023):

Section	Observations	Response
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications.	• *The firm submitted that drug product manufacturer tested their material on both specifications* to meet customer requirement while drug product manufacturer only tested the material as per USP.

	• Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021)	• The firm has submitted revised COA of batch No#(00510011 / 280 / 2021) from drug substance manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	Firm has submitted both COA of primary / secondary reference standard
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	The firm submitted that in specification and testing method on page No.09 on 3.6.3 in dissolution procedure time 30 minutes is mentioned while it was not mentioned in dissolution parameters and specifications so revised specification and testing method is submitted
3.2.P.8	• Documents for the procurement of API is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm has submitted purchase order from M/s Pinnacle Biotech and sale tax invoice and delivery note from M/s Pharmagen Limited for procurement of API • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) 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.**

720.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 22-11-2022 based on inspection conducted on 21-10-2022.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13/09/2021. Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1370 dated 16/01/2023
	Details of fee submitted	PKR 30,000/-: dated 06/01/2023 (Deposit slip#100252509767)
	The proposed proprietary name / brand name	**Neptune 250mg Tablets**
	Strength / concentration of drug of	Each film coated tablet contains:

	Active Pharmaceutical ingredient (API) per unit	Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin…….250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO (250mg) film coated tablet, USFDA Approved.
	For generic drugs (me-too status)	Ciproxin 250mg Tablet by M/s Bayer Pakistan Private Limited (Reg# 10118)
	Name and address of API manufacturer.	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data as per zone IV-A. Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: 00510011/001/2014, 00510011/002/2014, 00510011/003/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against ciproxin 250mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) by performing quality tests (Identification, average weight, disintegration time, uniformity of dosage units, dissolution, assay) CDP has been performed against the product ciproxin 250mg tablet by M/s Novartis Pharma (mfgr) / Bayer Pakistan (MAH) in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore
API Lot No.	00510011 / 279 / 2021
Description of Pack	Alu-Alu blister packed in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T049	T051	T052
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	12-05-2022	16-05-2022	16-05-2022
Date of Initiation	01-06-2020	01-06-2020	01-06-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of M/s Pharmagen Limited., Kot Nabi Bukhsh Wala 34-Km, Ferozpur Road, Lahore issued on 22-11-2022 based on inspection conducted on 18-11-2022 valid for two years from date of inspection
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 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	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)	Not Submitted

Remarks of Evaluator [XI]:

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

	• Documents for the procurement of API is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	

Previous Decision (327th–DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm (10th April 2023):

Section	Observations	Response
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Clarification is required as Drug substance manufacturer has given both USP and BP specifications and analytical method while drug product manufacturer has given USP specifications. • Clarification is required as the batch number mentioned on COA of drug substance by drug substance manufacturer (00510011 / 279 / 2021) is different than that of drug product manufacturer (00510011 / 280 / 2021)	• *The firm submitted that drug substance manufacturer tested their material on both specifications* to meet customer requirement while drug product manufacturer only tested the material as per USP. • The firm has submitted revised COA of batch No#(00510011 / 280 / 2021) from drug substance manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	Firm has submitted both COA of primary / secondary reference standard
3.2.P.5	• Justification is required for not mentioning the time for dissolution test in finished product specifications as recommended by USP.	The firm submitted that in specification and testing method on page No.09 on 3.6.3 in dissolution procedure time 30 minutes is mentioned while it was not mentioned in dissolution parameters and specifications so revised specification and testing method is submitted
3.2.P.8	• The batch number mentioned on chromatograms for assay test at 3rd month time point of real time and accelerated stability study is T047 instead of T049 clarify • In real time stability study at 3rd month and 6th month time point of batch#T052, chromatograms of Batch#T051 is submitted instead of Batch#T052, clarify • Documents for the procurement of API is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm submitted that for stability study 03 batches has been manufactured that is T049, T051 and T052. In chromatograms it was typo error, correction marked with initial of analyst. Revised report is submitted • In real time stability study at 3rd month, in sample 2 chromatogram, it was data entry error that during making batch file T-051 was mistakenly written instead of T-052, correction marked with the initials of analyst. While in sample 1 correct batch No. T-052 is already mentioned. Revised report is submitted. • At 6th month time point, during scanning of documents chromatograms of T052 was mistakenly replaced by T051. Revised report is submitted. • Firm has submitted purchase order from M/s Pinnacle Biotech and sale tax invoice and delivery note from M/s Pharmagen Limited for procurement of API • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved.

- **Registration board decided that firm shall submit the fee of Rs. 7,500/- for correction/pre-approval change (typo error), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case No. 7: Registration applications of Human Drugs on form 5F (New DML):
M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.

The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following seven (07) sections to M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot under Drug Manufacturing License No. 000944 vide approval letter No. F.1-5/2017-Lic dated 17/09/2021. The Drug Manufacturing License No. 000944 by way of formulation is hereby issued w.e.f. 13-09-2021.

S No.	Section
1.	Tablet (General)
2.	Capsule (General)
3.	Oral Liquid (General)
4.	Liquid Injectable – Vial & Ampoule (General)
5.	Capsule (Cephalosporin)
6.	Dry Powder Injectable (Cephalosporin)
7.	Oral Dry Powder Suspension (Cephalosporin)

Following applications have been submitted for registration by the firm.

721.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 17-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3131 : 02/02/2023
	Details of fee submitted	PKR 30,000/-: 12/12/2022 (Deposit slip#7485549404)
	The proposed proprietary name / brand name	Praq 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (8.5%) of omeprazole equivalent to omeprazole …….20mg
	Pharmaceutical form of applied drug	Hard gelatine capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 20 mg Gastro-resistant Capsules MHRA Approved
	For generic drugs (me-too status)	Risek Capsule 20mg by M/s Getz Pharma

		(Reg#19364)
	Name and address of API manufacturer.	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP073,)
	Module-III Drug Product:	Firm has submitted data of drug product including 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 results of pharmaceutical equivalence for their product against Risek 20mg capsule by performing quality tests (appearance, identification, dissolution, assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, linearity, range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	OMP1199		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 capsule	658 capsule	658 capsule

Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	27-04-2022	27-04-2022	27-04-2022
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)	No reference is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firms 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)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
2.3.R.1	• Justification is required for using 2% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	•
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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	•
3.2.S.7	• Stability study of at least three batches of drug substance till claimed shelf life shall be submitted	•
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	•
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP.	•

	• Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T001 Accelerated conditions at 6th month time point, T002 Accelerated conditions at 6th month time point, T003 real time conditions at 3rd and 6th month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than 90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	•

Previous Decision (M-327-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response:

Section	Observations	Response
2.3.R.1	• Justification is required for using 2% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	• Firm submitted that No overage has been used in the formulation of finished product • In the BMR 240mg of omeprazole pellets has been used equivalent to 20mg of omeprazole on the basis of assay analysis by M/S Qadir pharmaceuticals i.e. 8.33% (on as is basis). COA of manufacturer of drug substance and drug product manufacturer are 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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is not submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is not submitted. • Firm has submitted revised batch analysis report of drug substance by drug product manufacturer in which complete testing has been performed including loss on drying, sugar test, pellet size, bulk density. • Firm has submitted COA of drug substance wherein potency of omeprazole has been calculated on "as is basis".
3.2.S.7	• Stability study of at least three batches of drug substance till claimed shelf life shall be submitted	*Firm has submitted stability study data of only one batch of drug substance at accelerated and real time conditions:*
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product	• Firm has provided details on innovator product against which pharmaceutical equivalence studies have been performed

	against which pharmaceutical equivalence studies have been performed • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	Losec 20mg capsule (Astra Zenenca) Barret hodgson Pakistan (Pvt) Ltd Lot No; YEWH Mfg. Date; 02-2022 Exp. Date: 01-2025 • Firm has submitted revised pharmaceutical equivalence report for their product against Losec 20mg capsule by M/s Barret Hodgson Pakistan (Pvt) Ltd by performing quality tests (appearance, identification, average weight, uniformity of dosage unit, dissolution, assay) • Firm has submitted CDP studies against the product Losec 20mg capsule by M/s Barret Hodgson Pakistan (Pvt) Ltd in 0.1N HCl (pH 1.2) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP. • Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	• Firm has submitted revised finished product specifications containing the test for uniformity of dosage units and time for dissolution test at buffer stage. • Firm has referred to USP dissolution test 2 in analytical procedure. • Unsigned Copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is submitted
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T001 Accelerated conditions at 6th month time point, T002 Accelerated conditions at 6th month time point, T003 real time conditions at 3rd and 6th month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than 90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	• The firm submitted that previously T001, T002 and T003 was used for all product that is why in stability sheet it is same while later on from R & D and production department for all dosage form a different batch series was introduced e.g. for capsule it is CTR001, for tablet it is TTR001 and liquid syrup it is LS001. As the stability sheet data of HPLC cannot be changed therefore it is requested to please allow us to change the BMR Batch no. • The calculation in the raw data sheet is incorrect. The undissolved pellets of acid stage were dissolved in the diluent and give a result more than 90%. So 100- dissolved %= Release in acid stage • The dissolution test 2 of USP 43 is followed in the stability studies which clearly indicate the buffer stage analysis that "Determine the amount of omeprazole dissolved from UV absorbances at the wavelength of maximum absorbance at about 305 nm" that is why acid stage is analyzed by HPLC and buffer by UV. • This is as given in USP Dissolution test 2 "Sample solution: After 2 h, remove each sample from the basket, and quantitatively transfer into separate volumetric flasks to obtain a solution having a final concentration of about 0.2 mg/mL. Proceed as directed for the Sample solution in the Assay, starting with "Add about 50 mL of Diluent " • Add about 50 mL of Diluent, and sonicate for 15 min. Cool, dilute with Diluent to volume, mix, and

		pass through a membrane filter of 0.45-µm or finer pore size. [NOTE— Bubbles may form just before bringing the solution to volume. Add a few drops of dehydrated alcohol to dissipate the bubbles if they persist for more than a few minutes. • The undissolved pellets of acid stage were dissolved in the diluent and give a result more than 90%. So 100- dissolved %= Release in acid stage • No document for procurement of API is submitted

Decision: Deferred for submission of following:

- **Justification for using overage in finished product as mentioned in BMR**
- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance**
- **Stability study of at least three batches of drug substance till claimed shelf life**
- **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.**
- **Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer**
- **Scientific justification for the calculation of dissolution test with reference to the pharmacopoeia monograph.**
- **Documents for procurement of API with approval from DRAP**

722.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 17-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5904 : 02/03/2023
	Details of fee submitted	PKR 30,000/-: 07/12/2022 (Deposit slip#556684006746)
	The proposed proprietary name / brand name	Praq 40mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatine capsule contains: Enteric coated pellets (22.5%) of omeprazole equivalent to omeprazole …….40mg
	Pharmaceutical form of applied drug	Hard gelatine capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg gastro-resistant capsules MHRA Approved
	For generic drugs (me-too status)	Risek Capsule 40mg by M/s Getz Pharma (Reg#22109)
	Name and address of API manufacturer.	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP065, OMP103, OMP083)
	Module-III Drug Product:	Firm has submitted data of drug product including 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 results of pharmaceutical equivalence for their product against Risek 40mg capsule by performing quality tests (appearance, identification, dissolution, assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, linearity, range, accuracy, precision (repeatability), system suitability.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals Pvt. Ltd, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
API Lot No.	OMP896
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 capsule	658 capsule	658 capsule
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	03-05-2022	04-05-2022	04-05-2022
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)	No reference is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 22-08-2022 based on inspection conducted on 14-06-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firms has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that our system is not 21 CFR compliant and audit trail reports on product testing is not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
2.3.R.1	• Justification is required for using 1.25% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	•
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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	•
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	•
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP.	•

	• Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T003 Accelerated conditions at 3rd month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than 90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	•

Previous Decision (M-327-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's Response:

Section	Observations	Response
2.3.R.1	• Justification is required for using 1.25% overage in finished product as mentioned in BMR • Justification shall be submitted for the dispensed quantity of Omeprazole pellets against the label claim with reference to the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma.	• Firm submitted that No overage has been used in the formulation of finished product • In the BMR 180mg of omeprazole pellets has been used equivalent to 40mg of omeprazole on the basis of assay analysis by M/S Qadir pharmaceuticals i.e. 22.5% (on as is basis). COA of manufacturer of drug substance and drug product manufacturer are 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. • Justification shall be submitted for incomplete testing of drug substance by drug product manufacturer as recommended by drug substance manufacturer (loss on drying, sugar test, pellet size, bulk density). • Clarification shall be submitted regarding declared the potency of Omeprazole pellets determined during drug substance analysis by M/s Qadir Pharma whether it is on "as is basis" or "anhydrous basis".	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is not submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is not submitted. • Firm has submitted revised batch analysis report of drug substance by drug product manufacturer in which complete testing has been performed including loss on drying, sugar test, pellet size, bulk density. • Firm has submitted COA of drug substance wherein potency of omeprazole has been calculated on "as is basis".
3.2.P.2	• Submit the details of manufacturer, batch No# and expiry date of innovator/reference/comparator product against which pharmaceutical equivalence studies have been performed • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product	• Firm has provided details of comparator product against which pharmaceutical equivalence studies have been performed Risek 40mg capsule by M/s Getz (Pvt) Ltd Lot No; C04059 Mfg. Date; 02-2022 Exp. Date: 02-2025

	including the tests recommended by USP (uniformity of dosage units). • Justification is required since pharmaceutical equivalence have not been conducted against the innovator product. • Submit CDP studies of applied product as per guidelines approved by the registration board in its 293rd meeting	• The firm submitted due to unavailability of Losec 40mg capsule in Pakistan Risek 40mg was used as comparator for Pharmaceutical equivalence and CDP studies. • Firm has submitted revised pharmaceutical equivalence report for their product against Risek 40mg capsule by M/s Getz (Pvt) Ltd by performing quality tests (appearance, identification, average weight, uniformity of dosage unit, dissolution, assay) • Firm has submitted CDP studies against the product Risek 40mg capsule by M/s Getz (Pvt) Ltd in 0.1N HCl (pH 1.2) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units in finished product specifications as recommended by USP. • Justification is required for not mentioning the test number and time for dissolution test in finished product specifications at buffer stage as recommended by USP. • Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is required from M.s Qadir Pharmaceuticals instead of referring to the USP monograph extract.	• Firm has submitted revised finished product specifications containing the test for uniformity of dosage units and time for dissolution test at buffer stage. • Firm has referred to USP dissolution test 2 in analytical procedure. • Unsigned Copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer is submitted
3.2.P.8	• The batch number of manufactured batches mentioned in BMR is CTR001, CTR002, CTR003 while batch number mentioned stability summary sheet is T001, T002, T003, clarify • Justification is required since results of dissolution test in stability summary sheets at acid stage of batch No#T003 Accelerated conditions at 3rd month time point show results in terms of negative percentage. • Justification shall be submitted for performing the dissolution test at acid stage on HPLC and at buffer stage on UV spectrophotometer in stability studies • Clarification shall be submitted regarding the calculation formula applied for the results of Acid stage dissolution test with reference to the USP monograph since firm has represented the dissolution results as more than 90% in raw data sheets of acid stage dissolution test and has further subtracted results of dissolution test at acid stage from assay test for calculating final results. • Submit document for procurement of API.	• The firm submitted that previously T001, T002 and T003 was used for all product that is why in stability sheet it is same while later on from R & D and production department for all dosage form a different batch series was introduced e.g. for capsule it is CTR001, for tablet it is TTR001 and liquid syrup it is LS001. As the stability sheet data of HPLC cannot be changed therefore it is requested to please allow us to change the BMR Batch no. • The calculation in the raw data sheet is incorrect. The undissolved pellets of acid stage were dissolved in the diluent and give a result more than 90%. So 100- dissolved %= Release in acid stage • The dissolution test 2 of USP 43 is followed in the stability studies which clearly indicate the buffer stage analysis that "Determine the amount of omeprazole dissolved from UV absorbances at the wavelength of maximum absorbance at about 305 nm" that is why acid stage is analyzed by HPLC and buffer by UV. • This is as given in USP Dissolution test 2 "Sample solution: After 2 h, remove each sample from the basket, and quantitatively transfer into separate volumetric flasks to obtain a solution having a final concentration of about 0.2 mg/mL. Proceed as directed for the Sample solution in the Assay, starting with "Add about 50 mL of Diluent "

		• Add about 50 mL of Diluent, and sonicate for 15 min. Cool, dilute with Diluent to volume, mix, and pass through a membrane filter of 0.45-µm or finer pore size. [NOTE— Bubbles may form just before bringing the solution to volume. Add a few drops of dehydrated alcohol to dissipate the bubbles if they persist for more than a few minutes.] • The undissolved pellets of acid stage were dissolved in the diluent and give a result more than 90%. So 100- dissolved %= Release in acid stage • No document for procurement of API is submitted

Decision: Deferred for submission of following:

- **Justification for using overage in finished product as mentioned in BMR**
- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance**
- **Stability study of at least three batches of drug substance till claimed shelf life**
- **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.**
- **Signed copies of the Drug product analytical procedures used for routine testing of the Drug product by Drug Product manufacturer**
- **Scientific justification for the calculation of dissolution test with reference to the pharmacopoeia monograph.**
- **Documents for procurement of API with approval from DRAP**

Case No. 08: Deferred Registration applications of Human drugs on Form 5-F (New Section)
M/s Titlis Pharma, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore

The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of following sections of **M/s Titlis Pharma, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore** under Drug Manufacturing License No. 000779 (Formulation) vide approval letter No. F. 1-11/2009-Lic (Vol-I) dated 10th May, 2022.

S No.	Section
	Tablet Section II (General) **New**
	Dry Powder Suspension Section. **New**
	Dry Powder Sachet Section (General). **New**

Following applications have been submitted for registration by the firm.

723.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26943 dated 23/09/2022

	Details of fee submitted	PKR 30,000/-: dated 09/09/2022 (Slip#1900631731)
	The proposed proprietary name / brand name	**Montit 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contain Montelukast Sodium equivalent to Montelukast …….4mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists (LTRAs)
	Reference to Finished product specifications	USP
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Montelukast 4 mg Granules MHRA Approved
	For generic drugs (me-too status)	Montika 4mg Sachet by M/s Sami Pharmaceuticals (Reg#50744)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China 317016
	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, specifications, analytical procedures, batch analysis and justification of specification, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (201310301, 201310302, 201310303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Montiget Sachet 4mg of M/s Getz Pharma by performing quality tests (weight variation, Assay, Dissolution, of dosage form).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy and precision.
STABILITY STUDY DATA		
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City,	

	Zhejiang Province, China 317016		
API Lot No.	11001-210505		
Description of Pack (Container closure system)	Aluminum foil (three layer) sachet packet packed in cardboard 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.	MT-01	MT-02	MT-03
Batch Size	200 sachet	200 sachet	200 sachet
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	02-12-2021	02-12-2021	02-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate No. ZJ20180033 of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China issued by China Food and Drug Administration valid till 14-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No# TY121643 dated 12th July 2021 in the name of M/s Titlis Pharma Lahore from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., for import of 20kg Montelukast Sodium Batch No# 11001-210505. ***However the invoice is not attested by AD (I&E) DRAP field office***
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)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
3.2.S.4	• Justification is required for not including the test for enantiomeric purity in drug substance specification by drug product manufacturer as recommended by USP. • Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (40:60) while USP recommends gradient method	

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
3.0	60	40
16.0	49	51

- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
- Submit readable copy of Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer.

3.2.S.5

- COA of primary / secondary reference standard including source and lot number shall be provided.

3.2.P.2

- Justify the difference in qualitative composition of applied product from that of reference / innovator product.

Applied product	Montelukast 4 mg Granules
Montelukast sodium	Montelukast sodium
Dextrose	Mannitol
	Hydroxy propyl cellulose
	Tribasic sodium phosphate
	Magnesium Stearate

- Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?
- CDP of the applied product has not been submitted.
- Only protocol for CDP is submitted

3.2.P.5

- Clarification is required as the method of preparation and concentration of standard solution in analytical method of dissolution test is different from USP.
- Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (30:70) while USP recommends gradient method

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	48	52
5	45	55
12	45	55
22	25	75
23	25	75
25	48	52
30	48	52

3.2.P.6

- Clarification is required since the submitted COA of reference / working standard states that it follows in house specifications while the product monograph is available in USP

3.2.P.8

- Submit DRAP attested documents for the procurement of API.
- Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time conditions)

Previous Decision (M-323rd –RB (6th -8th December 2022) (Publication date of Minutes; 10th January 2023): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's Response (6th June 2023):

Section	**Observations**	**Response**

<table>
<tr><td>1.3.2</td><td>• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required</td><td>The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board held on 18th February 2021, and the new approved title is “Titlis Pharma (Private) Limited”. The change of title approval letter No. F. 1-11/2009-Lic (Vol-I) from Central Licensing Board in the name of “Titlis Pharma (Private) Limited” is submitted.</td></tr>
<tr><td>3.2.S.4</td><td>• Justification is required for not including the test for enantiomeric purity in drug substance specification by drug product manufacturer as recommended by USP.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
• Submit readable copy of Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer.</td><td>• The firm submitted that we have imported Montelukast Sodium from Zhejiang Tianyu Pharmaceutical Co., Ltd, which is well reputed API manufacturer and supplying its Montelukast Sodium to leading companies of Pakistan like Highnoon Laboratories, CCL Pharmaceuticals, Sami Pharmaceuticals, Getz Pharma, and The Searle Company limited.
Our API manufacturer Zhejiang Tianyu Pharmaceutical Co., Ltd has performed the test for Enantiomeric purity and we rely on our API Manufacturer for Enantiomeric purity test. (COA of Drug Substance Manufacturer is attached for reference).
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
• Readable copy of Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer is submitted.</td></tr>
<tr><td>3.2.S.4</td><td colspan="2">• Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (40:60) while USP recommends gradient method
Table 1
<table><tr><th>Time (min)</th><th>Solution A (%)</th><th>Solution B (%)</th></tr><tr><td>0</td><td>60</td><td>40</td></tr><tr><td>3.0</td><td>60</td><td>40</td></tr><tr><td>16.0</td><td>49</td><td>51</td></tr></table>Firm’s Response:
• The firm submitted that we have revised our testing method and now implemented the gradient method for assay testing truly according to the USP (revised method is submitted)
• We have also tested the API as per our revised method. (Revised method and chromatogram are submitted).</td></tr>
<tr><td>3.2.S.5</td><td>• COA of primary / secondary reference standard including source and lot number shall be provided.</td><td>Copy of Certificate of analysis of primary / secondary reference standard is submitted.</td></tr>
<tr><td>3.2.P.2</td><td>• Justify the difference in qualitative composition of applied product from that of reference / innovator product.<table><tr><td>Applied product</td><td>Montelukast 4 mg Granules</td></tr><tr><td>Montelukast sodium</td><td>Montelukast sodium</td></tr><tr><td>Dextrose</td><td>Mannitol</td></tr><tr><td></td><td>Hydroxy propyl cellulose</td></tr></table></td><td>• The firm submitted that as per literature review, it is notable that the active ingredient and all the excipients used in our formulation are inert, and are compatible with active pharmaceutical ingredient of Montit sachet 4mg. Moreover, their safety and compatibility have also been established as no harsh effect has been observed in our stability studies.
• The firm further stated that we have also performed Drug Excipients Compatibility</td></tr>
</table>

<table>
<tr>
<td></td>
<td>
<table>
<tr><td></td><td>Tribasic sodium phosphate</td></tr>
<tr><td></td><td>Magnesium Stearate</td></tr>
</table>
• Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?
• CDP of the applied product has not been submitted.
• Only protocol for CDP is submitted
</td>
<td>studies, which concludes that all the excipients are inert and has no harsh effect on product stability (Reports are submitted).
• The firm submitted that as the innovator product is not registered in Pakistan therefore, Pharmaceutical equivalence of Montit 4mg Sachet was performed against the reference product Montiget 4mg Sachet manufactured by Getz Pharma (Private) Limited. (Reports are submitted).
• As the innovator product is not registered in Pakistan therefore, Comparative Dissolution Profile of Montit 4mg Sachet was performed against the reference product Montiget 4mg Sachet manufactured by Getz Pharma (Private) Limited in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range. (Reports are submitted).
• However, Innovator product singulair 4mg granules is registered in Pakistan
</td>
</tr>
<tr>
<td>3.2.P.5</td>
<td>• Clarification is required as the method of preparation and concentration of standard solution in analytical method of dissolution test is different from USP.</td>
<td>• The firm submitted that method of preparation and concentration of standard solution in analytical method of dissolution test is same per USP. There was a typographic error in already submitted method. However, the calculation sheet was accurately same as that of USP method. Moreover, we have also revised our testing method and the revised method is submitted.
• However the concentration of standard solution in dissolution test is still not as per USP monograph and firm have submitted details of dissolution test 1 in reply while in original dossier it was dissolution test 3.</td>
</tr>
<tr>
<td>3.2.P.5</td>
<td colspan="2">• Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (30:70) while USP recommends gradient method
Table 1
<table>
<tr><th>Time (min)</th><th>Solution A (%)</th><th>Solution B (%)</th></tr>
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<tr><td>22</td><td>25</td><td>75</td></tr>
<tr><td>23</td><td>25</td><td>75</td></tr>
<tr><td>25</td><td>48</td><td>52</td></tr>
<tr><td>30</td><td>48</td><td>52</td></tr>
</table>
Firm's Response:
• The firm submitted that we have revised our testing method by using gradient method for assay testing truly according to the USP (revised method is submitted)
• Moreover, we have manufactured 3 new batches (Batch numbers: MT-04, MT-05 and MT-06) and performed accelerated and long run stability testing by using gradient method for assay testing truly according to the USP, "0", & 3rd month testing has been completed and results are complying the specs. (Reports and chromatograms are submitted)
<table>
<tr><td>Batch No.</td><td>MT-04</td><td>MT-05</td><td>MT-06</td></tr>
</table>
</td>
</tr>
</table>

	Batch Size	14 packs	14 packs	14 packs
	Manufacturing Date	12-2022	12-2022	12-2022
	Date of Initiation	31-12-2022	31-12-2022	31-12-2022
3.2.P.6	• Clarification is required since the submitted COA of reference / working standard states that it follows in house specifications while the product monograph is available in USP		The firm submitted that we have revised our testing method and manufactured 3 new batches (Batch numbers: MT-04, MT-05 and MT-06) for performance of accelerated and long run stability testing by using gradient method for assay testing truly according to the USP and "0", & 3rd month testing has been completed and results are complying the Specs. The firm further stated that we have used the working standard (Batch No: WRS 20221017) that complies with the USP Specifications for the testing of our New Batches. (COA of reference standard used for testing of our product is enclosed herewith)	
3.2.P.8	• Submit DRAP attested documents for the procurement of API. • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time conditions)		• Firm has submitted copy invoice No. TY121643 dated 12-07-2021 for import of 20kg Montelukast Sodium in name of M/s Titlis Pharma attested by AD (I&E) DRAP Lahore dated 15-07-2021. • Record of Digital data logger for temperature and humidity monitoring of stability chambers at real time conditions is submitted	

Decision: Deferred for submission of following:

- **Fee of Rs. 30,000/- for revision in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Clarification as the method of preparation and concentration of standard solution in analytical method of dissolution test is different from USP monograph.**
- **Submission of 6th month time point stability data of the newly developed trial batches**

Case No. 09: Routine Registration applications of Human drugs on Form 5-F (Local)

724.	Name, address of Applicant / Marketing Authorization Holder	M/s Maxitech Pharma (Pvt) Ltd., Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Name, address of Manufacturing site.	M/s Maxitech Pharma (Pvt) Ltd., Plot No. E-178, 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 Finished product manufacturer	Firm has submitted copy of routine GMP inspection report dated 07-07-2021 which conclude as: Based on the stated facts and keeping in view the attitude of firm towards constant improvements their current GMP compliance level is rated a GOOD.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/2012-Lic dated 25-11-2016 which specifies ointment / cream/ lotion (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 3330 dated 03-02-2022
	Details of fee submitted	Rs.75,000/- dated 17-11-2021 (Deposit slip#35586726772)
	The proposed proprietary name / brand name	**Eurisa 2% Ointment**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Crisaborole……20mg
	Pharmaceutical form of applied drug	Topical ointment
	Pharmacotherapeutic Group of (API)	PDE-4 Inhibitor (Phosphodiesterase-4 inhibitor)
	Reference to Finished product specifications	N/A
	Proposed Pack size	10gm, 20gm, 30gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EUCRISA (crisaborole) 2% (w/w) ointment, USFDA Approved EUCRISA Crisaborole Ointment, 2 % Health Canada Approved STAQUIS crisaborole 2% w/w ointment TGA Approved
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Jintang Industry Zone, Shaowu City, Fujian Province China
	Module-II (Quality Overall Summary)	Not submitted as per requirement
	Module III (Drug Substance)	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, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 25 ± 2°C / 60 ± 5% RH) for 24 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (170101, 170102, 170103)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, 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 Staquis ointment 2% by M/s Pfizer Pharma USA**.**
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, Accuracy, Precision-Repeatability, Intermediate Precision, detection limit, quantitation limit, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Jintang Industry Zone, Shaowu City, Fujian Province China
API Lot No.	191201
Description of Pack (Container closure system)	Alu- lined 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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-003	TR-004	TR-005
Batch Size	133 tubes	133 tubes	133 tubes
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	16-12-2020	16-12-2020	16-12-2020
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.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 6 dated 31-01-2020 for import of 0.5kg of Crisaborole in name of M/s Maxitech Pharma (Pvt) Ltd attested by AD (I&E) DRAP Karachi dated 31-01-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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)	Not submitted

Remarks of Evaluator [XI]:

THERAPEUTIC INDICATIONS

EUCRISA is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in adult and paediatric patients 3 months of age and older.

Section	Observations	Response
1.5.6	• Mention the reference specifications of the finished product	• No specifications submitted
1.6.5	• Name and address of drug substance manufacturer along with valid GMP certificate / DML issued by relevant regulatory authority of country of origin is required	• No details submitted in this section • The firm has submitted copy of cGMP certificate of M/s Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Jintang Industry Zone, Shaowu City, Fujian Province China issued by China Food and Drug Administration China valid till 22-02-2021. Firm has submitted declaration letter from API manufacturer wherein API manufacturer has informed that according to regulations of CFDA that GMP and GSP certification will be cancelled. The CFDA authority is not issuing the GMP certificates for now.
2.3	• Submit module 2 as per the CTD guidance document without referring to other modules	• Module 2 of form 5F is submitted
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the

	which stability studies data is provided in Module 3 section 3.2.P.8.3>	batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> • BMR shows pack size **15gm** which is different from that given in proposed pack size in module 1.
3.2.S.4	• Justification is required for not including the test for polymorphic form and palladium content in drug substance specification by drug substance manufacturer as recommended by innovator product review document • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product 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. • Provide results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis of the same batch from Drug Substance manufacturer	• The firm has submitted declaration that crisaborole manufactured by API manufacturer is the most stable form i.e., form-I which is supported by XRPD spectra. The polymeric form identification is part of developmental studies that has been done as per innovator study. *No clarification for not including palladium content in drug substance specification by drug substance manufacturer is provided* • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug product is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is not submitted. • COA of Drug Substance from Drug Product manufacturer and Drug Substance manufacturer is provided
3.2.S.7	• Submit stability study of drug substance till claimed shelf life as per zone-IV-A conditions	Stability study of drug substance till claimed shelf life as per zone-IV-A conditions is submitted Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 24 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months • Batches: (190601, 190602, 190603)
3.2.P.2	• Justification is required for using 2% overage in the formulation • Submit pharmaceutical equivalence report of the applied product	• The firm submitted that at the time of product development overage was proposed but after detail study it has been reviewed that no overage is required and all trial batches were manufactured without overages. • Pharmaceutical equivalence report of the applied product is not submitted
3.2.P.5	• Justification is required for not including the test for content uniformity in container, EDTA, apparent viscosity, package integrity and minimum fill as recommended by innovator product review document • Justification is required for using different chromatographic conditions in analytical method validation(mobile phase; purified water:ACN:TFA 650ml;350ml;0.5ml) wavelength 250nm, flow rate 2ml/min, column c18, 4.6mmx150mm; injection volume 10 ul) than that submitted in analytical procedure (mobile phase A; purified water:ACN:Acetic acid 950;50;5, Mobile phase B purified water:ACN:Acetic acid 50;950;5…mix mobile phase A&B 550;450)	• The firm submitted that test for content uniformity in container, EDTA, apparent viscosity, package integrity will be implemented on commercial batches and minimum fill test is already performed at initial stage. Now included in revised STM. • Firm has submitted revised testing method • Assay limits (90-115%) mentioned in COA is a typographical error. The specification limit is (90-110%) which is mentioned in stability data as well.

	wavelength 254nm, flow rate 1ml/min, column c18, 4.6mmx25cm; 5umpacking, injection volume 10 ul) • Assay limits mentioned in finished product specification is 90-110% while in batch analysis assay limit is mentioned as 90-115% clarify?	
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard is not submitted
3.2.P.8	• The retention time of standard and sample solution at both accelerated and real time conditions after 3rd month time point is after 11 min while retention time of standard and sample solution after 6th month time point is after 04 min, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required • Submit documents / commercial invoice for the procurement of API with approval from DRAP	• The firm submitted that retention time on 3rd month stability study varied due to the reason that column (C18-4.6mmx250mm) used instead of 150mm length column at that time of stability testing which causes delay in retention time • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted • No documents / commercial invoice for the procurement of API is submitted

Decision: Deferred for submission of following:

- **Reference specifications of the finished product**
- **Details of drug substance manufacturer in section 1.6.5 of module 1 of form 5F**
- **Clarification as the proposed pack size (15gm) of trial batches is different from that proposed in section 1.5.4 of module 1 form 5-F**
- **Clarification for not including palladium content in drug substance specification by drug substance manufacturer**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance**
- **Pharmaceutical equivalence report of the applied product against the innovator product**
- **Justification for not including the test for content uniformity in container, EDTA, apparent viscosity, package integrity and minimum fill in finished product specifications**
- **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.**
- **COA of primary / secondary reference standard including source and lot number**
- **Scientific justification for using different length column at different time point (3rd month and 6th month) and stability study conditions.**
- **Documents for the procurement of API with approval from DRAP**

725.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	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 GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018 which specifies Tablet section (General/Antibiotic)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3728 dated 09/02/2022
	Details of fee submitted	PKR 30,000/-: dated 15/09/2021 (Deposit Slip#675681277631)
	The proposed proprietary name / brand name	**Empawrd-M 5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (In-House)……..……5mg Metformin HCl (USP)…….……...500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5 mg/1000 mg) film-coated tablet USFDA approved
	For generic drugs (me-too status)	Xenglu-Met 5/500mg Tablets by M/s Hilton Pharma (Reg#105290)
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fumeng County, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and 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: **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410029, MEF/1410028, MEF/1410027) **Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20160606, 20161017, 20161219)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of

		manufacturing process and controls, specifications, validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Empaa-M 5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). CDP has been performed against the same brand that is Empaa M 5/500 mg Tablet by M/s Weatherfolds Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted summary of analytical method validation studies including linearity, range, accuracy, precision, LOD, LOQ.

STABILITY STUDY DATA

Manufacturer of API	**<u>Empagliflozin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India		
API Lot No.	**Metformin HCl:** MEF/18091912 **Empagliflozin:** E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Alu-Alu Blister packed in bleech card 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: 0,1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	900 tab	900 tab	900 tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	11/08/2020	11/08/2020	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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Empagliflozin:</u>** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fuxin City, Liaoning Province - 123000, China issued by Fuxin Food and Drug Administration China valid upto 27-09-2020. Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., China valid upto 20-12-2022. **<u>Metformin HCl:</u>**

		The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 09-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice No. HN190108-C dated 08-01-2019 for import of 0.41Kg of Empagliflozin (Batch No# E-20181027-D02-E06-01) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. Firm has also submitted copy of form 6 dated 23-01-2019 for import of 0.41Kg of Empagliflozin in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/1678/18-19 dated 21-11-2018 for import of 500Kg of Metformin HCl (Batch No# MEF/18091912) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 05-12-2018.
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 data of stability batches supported by attested respective documents like chromatograms, summary data sheets etc. Raw data sheets and COAs are 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

Remarks of Evaluator [XI]:

Section	Observations	
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of cGMP certificate issued on 10-06-2022 based on inspection conducted on 30-03-2022
1.4.1.	• The applied drug product is a generic drug product while you have applied for a new drug product, clarify	• Firm has corrected the application type in form 5F as Generic drug product
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for Empagliflozin and Metformin issued by relevant regulatory authority of country of origin is required • Address of M/s Aarti drugs Limited in submitted application is different than that mentioned in GMP certificate, clarify	**Empagliflozin:** The firm has submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Empagliflozin confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Firm has also submitted copy of DML (License#Liao20150233) of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China valid upto 17-11-2027 verified from NMPA website. **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. *The certificate is valid till 19-03-2023*

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.3	• Submit details in this section as per the guidance document	• Details in this section are submitted as per guidance document
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by Drug Product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin 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 Metformin HCl and Empagliflozin shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP. • Justification is required for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP • Justification is required for not performing test for identification and residue on ignition for drug substance empagliflozin in batch analysis by drug product manufacturer as recommended by drug substance manufacturer. • Provide Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is not submitted. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by Drug Product manufacturer is not submitted. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin by Drug Product manufacturer is not submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Metformin HCl and Empagliflozin is submitted • *No response submitted* • *No response submitted* • *No response submitted* • Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies from Drug Substance manufacturer is submitted. However, the batch No# (MEF/19040649) of Metformin HCl is different from that mentioned in batch analysis of drug product manufacturer.
3.2.P.2	• Justify why Pharmaceutical equivalence and CDP of the applied product has not been performed against the innovator product? • Submit detailed CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters used and f2 factor calculation	• Firm has again submitted Pharmaceutical Equivalence of applied product against the brand that is Empaa-M 5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). • Firm has submitted details of CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters. *However CDP has been performed against the comparator product Empaa-M 5/500mg tablet by M/s Weatherfolds Pharmaceuticals.*

3.2.P.5	• Justification is required for not including the test for assay in finished product specifications • Detailed analytical procedures used for testing the drug product shall be provided. • Complete analytical method validation studies including specificity test shall be submitted • Justification is required for not performing test for uniformity of dosage units (content uniformity/weight variation) in batch analysis as recommended by innovator product review document • Submit readable copies of batch analysis report of three batches	• Firm has submitted revised finished product specifications containing content uniformity test, time point for dissolution studies and details of assay test. • Firm has submitted detailed analytical procedures used for testing the drug product shall be provided • Firm has submitted analytical method validation studies including results of specificity test. • Firm has submitted copy of revised batch analysis report containing results of content uniformity test
3.2.P.6	Clarification is required whether the same Reference Standards or Materials of empagliflozin was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials is 18.04.2018 while manufacturing date of drug product as per submitted COA is 08-2020	• Firm has not submitted any clarification. However, Firm has submitted COA of another working standard. The expiry date mentioned on this reference standard is 05-08-2020 and manufacturing of trial batches is subsequent to this date.
3.2.P.8	• Submit complete analytical record of stability study including summary data sheets, COA, Raw data sheets, and chromatograms. Chromatograms of accelerated stability study are attached with summary sheet of real time study and vice versa • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm has submitted analytical record of stability study including summary data sheets, COA. *However detailed Raw data sheets and chromatograms are not submitted* • Compliance Record of HPLC software 21CFR & audit trail reports on product testing 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:

- **Valid GMP certificate / DML of drug substance manufacturer for Metformin issued by relevant regulatory authority of country of origin**
- **Copies of the Drug substance analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer.**
- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl and Empagliflozin by Drug Product manufacturer.**
- **Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as per USP monograph.**
- **Justification for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as per USP monograph**
- **Justification for not performing test for identification and residue on ignition for drug substance Empagliflozin in batch analysis by drug product manufacturer as recommended by drug substance manufacturer.**
- **Certificate of Analysis of the relevant batch of Drug Substance used during product development and stability studies batch from Drug Substance manufacturer.**
- **Pharmaceutical equivalence and CDP of the applied product against the innovator product**
- **Clarification whether the same Reference Standards or Materials of empagliflozin was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials is 18.04.2018 while manufacturing date of trial batches is subsequent to this date.**
- **Detailed Raw data sheets and chromatograms are not submitted**
- **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.**

726.	Name, address of Applicant / Marketing	M/s Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector-24,

	Authorization Holder	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)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30259 dated 05-11-2021
	Details of fee submitted	Rs.20,000/- dated 26-02-2021
	The proposed proprietary name / brand name	**Ophth Cyclovir Topical Cream 5%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Acyclovir BP……..…50mg/g
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	Antiviral
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	10gm tube
	Proposed unit price	Rs. 800
	The status in reference regulatory authorities	ZOVIRAX Cream 5% w/w, USFDA Approved
	For generic drugs (me-too status)	Hepex Cream 5% by M/s Evolution Pharmaceuticals (Reg# 091965)
	GMP status of the Finished product manufacturer	The firm has submitted GMP certificate issued on 02nd October 2020 based on inspection conducted on 27th September 2019
	Name and address of API manufacturer.	M/s Hubei Yitai Pharmaceutical Co. Ltd., Fengchengyuan, Suburban District of Tianmen City, Hubei 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, specifications, batch analysis and stability studies of drug substance
	Stability studies	Stability study conditions: ***Real time: 30°C ± 2°C / 75% ± 5%RH for 12 months*** Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(02190501, 02190502, 02190503)
	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, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand that is Zovirax Topical Cream by M/s Barrett Hodgson by performing quality tests (appearance, identification, fill weight, drug release).
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Hubei Yitai Pharmaceutical Co. Ltd., Fengchengyuan, Suburban District of Tianmen City, Hubei Province, China		
API Lot No.			
Description of Pack (Container closure system)	Printed aluminum tube with nozzle and 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: 12 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TB 101	TB 102	TB 103
Batch Size	5 Kg	5 Kg	5 Kg
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	9-12-2019	17-12-2019	26-12-2019
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.	No GMP certificate 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.	Firm have submitted Data of stability batches supported by respective documents like UV spectra, raw data sheets and summary data sheets etc. ***Raw data sheets does not show the storage conditions and time point at which performance is done***
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	Response
1.3.4	• Submit valid copy of DML as the submitted DML is expired on 04-05-2021 and renewal of DML submitted on 17-05-2021	

<table>
<tr><td>1.3.5</td><td>• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted</td><td></td></tr>
<tr><td>1.6.5</td><td>• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required</td><td></td></tr>
<tr><td>2.3.R.1</td><td>• 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></td><td></td></tr>
<tr><td>3.2.S.4</td><td>• Copies of the analytical procedures used for routine testing of the Drug substance by Drug substance 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.</td><td></td></tr>
<tr><td>3.2.S.4.4</td><td>• Batch analysis of drug substance by drug substance manufacturer follow USP specifications while Finished product manufacturer have tested the API as per BP monograph, clarification is required
• Drug substance was tested on 18.05.2020 as per submitted COA of API by drug product manufacturer while batches were manufactured in 12-2019 before testing of API, clarify</td><td></td></tr>
<tr><td>3.2.S.5-6</td><td>• Container closure system data and reference standard details are not submitted</td><td></td></tr>
<tr><td>3.2.S.7</td><td>• Long term stability data of drug substance is submitted for 12 months only</td><td></td></tr>
<tr><td>3.2.P.1</td><td>• Justify the use of butylene paraben and methyl paraben in formulation as the innovator product does not contain these excipients.
<table>
<tr><td>Applied product</td><td>Innovator product (ZOVIRAX)</td></tr>
<tr><td>Stearic acid powder</td><td>cetostearyl alcohol,.</td></tr>
<tr><td>Ethylene glycol monostearate</td><td>mineral oil,</td></tr>
<tr><td>Isopropyl myristate</td><td>poloxamer 407,</td></tr>
<tr><td>Tween 80</td><td>propylene glycol,</td></tr>
<tr><td>Butylene paraben</td><td>sodium lauryl sulfate,</td></tr>
<tr><td>Propylene glycol</td><td>water</td></tr>
<tr><td>Methyl paraben</td><td>white petrolatum</td></tr>
<tr><td>Sorbitol solution 70%</td><td></td></tr>
<tr><td>Lavender oil</td><td></td></tr>
<tr><td>Purified water QS</td><td></td></tr>
</table>
• Pharmaceutical equivalence of applied product states that product follows the USP specification, while you have applied for BP specifications for the applied product, justification is required
• Process validation protocols for applied product shall be submitted</td><td></td></tr>
<tr><td>3.2.P.5</td><td>• The limits of assay test as per monograph of BP pharmacopeia is 95-105% while you have applied 45-55mg/g (90-110%) which is different from BP, clarification is required.
• Clarification is required since procedure of assay test given in analytical procedure is by UV while BP monograph for applied products states performance by HPLC.
• Submit Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) for drug product as per BP method.
• The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?</td><td></td></tr>
<tr><td>3.2.P.6</td><td>• No details of reference standard is submitted</td><td></td></tr>
<tr><td>3.2.P.8</td><td>• Clarification is required since assay test is performed by UV throughout stability study instead by HPLC as recommended by BP.
• Submit documents for the procurement of API with approval from DRAP (in case of import).
• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
• Submit data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td></td></tr>
</table>

Previous Decision (M-322-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the firm:

Section	Observations	Response
1.3.4	• Submit valid copy of DML as the submitted DML is expired on 04-05-2021 and renewal of DML submitted on 17-05-2021	Firm has submitted valid copy of DML renewed w.e.f. 05-05-2021
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	Firm has submitted cGMP certificate issued on 29th September 2021 based on inspection conducted on 27th September 2021.
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of cGMP certificate of M/s Hubei Yitai Pharmaceutical Co. Ltd., Fengchengyuan, Suburban District of Tianmen City, Hubei Province, China issued by Hubei Provincial Food & Drug Administration valid up to 17-09-2022.
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>	Not submitted
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance by Drug substance 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 by Drug substance and 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.4.4	• Batch analysis of drug substance by drug substance manufacturer follow USP specifications while Finished product manufacturer have tested the API as per BP monograph, clarification is required • Drug substance was tested on 18.05.2020 as per submitted COA of API by drug product manufacturer while batches were manufactured in 12-2019 before testing of API, clarify	• *No clarification is submitted* • Firm has submitted another COA of API by drug product manufacturer in which date of analysis has been changed to 29-10-2019
3.2.S.5-6	• Container closure system data and reference standard details are not submitted	Details of container closure system and COA of primary / secondary reference standard are submitted
3.2.S.7	• Long term stability data of drug substance is submitted for 12 months only	Firm has submitted stability study data of other batches of drug substance at real time and accelerate conditions. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(02150501, 02150502, 02150503)
3.2.P.1	• Justify the use of butylene paraben and methyl paraben in formulation as the innovator product does not contain these excipients. Applied product | Innovator product (ZOVIRAX)	• The firm has not submitted any justification for use of butylene paraben and methyl paraben in formulation. However, the firm has changed the composition of applied formulation which does not contain butylene paraben and methyl paraben.

	<table><tr><td>Stearic acid powder</td><td>cetostearyl alcohol,.</td></tr><tr><td>Ethylene glycol monostearate</td><td>mineral oil,</td></tr><tr><td>Isopropyl myristate</td><td>poloxamer 407,</td></tr><tr><td>Tween 80</td><td>propylene glycol,</td></tr><tr><td>Butylene paraben</td><td>sodium lauryl sulfate,</td></tr><tr><td>Propylene glycol</td><td>water</td></tr><tr><td>Methyl paraben</td><td>white petrolatum</td></tr><tr><td>Sorbitol solution 70%</td><td></td></tr><tr><td>Lavender oil</td><td></td></tr><tr><td>Purified water QS</td><td></td></tr></table> • Pharmaceutical equivalence of applied product states that product follows the USP specification, while you have applied for BP specifications for the applied product, justification is required • Process validation protocols for applied product shall be submitted	<table><tr><td>Applied product</td><td>Innovator product (ZOVIRAX)</td></tr><tr><td>Cetostearyl alcohol,</td><td>cetostearyl alcohol,.</td></tr><tr><td>Liquid Parafin,</td><td>mineral oil,</td></tr><tr><td>propylene glycol,</td><td>propylene glycol,</td></tr><tr><td>sodium lauryl sulfate,</td><td>sodium lauryl sulfate,</td></tr><tr><td>white soft paraffin</td><td>white petrolatum</td></tr><tr><td></td><td>poloxamer 407,</td></tr><tr><td>Purified water q.s</td><td>water</td></tr></table> • No justification is submitted. However firm has submitted Pharmaceutical Equivalence against the brand that is Clovirex Cream by M/s Brookes Pharmaceuticals by performing quality tests (appearance, identification, fill weight, drug release, assay). • Process validation protocols for applied product is not submitted
3.2.P.5	• The limits of assay test as per monograph of BP pharmacopeia is 95-105% while you have applied 45-55mg/g (90-110%) which is different from BP, clarification is required. • Clarification is required since procedure of assay test given in analytical procedure is by UV while BP monograph for applied products states performance by HPLC. • Submit Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) for drug product as per BP method. • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• Firm has submitted revised finished product specifications in which limits of assay test are revised as per BP monograph 47.5-52.5mg/g (95-105%) • Firm has submitted revised analytical procedure in which method of assay test is by HPLC as per BP monograph (BP-2022). *Firm has also submitted UV spectrophotometric method for assay test stating that it is as per BP 2003.* • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) *for drug product is performed as per UV method instead of HPLC.* • Complete batch analysis of three batches are submitted
3.2.P.6	• No details of reference standard is submitted	COA of primary / secondary reference standard is submitted
3.2.P.8	• Clarification is required since assay test is performed by UV throughout stability study instead by HPLC as recommended by BP. • Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Submit data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	• No clarification is submitted • Firm has submitted copy of invoice No. HYP191018-1 dated 18-10-2019 for import of 25kg of Acyclovir USP (Batch# 02190314) in name of M/s Ophth Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 24-10-2019 • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted • Firm has only submitted summary data sheet of real time conditions. COA and UV spectra for initial time point is also submitted. *Summary data sheet for accelerated conditions is not submitted. Stability studies data supported by attested respective documents like chromatograms, Raw data sheets, COA are not submitted*

Decision: Deferred for submission of following:

- **Valid GMP certificate / DML of 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>**
- **Clarification for following BP monograph in Batch analysis of drug substance by drug product manufacturer instead of USP monograph by drug substance manufacturer**
- **Clarification as Drug substance was tested on 18.05.2020 as per submitted COA of API by drug product manufacturer while batches were manufactured in 12-2019 before testing of API**
- **Process validation protocols for applied product**
- **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.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) for drug product as per BP method.**
- **Submit the stability study by using pharmacopial method/specs.**
- **Stability summary data sheet for accelerated conditions is not submitted. Stability studies data supported by attested respective documents like chromatograms, Raw data sheets, COA are not submitted**

Case No. 10: Deferred Registration applications of Human drugs on Form 5-F (Local)

727.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 which specifies Liquid Injection (Ampoule, Vial, Infusion) (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. 1013 dated 11-01-2022
	Details of fee submitted	PKR 75,000/-: dated: 23-12-2021 (Deposit sip#8155830888)
	The proposed proprietary name / brand name	**Genfer Injection 100mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ferric hydroxide polymaltose complex equivalent to Iron(III)……100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Use to treat Iron deficiency
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5's x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ferrosig Injection 100mg/2ml by M/s Sigma Company Limited., TGA Approved

	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
	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, 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)	Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 36 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 002 FP 01, FPJ 003 FP 01, FPJ 004 FP 01)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, 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 Hemafer 100mg/2ml Injection by M/s UNI-PHARMAKLEON LAORATORIES S.A by performing quality tests (Identification, pH, Assay)
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, Accuracy, Precision-Repeatability, Intermediate Precision, Robustness.

STABILITY STUDY DATA

Manufacturer of API	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy		
API Lot No.	FPJ014FV20		
Description of Pack (Container closure system)	Amber glass Type I 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.	21SB(A)-098-01	21SB(A)-099-02	21SB(A)-100-03
Batch Size	500ampoules	500ampoules	500ampoules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-07-2021	15-07-2021	15-07-2021

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	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 name of Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy issued by Italian Medicines Agency valid upto three years from the date of inspection (date of inspection 28/06/2019)
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 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 Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for three months is submitted

Remarks of Evaluator [XI]:

THERAPEUTIC INDICATIONS

FERROSIG is indicated for the treatment of iron deficiency anaemia in the following circumstances:

- When oral therapy is contraindicated.
- When enteric absorption of iron is defective.
- When patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical.

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of cGMP certificate issued on 07-10-2021 based on inspection conducted on 15-06-2021.
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference	• Parenteral iron preparations. Anti-anaemic
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm submitted clarification from AIFA Italy stating that due to restrictions caused by covid-19, the period of validity of the GMP certificate is automatically extended until the end of 2023. Onsite inspections will resume as soon as there is a consensus that the period of public health crisis has passed
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Not submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	According to Biofer MOA no working standard are required for release analysis of the API Ferric Hydroxide Polymaltose Complex so, we cannot provide any CoA.
3.2.S.7	• Results of Assay test for iron is not submitted in stability study of drug substance, clarify	Firm submitted revised real time stability study data of drug substance wherein Assay test for iron and polymaltose has been performed. However, time point of stability study as per ICH guideline is not submitted. Furthermore accelerated stability study data is not submitted.

3.2.P.1	• Justification is required for not using hydrochloric acid or sodium hydroxide for pH adjustment in formulation	• In development of Genfer Injection 100mg/2ml, the active substance (Ferric Hydroxide Polymaltose Complex Inj.Grade) is dissolved in water for injection and mix until homogenization of solution will be formed. Then Check the pH of the solution. pH limit = 5.2 – 6.50. • The pH of the solution observed in the range as described above therefore no need to the addition of HCl or NaOH for pH adjustment in the formulation. • The product kept on stability and no changes observed in pH of the formulation and any other physical and chemical parameters. • Stability studies also demonstrated that the formulation is stable without the addition of pH adjusting agents.
3.2.P.2	• Submit details of country of origin of reference product against which pharmaceutical equivalence studies have been performed. • Justification is required for not performing test for bacterial endotoxin and particulate matter in pharmaceutical equivalence as submitted in finished product specifications	• The firm submitted details of country of origin: UNI-PHARMA KLEON TSETIS Pharmaceutical Laboratory S.A 14Km National Road 1, GR-145 64K, Kifissia GREECE • The firm has submitted revised pharmaceutical equivalence report wherein results of test for bacterial endotoxin and particulate matter has been submitted
3.2.P.5.2	• You have applied for innovator specifications in module 1 section 1.5.6 while in-house specification in this section, justify?	The firm submitted that this is typographic error and submitted revise specification stating innovator specifications
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	We have conducted assay of Iron by complexometric titration, in this method working standard is not required.
3.2.P.8	• You have written liraglutide on initial page of summary sheet while applied product is ferric hydroxide polymaltose complex, clarify? • 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) upto 6th months is required • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit 6th month stability data of applied product	• The firm submitted that this is typographic error and submitted corrected summary reports. • Audit trial is not applicable as product testing is carried out via titration method • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted • Firm has submitted copy of invoice for import of 01Kg of Ferric Hydroxide Polymaltose Complex (Batch No# FPJ014FV20) in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021. • 6th month stability data of applied product is submitted

Previous Decision (M-326-DRB): Deferred for submission of following:

- Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.
- Stability study data of drug substance as per zone IV-A conditions till claimed shelf life.
- Pharmaceutical equivalence of applied product against innovator product

- Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Firm's Response:

Section	Observations	Response
1	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted
2	• Stability study data of drug substance as per zone IV-A conditions till claimed shelf life.	Firm submitted revised stability study data of drug substance wherein Assay test for iron has been performed. Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 60 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 001 FV 17, FPJ 005 FV 16, FPJ 006 FV 15)
3	• Pharmaceutical equivalence of applied product against innovator product	• The firm has submitted pharmaceutical equivalence against Ferrosig 100mg/2ml injection by M/s Sigma Company Limited Rowville, VIC, 3176 Australia by performing quality test (Appearance, Identification, pH, Assay, BET, Particulate matter) • The firm has submitted revised pharmaceutical equivalence report wherein results of test for bacterial endotoxin and particulate matter has been submitted
4	• Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	• Firm has submitted fee Rs. 7,500/- for correction/pre-approval changes in specifications vide deposit slip#24404399145.

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.**

728.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on 21-05-2019 based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012 which specifies Lyophilized Vials (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. 2523 dated 26-01-2022
	Details of fee submitted	PKR 30,000/-: dated 20-12-2021 (Deposit Slip#1799701158)
	The proposed proprietary name / brand name	**Voricol 200mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Voriconazole lyophilized powder…….200mg
	Pharmaceutical form of applied drug	Lyophilized powder
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	In-House specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VFEND 200mg lyophilized powder for injection, USFDA approved
	For generic drugs (me-too status)	V.Zde 200mg/Vial Injection by M/s Neutro Pharma (Reg. No. 097657)
	Name and address of API manufacturer.	M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 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, 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 study.
	Module III (Drug Substance)	Firm has submitted detailed data of drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 $40^{O} \pm 2^{O}$ 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. (Batches: VR0411003, VR0411004, VR0411005)
	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 brand that is Vfend injection by M/s Pfizer by performing quality tests (Identification, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, robustness, LOD, LOQ, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 India.		
API Lot No.	VZFP21019		
Description of Pack (Container closure system)	30ml transparent type I tubular Glass vial with rubber stopper and 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: 0, 3 months Accelerated: 0, 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	VOR 21-082	VOR 21-083	VOR 21-084
Batch Size	200 Vials	200 Vials	200 Vials
Manufacturing Date	22-07-2021	23-07-2021	24-07-2021
Date of Initiation	25-7-2021	25-7-2021	25-7-2021
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)	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 in the name of M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 India issued by Drugs Control Administration Government of Telangana valid upto 16-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 1108/LP/2021-22 dated 18-06-2021 for import of 1.5kg of Voriconazole EP (Batch No# VZFP21019) in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 06-07-2021. Firm has also submitted copy of form 6 dated 06-07-2021 for import of 1.5kg of Voriconazole EP in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 06-07-2021.
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	Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 03 months 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) upto 03 months is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Clarification is required for use of placebo in specificity test of method verification studies for drug substance
3.2.P.1.3	• Reference shall be provided for recommending the use of 0.9% sodium chloride as diluent for reconstitution
3.2.P.5	• Justification is required for not including the test for water content, appearance and clarity of reconstituted solution, colour of solution, reconstitution time, uniformity of dosage units, osmolality, and particulate contamination in finished product specification as recommended by EMA public assessment report. • Justification is required for not including the test for filled weight in finished product specifications • Submit reference for selecting the limits of pH test in finished product specifications
3.2.P.6	• The submitted COA of Reference Standards or Materials states that it is valid upto 01-08-2021. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the 3rd month time point and 6th month time stability study have been performed on October 2021 (10-2021) and January 2022 (01-2022).
3.2.P.8	• Submit details of minimum handling capacities of the equipment used in manufacturing of trial batches • Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 06 months is not submitted

Previous Decision (M-326 –RB (14th -16th March 2023) (Publication date of Minutes; 108th May 2023): Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting firm reply.

Firm's Response (19th June 2023):

Section	Observations	
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of cGMP certificate issued on 28th February 2022, based on inspection conducted on 03-08-2021
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate in the name of M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (V), Jinnaram (M), Sangareddy (D) Telangana State, 502319 India issued by Drugs Control Administration Government of Telangana valid upto 08-05-2023.
3.2.S.4	• Clarification is required for use of placebo in specificity test of method verification studies for drug substance	• The firm submitted that placebo details are mistakenly added in the AMV verification report and protocol of Raw material. The revised report and protocol are submitted.
3.2.P.1.3	• Reference shall be provided for recommending the use of 0.9% sodium chloride as diluent for reconstitution	• The firm submitted that as per EMC assessment report dated, 26 March 2015 "EMA/CHMP/151531/2015 Committee for Medicinal Products for Human Use (CHMP)" Voriconazole is physically compatible and chemically stable when

		reconstituted with water for injection or Sodium chloride 0.9%.
3.2.P.5	• Justification is required for not including the test for water content, appearance and clarity of reconstituted solution, colour of solution, reconstitution time, uniformity of dosage units, osmolality, and particulate contamination in finished product specification as recommended by EMA public assessment report. • Justification is required for not including the test for filled weight in finished product specifications • Submit reference for selecting the limits of pH test in finished product specifications	• Firm has submitted revised SAP wherein test for water content, appearance after reconstitution, reconstitution time, uniformity of dosage units, are included in finished product specification. However, test for osmolality, and particulate contamination are still not included in specifications. • No justification is submitted • No reference provided
3.2.P.6	• The submitted COA of Reference Standards or Materials states that it is valid upto 01-08-2021. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the 3rd month time point and 6th month time stability study have been performed on October 2021 (10-2021) and January 2022 (01-2022).	• The firm submitted that we have used another working standard at 3rd month and 6th month time. The COA of reference standard is submitted.
3.2.P.8	• Submit details of minimum handling capacities of the equipment used in manufacturing of trial batches • Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 06 months is not submitted	• Minimum handling capacity of equipment used for trials bathes is 100 vials. • Stability study data of applied product at 6th month time point is submitted • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 06 months is submitted

Decision: Deferred for submission of following:

- **Justification for not including the test for osmolality, filled weight and particulate contamination in finished product specification**
- **Submit reference for selecting the limits of pH test in finished product specifications**
- **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.**

Case No. 11; Deferred Registration Application of Human Drugs on form 5F (cases of Dr. Akbar Ali): Priority applications as per 257th meeting of RB

729.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan, Pakistan
	Details of Drug Sale License of importer	License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing	Bioprofarma Bagó S.A. Terrada 1270 - Autonomous City

	authorization holder (abroad)	of Buenos Aires, Argentine Republic.
	Name, address of manufacturer(s)	Laboratorio Kemex S.A. Nazarre 3446/54 - Autonomous City of Buenos Aires, Argentine Republic.
	Name of exporting country	Argentine Republic
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. IF-2022-09064835-APN-DFYGR#ANMAT) dated 04-01-2022 issued by National Institute of Drugs Avenida Caseros 2161 Ciudad Autonoma de Buenos Aires-Republica Argentina for Fulvestrant injection 250mg. 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 copy of letter of distribution certificate from Bioprofarma Bagó S.A. The letter species that the manufacturer appoints M/s BF Biosciences Ltd. to register their products in Pakistan. The authorization letter is valid till 31-01-2023.
	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
	Dy. No. and date of submission	Dy.31009 dated No 01-11-2022
	Details of fee submitted	PKR 75,000/-:slip No. 04893286804 dated 25-04-2022
	The proposed proprietary name / brand name	**DIMERE injection 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Fulvestrant ……..….250mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	oestrogen receptor antagonists (L02BA03)
	Reference to Finished product specifications	In house
	Proposed Pack size	2’s
	Proposed unit price	Rs 45,000 /- single dose vial
	The status in reference regulatory authorities	FASLODEX 250mg Injection (AstraZeneca UK Limited). (Pre Filled Syringe of 5 ml)
	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	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) – Italy
	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 as well as real time conditions. The real time stability data is conducted at 5oC ± 3oC. The stability study data is till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	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	USP type-I glass
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25 °C ± 2ºC/ 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5 °C ± 3ºC. The real time stability study data of 3 batches is for 24 months

Evaluation by PEC:

Sr. No	Observations
01	DSL of Importer /applicant is expired till 29-06-2022.
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.

Previous Decision (M-324DRB): 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 firm:

Sr#	Observations	Response of Firm
01	DSL of Importer /applicant is expired till 29-06-2022.	Firm has submitted valid copy of DSL. Details of DSL are; License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind,

		District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.	Firm has submitted valid copy of GMP certificate of API/Drug substance manufacturer, i.e. M/s Farmabios S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 2020-06-12 was valid for three years from date of inspection.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.	Dimere 250mg solution for injection is a generic drug product whose formulation, strength, pharmaceutical form and dosage form are the same as innovator product Falsodex 250mg (Lab. Astra Zeneca) Dimere container closure system differs from Faslodex finished product which is a pre-filled syringe. It consists of vials appropriately closed with stoppers and flip-off aluminium seals evidencing the same quality on materials as pre-filled syringe. Stability studies performed on Dimere dosage form confirms compatibility and that the finished product keeps the original attributes without alteration. Selecting the right primary container presentation for a product is important decision. Dimere is packed in glass vials despite pre-filled syringes advantages due to cost / benefit analysis and unavailability to access to required technology facilities to use that container.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.	The firm submitted explanation as: 0.4ml (0.8%) in excess is added per vial during the filling process to ensure the deliverable volume and administration of the labelled doses. The final volume overage was empirically decided during pilot batches evaluation and compliance is confirmed batch to batch by analysis extractable volume

Previous Decision (M-326-DRB): Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting in glass vial

Firm's Response:

The firm has submitted following response;

- Whereas, FULL V (Fulvestrant) 250mg Injection in Vial Form (M/s Laboratorios IMA S.A.I.C, Argentina) is approved for another applicant/importer during 316th (15-18 March 2023) with decision i.e. Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility. **(**Copy of minutes attached). *However, registration letter has not been issued.*
- Additionally, Fulvestrant 250mg/5ml in Vial Form is also suggested to add in WHO Model List of Essential Medicines, WHO Official link and document is attached for your kind reference.
  - *https://www.who.int/news/item/01-10-2021-who-prioritizes-access-to-diabetes-and-cancer-treatments-in-new-essential-medicines-lists*
  - *Application to add Fulvestrant to WHO Model List of Essential Medicines*

In view of above facts and references, we kindly request to re-visit the decision and allow fair chance to BF Biosciences Limited for registration of imported finished drug in Vial form, as BF Biosciences Limited is the joint venture of Ferozsons Laboratories Limited and Bago Laboratories Argentina, and through this joint venture, a number of lifesaving drugs are already registered by DRAP (eg. Panataxel, Donataxel and Oxaltie).

We also would like to apply for exemption of manufacturer abroad as **ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) Argentina is the member of PIC/s.**

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 in glass vial.

Case No. 12: Deferred cases of form 5F (Export Facilitation):

730.	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 CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 13-05-2019 based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1308 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#4452496739)
	The proposed proprietary name / brand name	**Gablin CR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…82.5mg
	Pharmaceutical form of applied drug	Pink colored, oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Lyrica CR 82.5mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017, by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against the same brand that is Lyrica CR 82.5mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017 in Acid media pH 1.2, acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method validation report is not submitted

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	PRGH/P2012004D		
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board 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.	PGA T2-21	PGA T3-21	PGA T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of

		M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
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	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)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.
1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for products is: Each film coated extended-release tablet contain: Pregabalin…….82.5mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP)	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why

	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021**.**
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***
3.2.P.5	• Justification is required for changing wavelength during assay procedure in analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	• The firm submitted that in product test method 300nm is used to suppress blank peak and the principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the COA of Reference Standards or Materials states that it is to be used before 11-07-2021, while manufacturing date of drug product as per submitted COA is April 2021 and 3rd month time point and 6th month time stability study are due on July 2021 (07-2021) and October 2021 (10-2021).	• The firm submitted that same reference standard was used for analysis of drug product as the sequence / chromatograms against this standard was saved during trial analysis and same sequence / chromatograms of standard was used at 3rd and 6th Month stability study time point for analysis of drug product. It is to submit that the Reference Standards or Materials used for test and analysis of drug product was expired at 6th month time point (October 2021 (10-2021)) of stability study.
3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required • Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm. • Firm has submitted results and calculation details for content uniformity test in raw data sheet at initial time point of stability study. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.

- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material 3) Verification of Analytical Method 4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Previous Decision (M-326-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that Testing for the 3rd and 6th month was conducted using a valid (Validity date 07/07/2023) working standard provided by the Drug substance manufacturer. (WKS no. WS/PRG IP IH/21/01). As indicated in our initial dossier, the 3rd month testing was carried out on August 20, 2021, while the 6th month testing was conducted on November 18, 2021. Additionally, our company regularly produces and supplies Gablin capsules. We also procure the reference standard on a regular basis. COA of Valid working standard is submitted. Email correspondence for procurement of Working standard is also submitted.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The dual wavelength is employed to suppress the peak of the diluent sodium disulfide, as shown in the attached chromatogram. The peak height of sodium disulfide is significantly larger compared to Pregabalin when the sample is run at 210nm. Consequently, the peak or area of Pregabalin will not be visible in the chromatogram. With a retention time of approximately 5.5 minutes, the

		quantification of Pregabalin remains unaffected by the wavelength shift. This fact is confirmed in the AMV (Assay Method Validation) report of the drug product. Furthermore, we conducted a pharmaceutical equivalence assessment of our product against the innovator, and we observed a similar behavior of the diluent in the innovator product as well. Comparative chromatograms submitted
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that the initial wavelength indicated on the chromatogram is 300nm, as there is no provision on the chromatogram format for both wavelengths. However, we have included the method audit trail which clearly shows that there was a wavelength shift from 300 nm to 210nm. (Acquisition method report is submitted).

Decision: Approved with innovator's specifications and following label claim:
Each film coated extended-release tablet contain:
Pregabalin…….82.5mg.

- **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.**

Registration letter will be issued after submission of fee of Rs. 75,000/- for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to film coated extended release tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

731.	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 CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 13-05-2019 based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1309 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#20328944978)
	The proposed proprietary name / brand name	Gablin CR 165mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…165mg
	Pharmaceutical form of applied drug	Light brown colored, oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-epileptics

	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Lyrica CR 165mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017, by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against the same brand that is Lyrica CR 165mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017 in Acid media pH 1.2, acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method validation report is not submitted

STABILITY STUDY DATA	
Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
API Lot No.	PRGH/P2012004D
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board 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.	PGB T2-21	PGB T3-21	PGB T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
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	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)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area

		FID. The firm's last GMP status is Compliant / Good.
1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for product is: Each film coated extended-release tablet contain: Pregabalin…….165mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP) • Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021**.**
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***
3.2.P.5	• Justification is required for changing wavelength during assay procedure in analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	• The firm submitted that in product test method 300nm is used to suppress blank peak and the principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the COA of Reference Standards or Materials states that it is to be used before 11-07-2021, while manufacturing date of drug product as per submitted COA is April 2021 and 3rd month time point and 6th month time stability study are due on July 2021 (07-2021) and October 2021 (10-2021).	• The firm submitted that same reference standard was used for analysis of drug product as the sequence / chromatograms against this standard was saved during trial analysis and same sequence / chromatograms of standard was used at 3rd and 6th Month stability study time point for analysis of drug product. It is to submit that the Reference Standards or Materials used for test and analysis of drug product was expired at 6th month time point (October 2021 (10-2021)) of stability study.
3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability	• The firm submitted that in product test method wavelength started from 300nm and then changed

	study show 300nm, justification is required • Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm. • Firm has submitted results and calculation details for content uniformity test in raw data sheet at initial time point of stability study. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material 3) Verification of Analytical Method 4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Previous Decision (M-326-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that Testing for the 3rd and 6th month was conducted using a valid (Validity date 07/07/2023) working standard provided by the Drug substance manufacturer. (WKS no. WS/PRG IP IH/21/01). As indicated in our initial dossier, the 3rd month testing was carried out on August 20, 2021, while the 6th month testing was conducted on November 18, 2021. Additionally, our company regularly produces and supplies Gablin capsules. We also procure the reference standard on a regular basis. COA of Valid working standard is submitted. Email correspondence for procurement of Working standard is also submitted.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The dual wavelength is employed to suppress the peak of the diluent sodium disulfide, as shown in the attached chromatogram. The peak height of sodium disulfide is significantly larger compared to Pregabalin when the sample is run at 210nm. Consequently, the peak or area of Pregabalin will not be visible in the chromatogram. With a retention time of approximately 5.5 minutes, the quantification of Pregabalin remains unaffected by the wavelength shift. This fact is confirmed in the AMV (Assay Method Validation) report of the drug product. Furthermore, we conducted a pharmaceutical equivalence assessment of our product against the innovator, and we observed a similar behavior of the diluent in the innovator product as well. Comparative chromatograms submitted
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that the initial wavelength indicated on the chromatogram is 300nm, as there is no provision on the chromatogram format for both wavelengths. However, we have included the method audit trail which clearly shows that there was a wavelength shift from 300 nm to 210nm. (Acquisition method report is submitted).

Decision: Approved with innovator's specifications and following label claim:
Each film coated extended-release tablet contain:
Pregabalin…….165mg.

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

Registration letter will be issued after submission of fee of Rs. 75,000/- for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to film coated extended release tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

732.	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 CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product	Firm has submitted cGMP certificate issued on 13-05-2019

	manufacturer	based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1310 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#683187860)
	The proposed proprietary name / brand name	**Gablin CR 330mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…330mg
	Pharmaceutical form of applied drug	Orange colored, oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Lyrica CR 330mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017, by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against the same brand that is Lyrica CR 330mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017 in Acid media pH 1.2, acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method validation report is not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	PRGH/P2012004D		
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board 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.	PGC T2-21	PGC T3-21	PGC T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
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	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)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.
1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for products is: Each film coated extended-release tablet contain: Pregabalin…….330mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP) • Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021.
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***
3.2.P.5	• Justification is required for changing wavelength during assay procedure in	• The firm submitted that in product test method 300nm is used to suppress blank peak and the

	analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the COA of Reference Standards or Materials states that it is to be used before 11-07-2021, while manufacturing date of drug product as per submitted COA is April 2021 and 3rd month time point and 6th month time stability study are due on July 2021 (07-2021) and October 2021 (10-2021).	• The firm submitted that same reference standard was used for analysis of drug product as the sequence / chromatograms against this standard was saved during trial analysis and same sequence / chromatograms of standard was used at 3rd and 6th Month stability study time point for analysis of drug product. It is to submit that the Reference Standards or Materials used for test and analysis of drug product was expired at 6th month time point (October 2021 (10-2021)) of stability study.
3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required • Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm. • Content uniformity for Gablin CR Tablet 330mg is performed by weight variation as per <USP 905>. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material

		3) Verification of Analytical Method 4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Previous Decision (M-326-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that Testing for the 3rd and 6th month was conducted using a valid (Validity date 07/07/2023) working standard provided by the Drug substance manufacturer. (WKS no. WS/PRG IP IH/21/01). As indicated in our initial dossier, the 3rd month testing was carried out on August 20, 2021, while the 6th month testing was conducted on November 18, 2021. Additionally, our company regularly produces and supplies Gablin capsules. We also procure the reference standard on a regular basis. COA of Valid working standard is submitted. Email correspondence for procurement of Working standard is also submitted.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The dual wavelength is employed to suppress the peak of the diluent sodium disulfide, as shown in the attached chromatogram. The peak height of sodium disulfide is significantly larger compared to Pregabalin when the sample is run at 210nm. Consequently, the peak or area of Pregabalin will not be visible in the chromatogram. With a retention time of approximately 5.5 minutes, the quantification of Pregabalin remains unaffected by the wavelength shift. This fact is confirmed in the AMV (Assay Method Validation) report of the drug product. Furthermore, we conducted a pharmaceutical equivalence assessment of our product against the innovator, and we observed a similar behavior of the diluent in the innovator product as well. Comparative chromatograms submitted
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that the initial wavelength indicated on the chromatogram is 300nm, as there is no provision on the chromatogram format for both wavelengths. However, we have included the method audit trail which clearly shows that there was a wavelength shift from 300 nm to 210nm. (Acquisition method report is submitted).

Decision: Approved with innovator's specifications and following label claim:
Each film coated extended-release tablet contain:
Pregabalin…….330mg.

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

Registration letter will be issued after submission of fee of Rs. 75,000/- for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to film coated extended release tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Case No.13; Deferred cases of Human Drugs on Form 5

733.	Name and address of manufacture / Applicant	M/s Efroze Chemical Industries Pvt Ltd. 146/23, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Dufanor 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dydrogesterone……..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11400 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Progestogens
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Duphaston 10mg film-coated tablets by M/s Mylan IRE Healthcare Limited (Ireland Approved)
	Me-too-status	Dydrstone 10mg Tablet by M/s Pharmasol (Pvt) Ltd (Reg#096477)
	GMP Status	GMP certificate issued to Efroze Chemical Industries (Pvt.) Ltd on dated 03-05-2020 based on inspection conducted on 17-03-2021
	Previous Remark of Evaluator [XI]	• Dydrogesterone is available as Cis and Trans isomer. The firm did not clarify about the type of isomer that will be used in formulation. (Trans Isomeric Form active) • The firm did not provide evidence of required manufacturing facility / section approval letter for the applied formulation
	Previous Decision (307-DRB)	Deferred for following: • Clarification about the type of isomer of Dydrogesterone that will be used in formulation • Evidence of required manufacturing facility / section from Licensing Division
	Evaluation by PEC	• The firm submitted that they will be using Trans-Isomer of dydrogesterone in their formulation and provided COA of API and GMP certificate of supplier M/s Yangzhou Aurisco Pharmaceutical Co., Ltd China. • The firm submitted letter No. F. 2-11/2000-Lic (Vol-V) dated 22nd November 2021 issued by Secretary Central Licensing Board showing the presence of Tablet section (Hormone)
	Previous Decision (316-DRB)	• Deferred for review of submitted COA of Dydrogesterone for compliance against the Pharmacopoeial monograph
	Evaluation by PEC	• The firm submitted that they will be using Trans-Isomer of dydrogesterone in their formulation and provided COA of API from supplier M/s Yangzhou Aurisco Pharmaceutical Co., Ltd China. • The submitted COA states that the API Dydrogesterone conforms to EP10.0 standard. The limits and number of tests are as per European Pharmacopeia monograph

	Previous Decision (322-DRB)	• Deferred for confirmation of already registered products in section of "Tablet (Hormone) section.)
	Firm's Response	• Firm has submitted copy of registration letter dated 30th May, 2023, of Eforeth-N 5mg tablets (Norethisterone) (Reg#115972)
	Decision: Approved as per decision of 312th meeting of Registration Board regarding formulation of "Dydrogesterone Tablet".	

Case No. 14: Withdrawal of Form 5-D Applications for Registration of Daplozmet XR 5mg/500mg Tablets, Daplozmet XR 5mg/1000mg Tablets, Daplozmet XR 10mg/500mg Tablets and Daplozmet XR 10mg/1000mg Tablets

The firm has written letter with reference to their product applied on Form 5-D details of which are given below:

S No.	Company Name	Applied product	Diary Number & R&I Date	Date of Submission
734.	M/s Highnoon Laboratories Ltd Lahore	Daplozmet XR 5mg/500mg Tablets Each tablets contains: Dapagliflozin……..5mg Metformin HCL (Extended release)……500mg	Form-5D Dy.No.2789 R&I date 12-07-2016	12-07-2016
735.	M/s Highnoon Laboratories Ltd Lahore	Daplozmet XR 10mg/500mg Tablets Each tablets contains: Dapagliflozin……..10mg Metformin HCL (Extended release) ……500mg	Form-5D Dy.No.2790 R&I date 12-07-2016	12-07-2016
736.	M/s Highnoon Laboratories Ltd Lahore	Daplozmet XR 5mg/1000mg Tablets Each tablets contains: Dapagliflozin……..5mg Metformin HCL (Extended release) ……1000mg	Form-5D Dy.No.2791 R&I date 12-07-2016	12-07-2016
737.	M/s Highnoon Laboratories Ltd Lahore	Daplozmet XR 10mg/1000mg Tablets Each tablets contains: Dapagliflozin……..10mg Metformin HCL (Extended release)……1000mg	Form-5D Dy.No.2792 R&I date 12-07-2016	12-07-2016

The firm informed that dossier of the same products were also applied on CTD/Form 5F and latterly got evaluated for registration by DRAP on export facilitation priority. The firm further stated that we are applying for the withdrawal of our applications of form 5-D as products are already under registration process through CTD/Form 5-D

Decision: Registration Board acceded the request of the firm and declared the above applications of Daplozmet XR Tablets of M/s Highnoon Laboratories Ltd as disposed off.

Case No. 15: Registration applications of Human Drugs on form 5F (New DML):

M/s Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat.

The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five sections to M/s, Carer Pharmaceuticals Industries Plot # 27, Main Road, Rawat Industrial Estate, Rawat under Drug Manufacturing License No. 000925 by way of Formulation vide approval letter No. F. 1-32/2016-Lic dated 07th June 2021. The Drug Manufacturing License No. 000925 by way of formulation is hereby issued w.e.f. 18-03-2021.

S No.	Section
7.	Capsule Section (General) Section
8.	Dry Powder Suspension (General) Section
9.	Sachet (General) Section
10.	Ampoule (General) Section
11.	Tablet (General) Section

Following applications have been submitted for registration by the firm.

738.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 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	Form-5F Dy.No 13768 dated 02-06-2023
	Details of fee submitted	Rs.30,000/- dated 02-06-2023 (Deposit slip#1826407677)
	The proposed proprietary name / brand name	**Caraflox 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Levofloxacin (as Hemihydrate)……..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVAQUIN 250mg film coated tablets, USFDA approved ***Discontinued****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** Levofloxacin 250mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Leflox 250mg Tablet by M/s Getz Pharma (Reg#26164)
	Name and address of API manufacturer.	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Economic Development Zone of Sanmen County, Zhejiang 31700, 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, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (DC-0401-1203001, DC-0401-1203002, DC-0401-1203003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against product Leflox 250mg tablet by M/s Getz Pharma by performing quality tests (Identification, uniformity of dosage units, disintegration test, dissolution, assay) CDP has been performed against the product Leflox 250mg tablet by M/s Getz Pharma in 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 method verification studies including Accuracy, precision (repeatability).

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang East-Asia Pharmaceutical Co., Ltd., Economic Development Zone of Sanmen County, Zhejiang 31700, P.R. China		
API Lot No.	DC-004-2112011		
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.	T001	T002	T003
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	26-11-2022	26-11-2022	26-11-2022
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 Zhejiang East-Asia Pharmaceutical Co., Ltd., Coastal Industrial city, Pubagang town, Sanmen County, Zhejiang China issued by China Food & Drug Administration valid

		upto 15-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate for import of 05kg Levofloxacin Hemihydrate from M/s Zhejiang East Asia Pharmaceutical Company., Ltd China attested by AD (I&E) DRAP Islamabad dated 11-05-2022.
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 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 Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address mentioned on submitted GMP certificate is different than that given in section 1.6.5	•
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	• Signed copies of drug substance specifications shall be submitted • Result for specificity test are not submitted in method verification study • Test for specific rotation is not performed in batch analysis by drug product manufacturer as recommended by USP monograph	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence and CDP studies against the innovator product • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	•
3.2.P.5	• Justification is required for not mentioning the number of USP test used for dissolution study • The rpm used in dissolution study (50rpm) is different than that recommended by USP monograph (75rpm) • Result for specificity test are not submitted in method verification study	•
3.2.P.8	• The submitted UV spectra does not depict the batch number or dosage form of applied formulation	•

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

739.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., Plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021.
	Evidence of approval of manufacturing facility	New license granted vide letter No. F. 1-32/2016-Lic dated 07/06/2021. Tablet (general), Capsule (general), Sachet (general), dry powder suspension (general) and ampoule (general) sections are approved.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9674; dated 11/04/2023
	Details of fee submitted	PKR 30,000/-: dated 24/01/2023 (Deposit slip#6724392307)
	The proposed proprietary name / brand name	**Krasil Injection 250mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	250mg/2ml ampoule
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Aminoglycoside Antibiotics
	Reference to Finished product specifications	BP
	Proposed Pack size	5s & 1s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Cimikan 250mg/2ml Injection by M/s Trigon Pharmaceuticals (Reg#46021)
	Name and address of API manufacturer.	M/s Shandong Anxin Pharmaceutical Co. Ltd., No. 849, Dongjia Town, Licheng District, Jinan, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	The firm has submitted details 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 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (120835205A, 120835505A, 120835805A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against Grasil 250mg Injection by M/s Sami Pharmaceuticals by performing quality tests (Description, acidity, particulate matter, assay, sterility test, bacterial endotoxin)
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Anxin Pharmaceutical Co. Ltd., No. 849, Dongjia Town, Licheng District, Jinan, China		
API Lot No.	**RA 2014A**		
Description of Pack (Container closure system)	Clear Glass ampoule type-I, 2mlx1'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.	KS/I-T01	KS/I-T02	KS/I-T03
Batch Size	1000 ampoule	1000 ampoule	1000 ampoule
Manufacturing Date	03-2022	03-2022	03-2022
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)	N/A
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 for import of 4.5kg Amikacin sulphate from M/s Shandong Anxin Pharmaceutical Co. Ltd., China dated 07-06-2022. However the clearance certificate is not attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted data of stability batches supported by 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 Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Submit your label claim as per reference formulation along with submission of applicable fee	•
1.5.9	• Provide evidence of applied formulation in reference regulatory authorities which were approved by registration board in its 275th meeting	•
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	• Unsigned copies of drug substance specification and analytical procedure used for routine testing of drug substance by drug product manufacturer is submitted • Justification is required for not including test for sulphate in drug substance specifications by drug substance manufacturer as recommended by BP monograph	•

	• Justification is required for selecting different chromatographic conditions (mobile phase composition, wavelength, column oven temperature, run time) by drug product manufacturer for drug substance (BP Monograph) than that recommended by drug substance manufacturer • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Justification is required as whether the drug substance follow BP specifications or USP specifications as both are mentioned on COA provided by drug substance manufacturer in batch analysis	
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product • Justification is required for not performing the pH test for applied product in pharmaceutical equivalence studies • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	•
3.2.P.5	• Unsigned copies of finished product specifications and analytical procedure is submitted	•
3.2.P.6	• COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be submitted	•
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP • Justification shall be submitted as the trial batches are manufactured before the import of API. • Label claim per injection is 250mg while calculated amount in assay test in raw data sheets of all batches at initial time point is more than 500mg, clarify • Label claim per injection mention in raw data sheets at 3rd month time point & 6th month time point at both real time and accelerated conditions of all batches is 500mg while applied product contains 250mg/2ml, clarify • Chromatograms, Raw data sheets, COA, summary data sheets etc. are not attested • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time) is not submitted	•

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

Case No. 16: Registration applications of Human Drugs on form 5F (New sections):
M/s Curatech Pharma Pvt. Ltd., 35-Km, Multan Road, Lahore

The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of following four additional sections to **M/s Curatech Pharma Pvt. Ltd.,** 35-Km, Multan Road, Lahore under Drug Manufacturing License No. 000619 (Formulation) vide approval letter No. F. 1-4/2002-Lic (Vol-I) dated 22nd December 2020.

S No.	Section
1.	Syrup/Suspension (General) Section (Revised New)
2.	Capsule (Cephalosporin) Section (New)
3.	Dry Powder for Suspension (Cephalosporin) Section (New)
4.	Dry Powder for Injection (Cephalosporin) Section (New)

Following applications have been submitted for registration by the firm.

740.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying Capsule Cephalosporin New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10838 dated 02-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#2573330204)
	The proposed proprietary name / brand name	**Curagon 250mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephalexin ……..….250mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	12’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	KEFLEX (250mg, 500mg, 750mg) capsule USFDA Approved ***Discontinued****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** Keflex Capsules 250mg MHRA Approved
	For generic drugs (me-too status)	Keflex Capsule 250mg by M/s AGP Ltd., (Reg#98686)
	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, 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	Firm has submitted stability study 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 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 Ceporex capsule 250mg by M/s GSK Pakistan Ltd by performing quality tests (Description, identification, average weight, disintegration, dissolution, assay). Firm has submitted CDP results of their product against the product Ceporex capsule 250mg by M/s GSK Pakistan Ltd in 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore		
API Lot No.	00214/013/2021		
Description of Pack (Container closure system)	Polished capsule of standard size filled with white to slightly yellow color powder in Alu-Alu blistered 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TR-CEP-24	TR-CEP-25	TR-CEP-26
Batch Size	1000	1000	1000
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	03-08-2021	03-08-2021	03-08-2021
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 Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 02-09-2020 based on inspection conduction on 22-06-2020 and valid upto two years from the date of inspection

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of proforma invoice from M/s Pharmagen Limited dated 30/04/2021 for purchase of Cephalexin (compacted) 3kg.
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 chromatograms, Raw data sheets, COA, 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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Submit your label claim as per reference formulation considering the hydrated form along with submission of applicable fee	• The firm has revised label claim as per reference formulation considering the hydrated form along with submission of Rs. 30000/- on deposit slip#39867954. The revised label claim is as under: Each capsule contains: Cephalexin monohydrate equivalent to Cephalexin……..….250mg
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• The firm has submitted the same previously submitted copy of cGMP certificate along with a copy of request letter dated 08-02-2022 made to area FID & Area Assistant Director (I&E) for renewal of cGMP and conduction of inspection.
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 certificate of M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 22-11-2022 based on inspection conduction on 18-11-2022 and valid upto two years from the date of inspection
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) performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.1	• Qualitative composition of applied formulation is not similar to innovator / reference product. Clarification shall be submitted **Applied product** / **KEFLEX capsule** Cephalexin / Cephalexin Magnesium stearate / Carboxymethylcellulose sodium Blue/blue empty shell size 2 / Microcrystalline cellulose, Dimethicone, Magnesium stearate, D&C Yellow No. 10, FD&C Blue No. 1, FD&C Yellow No. 6, Gelatin, Titanium dioxide.	• The firm submitted that composition of applied formulation is same as per the reference formulation ceporex 250mg capsule and submitted evidence of reference formulation ceporex 250mg capsule. • Firm has submitted revised pharmaceutical equivalence report of their product against the product Ceporex capsule 250mg by M/s GSK Pakistan Ltd containing test for uniformity of dosage units. • Firm has submitted values of f2 factor in CDP studies which are in acceptable range. • The image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed is submitted

	• Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP monograph • Submit the values of f2 factor in CDP studies • Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product	
3.2.P.6	Clarification is required whether the same Reference Standards or Materials of cephalexin was used for test and analysis of drug product as it is mentioned on the COA of Reference Standards or Materials that it is to be used before 26th September, 2021 while drug product stability testing has been performed subsequent to this date.	• The firm has submitted complete trial of the COAs of reference standards that were used throughout testing of stability studies. The firm has submitted COAs of five reference standard that were used during stability testing.

Decision: Approved with following Label claim:
Each capsule contains:
Cephalexin monohydrate equivalent to Cephalexin……..….250mg

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

741.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying Capsule Cephalosporin New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 13374 dated 30-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#671147973107)
	The proposed proprietary name / brand name	**Curagon 500mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cephalexin ……..….500mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications

	Proposed Pack size	2x6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	KEFLEX (250mg, 500mg, 750mg) capsule USFDA Approved ***Discontinued****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*** Keflex Capsules 500mg MHRA Approved
	For generic drugs (me-too status)	Keflex Capsule 500mg by M/s AGP Ltd., (Reg#98687)
	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, 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	Firm has submitted stability study 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 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 Ceporex capsule 500mg by M/s GSK Pakistan Ltd by performing quality tests (Description, identification, average weight, disintegration, dissolution, assay). Firm has submitted CDP results of their product against the product Ceporex capsule 500mg by M/s GSK Pakistan Ltd in 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and

		Specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore		
API Lot No.		00214/013/2021		
Description of Pack (Container closure system)		Polished capsule of standard size filled with white to offwite color powder in Alu-Alu blistered 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: 12 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.		TR-CEP-27	TR-CEP-28	TR-CEP-29
Batch Size		1000	1000	1000
Manufacturing Date		07-2021	07-2021	07-2021
Date of Initiation		03-08-2021	03-08-2021	03-08-2021
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 Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 02-09-2020 based on inspection conduction on 22-06-2020 and valid upto two years from the date of inspection		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of proforma invoice from M/s Pharmagen Limited dated 30/04/2021 for purchase of Cephalexin (compacted) 3kg.		
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 chromatograms, Raw data sheets, COA, 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) is submitted		

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Copy of fee challan is submitted…original fee challan shall be submitted	• Firm has submitted copy of online DRAP verified fee challan No#671147973107.
1.5.2	• Submit your label claim as per reference formulation considering the hydrated form along with submission of applicable fee	• The firm has revised label claim as per reference formulation considering the hydrated form along with submission of Rs. 30000/- on deposit slip#37593881707. The revised label claim is as under: Each capsule contains: Cephalexin monohydrate equivalent to Cephalexin……..….500mg
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• The firm has submitted the same previously submitted copy of cGMP certificate along with a copy of request letter dated 08-02-2022

<table>
<tr><td></td><td></td><td>made to area FID & Area Assistant Director (I&E) for renewal of cGMP and conduction of inspection.</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 Pharmagen Limited., Kot Nabi Bukshwala, 34-Km Ferozepur Road, Lahore issued on 22-11-2022 based on inspection conduction on 18-11-2022 and valid upto two years from the date of inspection</td></tr>
<tr><td>3.2.S.4</td><td>• 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.</td><td>• 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.</td></tr>
<tr><td>3.2.P.1</td><td>• Qualitative composition of applied formulation is not similar to innovator / reference product. Clarification shall be submitted
<table>
<tr><th>Applied product</th><th>KEFLEX capsule</th></tr>
<tr><td>Cephalexin</td><td>Cephalexin</td></tr>
<tr><td>Magnesium stearate</td><td>Carboxymethylcellulose sodium</td></tr>
<tr><td>Blue/blue empty shell size 2</td><td>Microcrystalline cellulose,</td></tr>
<tr><td></td><td>Dimethicone,</td></tr>
<tr><td></td><td>Magnesium stearate,</td></tr>
<tr><td></td><td>D&C Yellow No. 10,</td></tr>
<tr><td></td><td>FD&C Blue No. 1,</td></tr>
<tr><td></td><td>FD&C Yellow No. 6,</td></tr>
<tr><td></td><td>Gelatin,</td></tr>
<tr><td></td><td>Titanium dioxide.</td></tr>
</table>
• Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP monograph
• Submit the values of f2 factor in CDP studies
• Submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product</td><td>• The firm submitted that composition of applied formulation is same as per the reference formulation ceporex 500mg capsule and submitted evidence of reference formulation ceporex 500mg capsule.
• Firm has submitted revised pharmaceutical equivalence report of their product against the product Ceporex capsule 500mg by M/s GSK Pakistan Ltd containing test for uniformity of dosage units.
• Firm has submitted values of f2 factor in CDP studies which are in acceptable range.
• The image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed is submitted</td></tr>
<tr><td>3.2.P.6</td><td>Clarification is required whether the same Reference Standards or Materials of cephalexin was used for test and analysis of drug product as it is mentioned on the COA of Reference Standards or Materials that it is to be used before 26th September, 2021 while drug product stability testing has been performed subsequent to this date.</td><td>• The firm has submitted complete trial of the COAs of reference standards that were used throughout testing of stability studies. The firm has submitted COAs of five reference standard that were used during stability testing.</td></tr>
</table>

Decision: Decision: Approved with following Label claim:
Each capsule contains:
Cephalexin monohydrate equivalent to Cephalexin……..….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.**		
742.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10839 dated 02-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#2434963668)
	The proposed proprietary name / brand name	**Rivoceph 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime Hydrochloride L-Arginine …..500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 500mg
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MAXIPIME (500mg, 1g, 2g) for injection USFDA Approved
	For generic drugs (me-too status)	Maxipime 500mg Injection by M/s GSK Pakistan Limited (Reg#25548)
	Name and address of API manufacturer.	Orchid Pharma Ltd., Plot No. 121-128, 128-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur, Kancheepuram District-603 110, Tamilnadu, 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	Firm has submitted stability study 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. However the results are not readable
	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 Celfime 500mg Injection manufactured by Norwich Pharmaceuticals by performing quality tests (Description, identification, clarity of solution, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	Orchid Pharma Ltd., Plot No. 121-128, 128-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur, Kancheepuram District-603 110, Tamilnadu, India.		
API Lot No.	CPAZ210021		
Description of Pack (Container closure system)	A white to pale yellow colored free flowing powder filled in clear glass vial with rubber stopper and aluminium 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12 (Months)		
Batch No.	TR-CEP-36	TR-CEP-37	TR-CEP-38
Batch Size	1220 vials	1220 vials	1220 vials
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	09-08-2021	09-08-2021	09-08-2021
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 Orchid Pharma Ltd., Plot No. 121-128, 128A-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur,

		Kancheepuram District-600110, India., issued by Director of Drugs Control, Tamilnadu India valid upto 31-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 90019504 dated 05-07-2021 for import of Cefepime HCl L-Arginine Sterile 10kg (Batch#CPAZ210021). However, the invoice is not attested by AD (I&E) field office
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 chromatograms, Raw data sheets, COA, 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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Submit your label claim as per reference formulation considering the salt form and arginine content along with submission of applicable fee	•
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
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. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer • Provide Certificate of Analysis of relevant batch of Drug Substance performed by Drug Substance manufacturer used during product development and stability studies	•
3.2.S.7	• Submit readable copy of stability study of drug substance performed at accelerated and real time conditions	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	•
3.2.P.6	• COA of Reference Standards or Materials of cefepime states that it is to be used before 12/04/2019. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as drug product stability testing has been performed subsequent to this date. • COA of Reference Standards or Materials of Arginine states that it is to be used before 08/03/2019. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as drug product stability testing has been performed subsequent to this date.	•
3.2.P.8	• Batch No. of API mentioned on stability summary sheet is CPAZ21/100/2021 while Batch No. of API mentioned on COA of drug product manufacturer is CPAZ210021, clarify? • Submit documents for procurement of API with approval from DRAP • Check dispensed quantity	•

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

743.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 11783 dated 15-05-2023
	Details of fee submitted	Rs.30,000/- dated 27-04-2023 (Deposit slip#03755441661)
	The proposed proprietary name / brand name	**Rivoceph 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime Hydrochloride L-Arginine……..1g
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 1g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MAXIPIME (500mg, 1g, 2g) for injection USFDA Approved
	For generic drugs (me-too status)	Maxipime 1g Injection by M/s GSK Pakistan Limited (Reg#25549)
	Name and address of API manufacturer.	Orchid Pharma Ltd., Plot No. 121-128, 128-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur, Kancheepuram District-603 110, Tamilnadu, 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	Firm has submitted stability study 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. However the results are not readable
	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 Celfime 1g Injection manufactured by Norwich Pharmaceuticals by performing quality tests (Description, identification, clarity of solution, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	Orchid Pharma Ltd., Plot No. 121-128, 128-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur, Kancheepuram District-603 110, Tamilnadu, India.		
API Lot No.	CPAZ210021		
Description of Pack (Container closure system)	A white to pale yellow colored free flowing powder filled in clear glass vial with rubber stopper and aluminium 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 ,9,12 (Months)		
Batch No.	TR-CEP-39	TR-CEP-40	TR-CEP-41
Batch Size	1220 vials	1220 vials	1220 vials
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	09-08-2021	09-08-2021	09-08-2021
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 Orchid Pharma Ltd., Plot No. 121-128, 128A-133, 138-151, 159-164, SIDCO Industrial Estate, Alathur, Kancheepuram District-600110, India., issued by Director of Drugs Control, Tamilnadu India valid upto 31-12-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 90019504 dated 05-07-2021 for import of Cefepime HCl L-Arginine Sterile 10kg (Batch#CPAZ210021). However, the invoice is not attested by AD (I&E) field office
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 chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR &	Compliance Record of HPLC software 21CFR & audit

	audit trail reports on product testing	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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Submit your label claim as per reference formulation considering the salt form and arginine content along with submission of applicable fee	•
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
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. • Justification is required for not performing test for Arginine content in batch analysis by drug product manufacturer as recommended by drug substance manufacturer • Provide Certificate of Analysis of relevant batch of Drug Substance performed by Drug Substance manufacturer used during product development and stability studies	•
3.2.S.7	• Submit readable copy of stability study of drug substance performed at accelerated and real time conditions	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product	•
3.2.P.6	• COA of Reference Standards or Materials of cefepime states that it is to be used before 12/04/2019. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as drug product stability testing has been performed subsequent to this date. • COA of Reference Standards or Materials of Arginine states that it is to be used before 08/03/2019. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as drug product stability testing has been performed subsequent to this date.	•
3.2.P.8	• Batch No. of API mentioned on stability summary sheet is CPAZ/2100/2021 while Batch No. of API mentioned on COA of drug product manufacturer is CPAZ210021, clarify? • Submit documents for procurement of API with approval from DRAP • Check dispensed quantity	•

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

744.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for suspension (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10840 dated 02-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#9867286824)
	The proposed proprietary name / brand name	Centric 40mg/5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefpodoxime Proxetil ……40mg
	Pharmaceutical form of applied drug	Suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin-ANTIBIOTICS
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x50ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefpodoxime Proxetil 40mg/5ml Powder for Oral Suspension MHRA Approved
	For generic drugs (me-too status)	Carelox Oral Suspension 40mg/5ml by M/s Nabiqasim Industries (Reg#82243)
	Name and address of API manufacturer.	M/s Dhanuka Laboratories Ltd., 7 Km, Old Manesar Road Village Mohammedpur, Gurgaon- 122004 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 manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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	Firm has submitted stability study 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 36months. (Batches: CPP#009/07, CPP#010/07, CPP#011/07)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Orelox 40mg/5ml suspension

		by M/s Sanofi-aventis Pakistan by performing quality tests (Description, water determination, pH, assay). Firm has submitted CDP results of their product against the product Orelox 40mg/5ml suspension by M/s Sanofi-aventis Pakistan in 0.1N HCl (pH 1.2) Acetate buffer (pH 4.5), & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Dhanuka Laboratories Ltd., 7 Km, Old Manesar Road Village Mohammedpur, Gurgaon- 122004 Haryana INDIA		
API Lot No.	CPP-2107011		
Description of Pack (Container closure system)	White to pale yellow or light brown powder filled in HDPE 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: 12 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6,9,12 (Months)		
Batch No.	TR-CEP-54	TR-CEP-55	TR-CEP-56
Batch Size	1900 Bottles	1900 Bottles	1900 Bottles
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	23-08-2021	23-08-2021	23-08-2021
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 Dhanuka Laboratories Ltd., 7 Km, Old Manesar Road Village Mohammedpur, Gurgaon - 122004 Haryana India., issued by Food & Drugs Administration Haryana India valid upto three years from the date of issue (date of issue (28/12/2018).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. SO/GE/2122/0029 dated 15-07-2021 for import of Cefpodoxime Proxetil USP Micronise 02kg (Batch#CPP-2107011). However, the invoice is not attested by AD (I&E) field office
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 chromatograms, Raw data sheets, COA, 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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Submit your label claim as per reference formulation considering the salt factor along with submission of applicable fee	•

1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
1.6.5	• Details of drug substance manufacturer in this section shall be submitted • Submit valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	•
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. • Clarification is required as Batch No. of API mentioned on COA of drug substance manufacturer is CPP-2107011while Batch No. of API mentioned on COA of drug product manufacturer is CPP-12107011	•
3.2.P.1	• Qualitative composition of applied formulation is not similar to innovator / reference product. Clarification shall be submitted	•
3.2.P.2	• Justification shall be submitted for not performing the test for uniformity of dosage units and deliverable volume in pharmaceutical equivalence studies as recommended by USP monograph • Submit the values of f2 factor in CDP studies	•
3.2.P.5	• Justification is required for not performing test for deliverable volume in batch analysis by drug product manufacturer as recommended by USP monograph	•
3.2.P.8	• Batch No. of API mentioned on stability summary sheet is CPP-12107011 while Batch No. of API mentioned on COA of drug substance manufacturer is CPP-2107011, clarify? • Submit documents for procurement of API with approval from DRAP	•

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

745.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 12101 dated 17-05-2023
	Details of fee submitted	Rs.30,000/- dated 08-03-2023 (Deposit slip#2130984365)
	The proposed proprietary name / brand name	Bril 500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefazolin (as Sodium)……..…...500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics

	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 500mg
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SRATOP 0.5g cefazolin (as sodium) 0.5g powder for injection vial TGA Approved
	For generic drugs (me-too status)	Kefzol 500mg Inj of M/s AGP Limited (Reg# 3755)
	Name and address of API manufacturer.	M/s Shandong Lukang Pharmaceutical Co., Ltd., 88 Deyuan Road, High-Tech Zone, Jining City, Shandong Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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	Firm has submitted stability study 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. (Batches; 2061801001, 2061801002, 2061801003)
	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 Kefzol 500mg Injection m by M/s AGP Limited by performing quality tests (Description, identification, clarity of solution, pH, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method verification studies including Accuracy, precision (repeatability) and Specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Lukang Pharmaceutical Co., Ltd., 88 Deyuan Road, High-Tech Zone, Jining City, Shandong Province, P.R. China
API Lot No.	2062103004
Description of Pack (Container closure system)	A white to off white practically odorless, crystalline powder or white to off white solid, filled in glass vial with rubber stopper and aluminium 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: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 , 9, 12, 18 (Months)		
Batch No.	TR-CEP-63	TR-CEP-64	TR-CEP-65
Batch Size	3081 vials	3081 vials	3081 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	11-09-2021	11-09-2021	11-09-2021
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 Shandong Lukang Pharmaceutical Co., Ltd., No. 88, Xinhua Road, Zoucheng Industrial Park, Zoucheng City, Shandong Province China issued by Shandong Food and Drug Administration China valid upto 08-07-2023. Firm has submitted copy of DML (License#LU20200470) of M/s Shandong Lukang Pharmaceutical Co., Ltd., 88, Deyuan Road, High-tech Zone, Jining, Shandong China issued by Shandong Provincial Drug Administration valid upto 01-09-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. 2021G126 dated 28-06-2021 for import of Cefazolin Sodium Sterile 5kg (Batch#2062103004). *However, the invoice is not attested by AD (I&E) field office*
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 chromatograms, Raw data sheets, COA, 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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify	•
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	•
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. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance 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.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	•

3.2.P.5	• Justification shall be submitted for not including the test for content uniformity and particulate matter in finished product specification as per USP monograph • Justification shall be submitted for not performing the test for content uniformity and particulate matter in batch analysis of finished product as per USP monograph	•
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be provided.	•
3.2.P.8	Documents for procurement of API with approval from DRAP shall be submitted	•

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

Agenda of Evaluator PEC-XIII.

Registration applications of locally manufactured New License / New Section on form 5F.

Firm has submitted copy of Acknowledgment of receipt of application for grant of additional section under DML No. 000465 (Formulations) to M/s Well Care Pharmaceuticals (Pvt.) Ltd., dated 24-11-2021 from Secretary Central Licensing Board. The letter specifies that CLB in its 283rd meeting held on 28-10-2021 has approved the grant of following additional section to M/s Well Care Pharmaceuticals (Pvt.) Ltd., A/7, Small Industrial Estate, Lahore Road, Sargodha:

1. Capsule (General) New.

746.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.**
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.
	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 conducted by a panel of three members dated 10-09-2021 wherein the panel concluded that M/s Well care pharma was considered to be operating at satisfactory level of compliance with GMP guidelines.
	Evidence of approval of manufacturing facility	Capsule (general) - New section approved vide letter No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	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. 8793 Dated 30-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 18335748 Dated 06-02-2023.
	The proposed proprietary name / brand name	**Welzole 20mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole (as omeprazole EC pellets 8.5%) …….. 20mg.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Pharmaceutical form of applied drug	Hard Gelatin capsule.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	2 x 7's, 1 x 10's & 10 x 10's.
	Proposed unit price	As per SRO.

	The status in reference regulatory authorities	Omeprazole 20mg & 40mg capsule (delayed release pellets), USFDA Approved.
	For generic drugs (me-too status)	Risek 20mg capsule, M/s Getz pharma Karachi, Reg. No. 019364.
	Name and address of API manufacturer.	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. OMP736, mfg. date 29-12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 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. B. No. (OMP076, OMP073 & OMP090).
	Module-III Drug Product:	Firm has submitted detailed information 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 results of pharmaceutical equivalence of their product against Risek 40mg capsule manufactured by Getz Pharma by performing quality tests (Description, identification, Uniformity of dosage unit, dissolution & assay). Firm has submitted CDP against the Risek 20mg capsules manufactured by Getz Pharma in acid media of pH 1.2 for 02 hours and Phosphate buffer with pH 6.8 for 45 minutes. Acid media has shown 0% release in both products till 120th minute while for phosphate buffer the F_2 value is in 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	Vision Pharmaceuticals Plot No. 22-23, industrial triangle, kahuta road, Islamabad-Pakistan.
API Lot No.	Not submitted.
Description of Pack (Container closure system)	14 capsules 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: 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	1400 Capsules	1400 Capsules	1400 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	11-07-2022	11-07-2022	11-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not 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. F.3-26/2019-Addl.Dir.(QA & LT-1)) dated 31-07-2019 issued on the basis of inspection conducted on 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted of copy of invoice mentioning 1 kg of Omeprazole EC pellets 8.5% from M/s Vision Pharmaceuticals.
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.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has initially submitted DML No. 000465 with renewal date of 30-06-2004. Now they have submitted a letter from Licensing division wherein panel has been constituted for renewal of their DML. It is also mentioned in the letter that their renewal is due w.e.f. 29-06-2019.
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. 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.
3.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted. Revised table for literature references with correct information regarding the drug substance and applicable fee shall be submitted.	Firm has submitted revised and corrected table for literature references with submission of 7500/- fee vide slip No. 70502699174 dated 10-07-2023.

4.	3.2.S.4.1	• Specification for the drug substance provided by the drug substance manufacturer has mentioned USP while there is no monograph available for Omeprazole pellets in the USP. Justify. • Specification of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted that mistakenly it was mentioned as USP specifications. Furthermore, they also provided corrected specification for the drug substance from both the drug substance and finished product manufacturer. Submitted.
5.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.5	Details/COA of the working standard used in the analysis shall be submitted.	Submitted.
8.	3.2.S.7	Real time stability data for drug substance with B. No. OMP090 shall be submitted.	Submitted.
9.	3.2.P.2.2	• Justification shall be submitted for performing pharmaceutical equivalence against Risek 40mg capsule of M/s Getz Pharma. • Justification shall be submitted for not performing CDP & PE against the innovator product. • Graphical representation of the CDP in acidic media has shown full release of the content. Clarification shall be submitted. • • Details of the comparator i.e. batch number, manufacturing date etc. are not submitted.	Firm has submitted that it was a typo error and in newly submitted CDP results they have corrected the same. Firm has submitted that comparator product i.e. Risek 20 mg was easily available at the time of trial batches manufacturing, so we used it for the pharmaceutical equivalence and CDP. Firm has submitted that it was a typo error and also provided new graphical representation for CDP results in acidic medium. B. No C03123, Mfg. date 05-2022, Exp. Date 09-2025 and MRP 483.
10.	3.2.P.5.2	• Justification shall be submitted for the Flow rate, wavelength (305nm), standard preparation, and sample preparation with respect to the USP as all these parameters are changed from the official pharmacopoeia.	Firm has submitted that all the parameters are according to USP. They also provided analytical procedures wherein all these parameters are as per USP. *However, in initially submitted analytical procedures, all these parameters were changed.*
11.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number. • Justification shall be submitted for carrying dissolution in acidic medium for 60 minute only. • Justification shall be submitted for dissolution in buffer medium with respect to official pharmacopoeia as it has mentioned NLT 80% in 60 minutes. • Justification shall be submitted for not performing uniformity of dosage units. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets with API lot number. Firm has submitted that it was typographical error and actually they have performed dissolution according to USP till 120 minutes. In revised stability data sheets, they have provided dissolution in acidic media till 120 minutes. Firm has submitted that by mistakenly uniformity of dosage unit is not performed, in real time next time point is performed. Firm has submitted audit trial report.

Decision: Registration Board decided to approve the case subject to onsite verification/authenticity of the product development and stability data by the QA/LT.

747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.**
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.
	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 conducted by a panel of three members dated 10-09-2021 wherein the panel concluded that M/s Well care pharma was considered to be operating at satisfactory level of compliance with GMP guidelines.
	Evidence of approval of manufacturing facility	Capsule (general) - New section approved vide letter No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	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. 7971 Dated 21-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 21475274451 Dated 06-02-2023.
	The proposed proprietary name / brand name	**Tzole 40mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Omeprazole (as omeprazole EC pellets 22.5%) …….. 40mg.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Pharmaceutical form of applied drug	Hard Gelatin capsule.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	2 x 7's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Omeprazole 20mg & 40mg capsule (delayed release pellets), USFDA Approved.
	For generic drugs (me-too status)	Risek 40mg capsule, M/s Getz pharma Karachi, Reg. No. 022109.
	Name and address of API manufacturer.	Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		verification, batch analysis (B. No. OMP1316, mfg. date 14-12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 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. B. No. (OMP065, OMP103 & OMP083).
	Module-III Drug Product:	Firm has submitted detailed information 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 results of pharmaceutical equivalence of their product against Risek 40mg capsule manufactured by Getz Pharma by performing quality tests (Description, identification, Uniformity of dosage unit, dissolution & assay). Firm has submitted CDP against the Risek 40mg capsules manufactured by Getz Pharma in acid media of pH 1.2 for 02 hours and Phosphate buffer with pH 6.8 for 45 minutes. Acid media has shown 0% release in both products till 120th minute while for phosphate buffer the F_2 value is in 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	Vision Pharmaceuticals Plot No. 22-23, industrial triangle, kahuta road, Islamabad-Pakistan.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	14 capsules 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: 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	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	12-07-2022	12-07-2022	12-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API	Firm has submitted copy of GMP Certificate (No. F.3-

	manufacturer issued by concerned regulatory authority of country of origin.	26/2019-Addl.Dir.(QA & LT-1)) dated 31-07-2019 issued on the basis of inspection conducted on 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted of copy of invoice mentioning 1 kg of Omeprazole EC pellets 22.5% from M/s Vision Pharmaceuticals.
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.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has initially submitted DML No. 000465 with renewal date of 30-06-2004. Now they have submitted a letter from Licensing division wherein panel has been constituted for renewal of their DML. It is also mentioned in the letter that their renewal is due w.e.f. 29-06-2019.
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. 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.
3.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted. Revised table for literature references with correct information regarding the drug substance and applicable fee shall be submitted.	Firm has submitted revised and corrected table for literature references with submission of 7500/- fee vide slip No. 07261217207 dated 10-07-2023.
4.	3.2.S.4.1	• Specification for the drug substance provided by the drug substance manufacturer has mentioned USP while there is no monograph available for Omeprazole pellets in the USP. Justify. • Specification of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted that mistakenly it was mentioned as USP specifications. Furthermore, they also provided corrected specification for the drug substance from both the drug substance and finished product manufacturer. Submitted.
5.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.5	Details/COA of the working standard used in the analysis shall be submitted.	Submitted.
8.	3.2.S.7	Clear and readable copies of stability data sheets for the drug substance shall be submitted.	***Firm has once again submitted the same stability data for the drug substance which is not in readable form.***

9.	3.2.P.2.2	• Justification shall be submitted for not performing CDP & PE against the innovator product. • Graphical representation of the CDP in acidic media has shown full release of the content. Clarification shall be submitted. • Details of the comparator i.e. batch number, manufacturing date etc. are not submitted.	Firm has submitted that comparator product i.e. Risek 40 mg was easily available at the time of trial batches manufacturing, so we used it for the pharmaceutical equivalence and CDP. Firm has submitted that it was a typo error and also provided new graphical representation for CDP results in acidic medium. B. No C04088, Mfg. date 06-2022, Exp. Date 06-2025 and MRP 675.
10.	3.2.P.5.2	• Justification shall be submitted for the Flow rate, wavelength (305nm), standard preparation, and sample preparation with respect to the USP as all these parameters are changed from the official pharmacopoeia.	Firm has submitted that all the parameters are according to USP. They also provided analytical procedures wherein all these parameters are as per USP. ***However, in initially submitted analytical procedures, all these parameters were changed.***
11.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number. • Justification shall be submitted for carrying dissolution in acidic medium for 60 minute only. • Justification shall be submitted for dissolution in buffer medium with respect to official pharmacopoeia as it has mentioned NLT 80% in 60 minutes. • Justification shall be submitted for not performing uniformity of dosage units. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets with API lot number. Firm has submitted that it was typographical error and actually they have performed dissolution according to USP till 120 minutes. In revised stability data sheets, they have provided dissolution in acidic media till 120 minutes. Firm has submitted that it was typographical error and actually they have performed dissolution according to USP for 45 minutes and limit is NLT 75%. In revised stability data sheets, they have corrected the same. Firm has submitted that by mistakenly uniformity of dosage unit is not performed, in real time next time point is performed. Firm has submitted audit trial report.

Decision: Registration Board decided to approve the case subject to onsite verification/authenticity of the product development and stability data by the QA/LT.

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.**
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.
	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 conducted by a panel of three members dated 10-09-2021 wherein the panel concluded that M/s Well care pharma was considered to be operating at satisfactory level of compliance with GMP guidelines.
	Evidence of approval of manufacturing facility	Capsule (general) - New section approved vide letter No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.

	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. 7972 Dated 21-03-2023
	Details of fee submitted	PKR 30,000/- vide slip No. 591486904043 Dated 06-02-2023.
	The proposed proprietary name / brand name	**Mzole 20mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release capsule contains: Esomeprazole (as Esomeprazole Magnesium EC pellets 8.5%) …….. 20mg.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Pharmaceutical form of applied drug	White to almost white EC Pellets filled in hard gelatin capsule shell.
	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	Nexium 20mg & 40mg delayed release capsule, 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-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, 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 related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. EMZ046605, mfg. date 03-01-2022) and 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. B. No. (EMZ045058, EMZ044632 & EMZ044858)
	Module-III Drug Product:	Firm has submitted detailed information 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 results of pharmaceutical equivalence of their product against Nexum 40mg capsule manufactured by Getz Pharma by performing quality tests (Description, identification, Uniformity of dosage unit, dissolution & assay) for their product against Nexum 20mg capsules manufactured by Getz Pharma. Firm has submitted CDP against the same brand i.e. Nexum 20mg capsules manufactured by Getz 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	Vision Pharmaceuticals Plot No. 22-23, industrial triangle, kahuta road, Islamabad-Pakistan.		
API Lot No.	EMZ046605		
Description of Pack (Container closure system)	14 capsules 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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1400 Capsules	1400 Capsules	1400 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	14-07-2022	14-07-2022	14-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not 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. F.3-26/2019-Addl.Dir.(QA & LT-1)) dated 31-07-2019 issued on the basis of inspection conducted on 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted of copy of invoice mentioning 1 kg of Esomeprazole Magnesium EC pellets 8.5% from M/s Vision Pharmaceuticals.
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.		First page of form 5 is not submitted.	Submitted.
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has initially submitted DML No. 000465 with renewal date of 30-06-2004. Now they have submitted a letter from Licensing division wherein panel has been constituted for renewal of their DML. It is also mentioned in the letter that their renewal is due w.e.f. 29-06-2019.
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. 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.
4.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted. Revised table for literature references with correct information regarding the drug substance and applicable fee shall be submitted.	Firm has submitted revised and corrected table for literature references with submission of 7500/- fee vide slip No. 7016326022 dated 05-07-2023.
5.	3.2.S.4.1	• Specification for the drug substance provided by the drug product manufacturer has no test for identification. Justify. • Specifications provided by the drug product manufacturer has no limits for dissolution in phosphate buffer and no time for acidic release. Justification shall be submitted.	Firm has submitted revised drug substance specifications wherein they added identification test. Firm has submitted revised drug substance specifications wherein they added both time for acidic medium i.e. 120 minutes and release limits for buffer medium.
6.	3.2.S.4.2	Analytical procedures for the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. Details/COA of the working standard used in the analysis shall be submitted.	Not Submitted. Submitted.
8.	3.2.S.7	Accelerated stability data for drug substance with B. No. EMZ045058 shall be submitted.	Submitted.
9.	3.2.P.1	This section has mentioned 265mg of pellets quantity per capsule. Justification shall be submitted.	Firm has submitted that 1mg of Esomeprazole is eq. to 1.1134mg of Esomeprazole magnesium trihydrate. Due to this reason factor of 1.1134 was used. 100/8.4 (pellets potency) x 20 (label claim) x 1.1134 (factor) = 265.09mg/ capsule.
10.	3.2.P.2.2	• Justification shall be submitted for submitting same results of CDP for both 20mg and 40mg formulations. • • Justification shall be submitted for performing pharmaceutical equivalence against 40mg capsule of M/s Getz Pharma. • Justification shall be submitted for not performing CDP & PE against the innovator product. • Graphical representation of the CDP in acidic media has shown full release of the content. Clarification shall be submitted.	Firm has submitted that by mistakenly same CDP was attached. They also provided new CDP results for the applied formulation with Nexum 20mg capsules. Firm has submitted that it was a typo error and in newly submitted CDP results they have corrected the same. ***No justification submitted against this point.*** They also submitted new graphical representation for CDP results in acidic medium.

		• Details of the comparator i.e. batch number, manufacturing date etc. are not submitted.	B. No C01021, Mfg. date 09-2021, Exp. Date 09-2024 and MRP 297.
11.	3.2.P.3.2	Batch formula has also mentioned 265mg of pellets per capsule. Justification shall be submitted.	Firm has submitted that 1mg of Esomeprazole is eq. to 1.1134mg of Esomeprazole magnesium trihydrate. Due to this reason factor of 1.1134 was used. 100/8.4 (pellets potency) x 20 (label claim) x 1.1134 (factor) = 265.09mg/ capsule.
12.	3.2.P.5.2	• Justification shall be submitted for the concentration of standard solution and sample solution as analytical procedure submitted by the firm has mentioned 0.05mg/ml while USP has mentioned 0.04mg/ml. • Justification shall be submitted for the wavelength applied i.e. 280nm while USP has mentioned 302nm.	Firm has submitted that it was typo error and they also submit new analytical procedures as per USP. They once again submitted that it was typo error and they also submit new analytical procedures wherein they have corrected the same as per USP.
13.	3.2.P.5.3	Analytical method verification for the finished product shall be submitted.	Not submitted.
14.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number. • Justify the weight of standard and sample taken in the calculation formula for the assay test. • Justify the wavelength applied in the submitted chromatograms with respect to the wavelength mentioned in analytical procedure.	Firm has submitted revised stability data sheets with API lot number. Firm has submitted that in initially submitted analytical procedures, there was a typo error. Now they have provided new analytical procedures which are in accordance with the submitted chromatograms. Same as above.

Decision: Registration Board decided to approve the case subject to onsite verification/authenticity of the product development and stability data by the QA/LT.

9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.**
	Name, address of Manufacturing site.	M/s Well care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha.
	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 conducted by a panel of three members dated 10-09-2021 wherein the panel concluded that M/s Well care pharma was considered to be operating at satisfactory level of compliance with GMP guidelines.
	Evidence of approval of manufacturing facility	Capsule (general) - New section approved vide letter No.F.1-12/97-Lic (Vol-II) dated 24-11-2021.
	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. 7973 Dated 21-03-2023

	Details of fee submitted	PKR 30,000/- vide slip No. 2927054548 Dated 06-02-2023.
	The proposed proprietary name / brand name	**Rezole 40mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each delayed release capsule contains: Esomeprazole (as Esomeprazole Magnesium EC pellets 22.5%) …….. 40mg.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)
	Pharmaceutical form of applied drug	White to almost white EC Pellets filled in hard gelatin capsule shell.
	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	Nexium 20mg & 40mg delayed release capsule, 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-Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, 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 related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. EMZ046595, mfg. date 12-12-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has only submitted accelerated 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. B. No. (EMZ044440, EMZ044265 & EMZ044152)
	Module-III Drug Product:	Firm has submitted detailed information 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 results of pharmaceutical equivalence of their product against Nexum 40mg capsule manufactured by Getz Pharma by performing quality tests (Description, identification, Uniformity of dosage unit, dissolution & assay) for their product against Nexum 20mg capsules manufactured by Getz Pharma. Firm has submitted CDP against the same brand i.e. Nexum 400mg capsules manufactured by Getz 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	Vision Pharmaceuticals Plot No. 22-23, industrial triangle, kahuta road, Islamabad-Pakistan.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	14 capsules 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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-10	T-11	T-12
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	13-07-2022	13-07-2022	13-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not 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. F.3-26/2019-Addl.Dir.(QA & LT-1)) dated 31-07-2019 issued on the basis of inspection conducted on 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted of copy of invoice mentioning 1 kg of Esomeprazole Magnesium EC pellets 22.5% from M/s Vision Pharmaceuticals.
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.		First page of form 5 is not submitted.	Submitted.
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has initially submitted DML No. 000465 with renewal date of 30-06-2044. Now they have submitted a letter from Licensing division wherein panel has been constituted for renewal of their DML. It is also mentioned in the letter that their renewal is due w.e.f. 29-06-2019.
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. 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.
4.	2.3	Table for literature references of the drug substance has mentioned drug substance in different pharmacopoeias. Clarification shall be submitted. Revised table for literature references with correct information regarding the drug substance and applicable fee shall be submitted.	Firm has submitted revised and corrected table for literature references with submission of 7500/- fee vide slip No. 7744647151 dated 05-07-2023.
5.	3.2.S.4.1	• Specification for the drug substance provided by the drug product manufacturer has no test for identification. Justify. • Specifications provided by the drug product manufacturer has no limits for dissolution in phosphate buffer and no time for acidic release. Justification shall be submitted.	Firm has submitted revised drug substance specifications wherein they added identification test. Firm has submitted revised drug substance specifications wherein they added both time for acidic medium i.e. 120 minutes and release limits for buffer medium.
6.	3.2.S.4.2	Analytical procedures for the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted. Details/COA of the working standard used in the analysis shall be submitted.	Not Submitted. Submitted.
8.	3.2.S.7	Real time stability study data for drug substance shall be submitted.	***Firm has submitted real time stability data sheets for the drug substance, however, they are not in readable form.***
9.	3.2.P.2.2	• Justification shall be submitted for submitting same results of CDP for both 20mg and 40mg formulations. • Justification shall be submitted for not performing CDP & PE against the innovator product. • Graphical representation of the CDP in acidic media has shown full release of the content. Clarification shall be submitted. • Details of the comparator i.e. batch number, manufacturing date etc. are not submitted.	Firm has submitted that by mistakenly same CDP was attached. They also provided new CDP results for the applied formulation with Nexum 40mg capsules. Firm has submitted that it was a typo error and in newly submitted CDP results they have corrected the same. ***No justification submitted against this point.*** They also submitted new graphical representation for CDP results in acidic medium. B. No C02032, Mfg. date 03-2022, Exp. Date 03-2025 and MRP 530.
10.	3.2.P.5.3	Analytical method verification for the finished product shall be submitted.	Not submitted.
11.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number. • Justify the weight of standard and sample taken in the calculation formula for the assay test.	Firm has submitted revised stability data sheets with API lot number. Firm has submitted that in initially submitted analytical procedures, there was a typo error. Now they have provided new analytical procedures which are in accordance with the submitted

		• Justify the wavelength applied in the submitted chromatograms with respect to the wavelength mentioned in analytical procedure.	chromatograms. Same as above.

Decision: Registration Board decided to approve the case subject to onsite verification/authenticity of the product development and stability data by the QA/LT.

CLB in its 284th meeting held on 16th December 2021 has considered and approved the grant of following four (04) additional section to M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura;

- Capsule (Penicillin). – New.
- Oral Dry Powder Suspension (Penicillin). – New.
- Dry Powder Injectable (Penicillin). – New.
- Dry Powder Injectable (Carbapenem). – New.

Following applications of M/s Fynk Pharma are placed before the Board for consideration.

750.	**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 F_2 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: 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.**

751.	**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 suspension (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. 14708 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 9880312550 Dated 05-06-2023.
	The proposed proprietary name / brand name	**Ampiwell Dry Powder Suspension 125mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ampicillin as trihydrate …… 125mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	60ml.
	Proposed unit price	As per SRO.

	The status in reference regulatory authorities	Ampicillin 125 mg/5ml Oral Suspension, Kent Pharmaceuticals Limited, MHRA Approved.
	For generic drugs (me-too status)	Ampcin 15 mg Dry Suspension, CSH Pharmaceuticals, Reg. No. 071538.
	Name and address of API manufacturer.	M/s Zafa Chemie, Raiwind Road Bypass, Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore, Pakistan. Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019.
	Module-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. 828, mfg. date 02-2021) 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 study 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. Real time: B. No. 804, 805 & 806. Accelerated: 808, 809 & 810.
	Module-III Drug Product:	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 Ampicillin dry powder suspension with B. No. SM-022, mfg. date 05-2022 manufactured by M/s Amros Pharmaceuticals by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Zafa Chemie, Raiwind Road Bypass, Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore, Pakistan.		
API Lot No.	828.		
Description of Pack (Container closure system)	Amber colour glass sealed labelled bottle securely 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-001	T-002	T-003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	16-08-2022	16-08-2022	16-08-2022
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.	Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019.
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)	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 once again submitted** Copy of GMP Certificate No. 79/2020-DRAP (AD/1992617-228) dated 20-04-2020 issued on the basis of inspection conducted on 23-10-2019. ***Not within last three years.***
2.	2.3	Table for literature references with correct information shall be submitted.	Firm has provided corrected information with submission of 7500/- fee vide slip No. 22193240162 dated 10-07-2023.
3.	3.2.S.7	Real time and accelerated stability study data of the drug substance for the same batches shall be submitted.	***Firm has once again submitted real time stability data of the drug substance for the same batches.*** ***Real time: B. No. 804, 805 & 806.*** ***Accelerated: 808, 809 & 810.*** ***Stability study data for same***

			batches is not provided.
4.	3.2.P.2.2	Justification for not performing the pharmaceutical equivalence test against the innovator product.	Firm has submitted that innovator product was not available in the market, so they used competitor product.
5.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Justification shall be submitted for the applied wavelength (230) in the submitted chromatograms with respect to the analytical procedures and BP (254). • Justification shall be submitted for the injection volume (20) in the submitted chromatograms with respect to the analytical procedures and BP (50µl). • Raw data sheets for calculation of ampicillin content at each time point shall be submitted. • Documents for procurement of API shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number in the stability data sheets. Firm has submitted that wavelength of 230nm was adopted from USP monograph of Ampicillin. ***However, finished product specifications, analytical procedures have mentioned BP specifications.*** Firm has submitted that to achieve system suitability, they used 20 µl injection volume as per USP <621>, method verification also has been conducted for this variation. They further submitted that at 11-month time point they had tested by using 50 µl injection volume and using 254 nm wavelength and found satisfactory results. Firm has submitted that they attached raw data sheets for calculation of ampicillin content. ***However, they have not submitted any calculation sheets.*** Firm has submitted copy of invoice No. 293913 mentioning 10kg quantity of Ampicillin trihydrate with batch No. 828.

Decision: Deferred for following;

- **Valid copy of GMP certificate/inspection report conducted within last three years of the drug substance manufacturer shall be submitted.**
- **Real time and accelerated stability study data of the drug substance for the same batches shall be submitted.**
- **Pharmaceutical equivalence test of the applied formulation against the innovator product shall be submitted.**
- **Justification shall be submitted for adopting wavelength (230nm) in the submitted chromatograms while the specification and analytical procedures of the finished product has mentioned BP specification with wavelength of (254nm).**
- **Raw data sheets for calculation of ampicillin content at each time point shall be submitted.**

752.	**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	Not submitted.

	humidity monitoring of stability chambers (real time and accelerated)	

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 of M/s Pfizer Pakistan limited. They also provided the new

		• Content uniformity test and particulate matter tests are not performed in the pharmaceutical equivalence studies. Justify?	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. ***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: 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.**

753.	**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 (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% 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.	Firm has submitted that they have also performed pharmaceutical equillance studies against the Meronem injection of M/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. ***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: 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.**

754.	**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 suspension (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. 14706 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 874651822159 Dated 06-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 125mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 125mg. Potassium Clavulanate eq. Clavulanic Acid……. 31.25mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	60ml, 75ml, 90ml, 100ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 125 mg/31.25mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Augmentin 125 mg/31.25mg, GSK Pakistan, Reg. No. 009264.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur 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. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**<u>Amoxicillin trihydrate:</u>** 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 (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** 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 (02NB2205007) and 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 trihydrate:** 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: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions: Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months Real time: 5°C ± 3°C for 36 months. Batches: (NA-201106301, NA-201106302 & NA-201106303)
	Module-III Drug Product:	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 Augmentin dry powder suspension 125mg with B. No. PV8L, mfg. date 06-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.
API Lot No.	Not provided.
Description of Pack	Amber colour Glass Bottle properly sealed with cap, labelled and packed in

(Container closure system)	cardboard 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	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
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 submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** 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. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 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 (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	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.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	**Amoxicillin Trihydrate:** 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. ***However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted.*** **Potassium Clavulanate:** ***Not submitted.***

3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Submitted. ***However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash.*** Firm has submitted specifications for the drug substance i.e. mixture of potassium Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	***Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.*** Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	Submitted. ***However, the submitted analytical procedure is completely different from BP monograph.*** ***Concentration of the standard solution for amoxicillin and potassium Clavulanate are different***

			from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical method has mentioned potassium Clavulanate as reference standard.
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths of Falamox suspension.	**Not submitted.** **Not submitted.** Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. ***Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.*** ***As per record of the executed BMRs of the trial batches with strength of* 125mg/5ml*, 37.23mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***37.23 x 12 = 446.76mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 446.76 = 670,140mg or 670gm.*** ***As per record of the executed BMRs of the trial batches with strength of* 250mg/5ml*, 74.38mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***74.38 x 12 = 892.56mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 892.56 = 1,338,840mg or 1338gm.*** ***As per record of the executed BMRs of the trial batches with strength of 400*mg/5ml*, 67.83mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***67.83 x 12 = 813.96mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 813.96 = 1,220,940mg or 1220gm***

			Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.

Decision: Deferred for following;

- **Justification shall be submitted for change in the submitted specifications i.e assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.**
- **Justification shall be submitted for submission of COA of the drug substance i.e Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.**
- **Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.**
- **Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.**
- **Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.**
- **Raw data sheets for calculation of assay at each time point with formula shall be submitted.**
- **Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.**

755.	**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 suspension (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. 14707 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 165628659 Dated 05-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 250mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 250mg. Potassium Clavulanate eq. Clavulanic Acid …….. 62.50mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.

	Proposed Pack size	60ml & 90ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 250mg/62.50mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Zamoclav suspension, Zafa Pharmaceutical, Reg. No. 035386.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur 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. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**Amoxicillin trihydrate:** 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 (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** 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 (02NB2205007) and 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 trihydrate:** 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: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions:

		Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 06 months Real time: 5˚C ± 3˚C for 36 months. Batches: (NA-201106301, NA-201106301 & NA-201106301)
	Module-III Drug Product:	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 Augmentin dry powder suspension 250mg with B. No. SY2R, mfg. date 05-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Amber colour Glass Bottle properly sealed with cap, labelled and packed in cardboard 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	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
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 submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** 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. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 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 (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	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.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	**<u>Amoxicillin Trihydrate:</u>** 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. ***However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted.*** **<u>Potassium Clavulanate:</u>** ***Not submitted.***
3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Submitted. ***However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash.*** Firm has submitted specifications for the drug substance i.e. mixture of potassium Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.

6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	***Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.*** Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	Submitted. ***However, the submitted analytical procedure is completely different from BP monograph.*** ***Concentration of the standard solution for amoxicillin and potassium Clavulanate are different from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical method has mentioned potassium Clavulanate as reference standard.***
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing	**Not submitted.** **Not submitted.** Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. ***Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of***

		and testing of all the three strengths of Falamox suspension.	***Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.*** ***As per record of the executed BMRs of the trial batches with strength of* 125mg/5ml*, 37.23mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***37.23 x 12 = 446.76mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 446.76 = 670,140mg or 670gm.*** ***As per record of the executed BMRs of the trial batches with strength of* 250mg/5ml*, 74.38mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***74.38 x 12 = 892.56mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 892.56 = 1,338,840mg or 1338gm.*** ***As per record of the executed BMRs of the trial batches with strength of 400*mg/5ml*, 67.83mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***67.83 x 12 = 813.96mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 813.96 = 1,220,940mg or 1220gm*** ***Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.***

Decision: Deferred for following;

- **Justification shall be submitted for change in the submitted specifications i.e assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.**
- **Justification shall be submitted for submission of COA of the drug substance i.e Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.**
- **Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.**
- **Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.**
- **Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.**
- **Raw data sheets for calculation of assay at each time point with formula shall be submitted.**
- **Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.**

756.	**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 suspension (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. 14709 dated 12-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 0036909442 Dated 06-06-2023.
	The proposed proprietary name / brand name	**Falamox Dry Powder Suspension 400mg/5ml.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as trihydrate …… 400mg. Potassium Clavulanate eq. Clavulanic Acid ….. 57mg.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Dry Powder Suspension.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	35ml & 70ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Augmentin 400mg/57mg Oral Suspension, USFDA approved.
	For generic drugs (me-too status)	Clav Forte 400mg + 57mg/5ml Dry Suspension, Amrose Pharmaceuticals, Reg. No. 058102.
	Name and address of API manufacturer.	**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur 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. **Potassium Clavulanate:** Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 valid till 05-06-2023.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has submitted summarized information for both the drug substances related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**<u>Amoxicillin trihydrate:</u>** 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 (000120/841/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Potassium Clavulanate:** 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 (02NB2205007) and 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 trihydrate:** 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: (00013/210/2009, 00013/211/2009, 00013/212/2009) **Potassium Clavulanate:** Stability study conditions: Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months Real time: 5°C ± 3°C for 36 months. Batches: (NA-201106301, NA-201106301 & NA-201106301)
	Module-III Drug Product:	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 Augmentin dry powder suspension 400mg with B. No. RY4P, mfg. date 06-2022 manufactured by M/s GSK Pakistan by performing quality test of identification, pH, average filled bottle weight, assay and microbial count test. Results of both the test product and reference product are within the specifications limit and comparable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		**Amoxicillin Trihydrate:** Pharmagen Limited; Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore.

	Potassium Clavulanate: Sinopharm Weiqida Pharmaceuticals Co., Ltd. Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Amber colour Glass Bottle properly sealed with cap, labelled and packed in cardboard 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	500 bottles	500 bottles	500 bottles
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	27-10-2022	27-10-2022	27-10-2022
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 submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amoxicillin Trihydrate:** 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. **Potassium Clavulanate:** Firm has submitted copy of GMP Certificate (No. SX20180229) issued by CFDA dated 06-06-2018 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 (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	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.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of both the drug substance manufacturer shall be submitted.	**Amoxicillin Trihydrate:** 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.

			However, in the submitted dossier, drug substance data from M/s Pharmagen Limited was submitted. **<u>Potassium Clavulanate:</u>** ***Not submitted.***
3.	3.2.S.4.1	• Specifications of both the drug substances from drug product manufacturer shall be submitted. • Specification of the drug substance provided by drug substance manufacturer has mentioned pH limit of 5.5 – 8 while the COA of finished product manufacturer has mentioned 4.8-8. Clarification shall be submitted.	Submitted. ***However, specifications from both the drug substance and drug product manufacturer are different from each other in assay, water content and sulphated ash.*** Firm has submitted specifications for the drug substance i.e. mixture of potassium Clavulanate with Avicel (1:1) wherein the pH is 4.8-8 for the mixture. They further submitted that the same mixture is used as drug substance instead of potassium Clavulanate alone.
4.	3.2.S.4.2	Analytical procedures for both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.3	• Verification studies of the drug substance (amoxicillin trihydrate) performed by the drug product manufacturer shall be submitted. • Verification studies of the drug substance (Potassium Clavulanate) performed by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	3.2.S.4.4	• COA of the drug substance from both drug substance manufacturer and finished product manufacturer with same batch numbers shall be submitted. • Specification submitted by the drug substance manufacturer are all changed in the COA of the finished product manufacturer. Justification shall be submitted.	***Firm has submitted COA of the drug substance Ampicillin trihydrate from drug substance manufacturer instead of Amoxicillin trihydrate.*** Firm has submitted that specifications are in compliance with the specifications of the Potassium Clavulanate Diluted (Avicel or Syloid) 1:1. They further submitted that since potassium Clavulanate is not stable, so, Avicel is added (in a ratio of 1:1 by weight) by drug substance manufacturer to make the final product stable during the storage, shipment and usage. They also provided specifications for the same.
7.	3.2.S.5	Details/COA of the working standard used in the analysis of Potassium Clavulanate shall be submitted.	Submitted.
8.	3.2.S.7.3	All the tests in the stability data sheets are in contrast to the specifications provided by the drug substance manufacturer. Justification is required.	Firm has submitted that stability data sheets of the drug substance is for the mixture of Potassium Clavulanate Diluted.
9.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	Submitted. ***However, the submitted analytical procedure is completely different from BP monograph.*** ***Concentration of the standard solution for amoxicillin and potassium Clavulanate are different from BP. Furthermore, BP specifies lithium Clavulanate as reference standard while firm in their analytical***

			method has mentioned potassium Clavulanate as reference standard.
10.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted. • Raw data sheets for calculation of assay at each time point with formula shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification regarding the quantity of drug substance i.e. Potassium Clavulanate shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of all the three strengths of Falamox suspension.	**Not submitted.** **Not submitted.** Firm has submitted that in DRB 323rd meeting their two products i.e. Faxcil 250mg & 500. Firm has submitted that quantity of potassium Clavulanate was calculated to make three strengths. They further submitted that calculation sheet is attached. However, no calculation sheet is attached with the file. ***Firm has submitted copy of clearance certificate (E-2827420227964) dated 26-Sep-2022 specifying 1.0 Kg of Potassium Clavulanate. The invoice is cleared by DRAP, Lahore.*** ***As per record of the executed BMRs of the trial batches with strength of* 125mg/5ml, *37.23mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***37.23 x 12 = 446.76mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 446.76 = 670,140mg or 670gm.*** ***As per record of the executed BMRs of the trial batches with strength of* 250mg/5ml, *74.38mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***74.38 x 12 = 892.56mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 892.56 = 1,338,840mg or 1338gm.*** ***As per record of the executed BMRs of the trial batches with strength of 400*mg/5ml, *67.83mg/5ml quantity of potassium Clavulanate is used.*** ***60ml of bottle is used in stability data.*** ***67.83 x 12 = 813.96mg/bottle.*** ***Total of 03 trial batches with batch size of 500 each were manufactured.*** ***1500 x 813.96 = 1,220,940mg or 1220gm*** ***Total of 1220 + 1338 + 670 = 3228gm or 3.22kg.***

Decision: Deferred for following;

- **Justification shall be submitted for change in the submitted specifications i.e assay, water content and sulphated ash between the specifications of drug substance manufacturer and drug product manufacturer.**
- **Justification shall be submitted for submission of COA of the drug substance i.e Amoxicillin trihydrate from drug substance manufacturer instead of Ampicillin trihydrate.**

• **Justification shall be submitted for Concentration of the standard solution for amoxicillin and potassium Clavulanate in the analytical procedure as both are different from BP.** • **Justification shall be submitted for using potassium Clavulanate as reference standard while BP has mentioned lithium Clavulanate as reference standard.** • **Stability data sheets as per decision of 293rd meeting of RB with inclusion of API lot number shall be submitted.** • **Raw data sheets for calculation of assay at each time point with formula shall be submitted.** • **Justification shall be submitted regarding the total quantity of drug substance Potassium Clavulanate imported i.e. 01kg vide clearance certificate (E-2827420227964) dated 26-Sep-2022 with respect to the total quantity of the drug substance used in manufacturing and testing of all the three strengths (09 trial batches) of Falamox suspension.**		
757.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-KM Chakbeli Road, Rawat, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-KM Chakbeli Road, Rawat, Rawalpindi.
	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 section approval letter No. F. 1-2/2019-Lic dated 14/02/2020 wherein they have Ampoule section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5679 dated 28-02-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 8013054618 Dated 15-02-2023
	The proposed proprietary name / brand name	**Biorolac 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)	NSAID**'s**
	Pharmaceutical form of applied drug	Solution for Injection for IM/IV
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	Not submitted.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Toradol 30mg/ml, USFDA Approved.
	For generic drugs (me-too status)	Toradol injection 30mg/ml, Martin Dow Marker Ltd., Reg. No. 108584.
	Name and address of API manufacturer.	Saurav Chemical Limited., 370 industrial area Phase II Panchkula, 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (KTM200008, mfg. date 01-2020) and 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 09 months. Batch No. KTMB100005, KTMB100006 & KTMB100007.
	Module-III Drug Product:	Firm has submitted details of the 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 comparator product Toradol 30 mg/ml by performing quality test of Identification, Particulate matter, pH, Assay, Bacterial endotoxin test and Sterility 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	Saurav Chemical Limited., 370 industrial area Phase II Panchkula, Haryana, India.		
API Lot No.	KTMD200008.		
Description of Pack (Container closure system)	Transparent glass USP type-I Ampoules, further packed in bleach board pack containing 5 ampoules with ALU/PVC BLISTER 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: 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	07-2022	07-2022	07-2022
Date of Initiation	03-07-2022	03-07-2022	03-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted that Biogen pharmaceutical is a new license facility hence no such inspection has been conducted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	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	Firm has submitted that their HPLC system are not 21 CFR compliant.
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	Observations	Reply by the firm
1.		First page of form 5F is not submitted.	Submitted.
2.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted. • Valid copy of GMP certificate of the applicant 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.***
3.	1.3.5	Section approval letter has mentioned Ampoule section SVP (General) while the applied formulation is in vial. Justification shall be submitted.	Firm has submitted that applied formulation is in ampoule and they also have ampoule general section.
4.	1.5.4	Proposed pack size shall be submitted.	1x5's Blister contain 5 ampoule of 1 ml packed in unit carton.
5.	2.3	Table for literature references with correct information regarding the drug product with applicable fee shall be submitted.	***Revised table for literature references is submitted without fee submission.***
6.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (3) pb. 2021/3124 dated 25-06-2021 issued by Food & Drugs Administration, Punjab in the name of M/s Saurav Chemical Limited., Derabassi-Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Saibzada Ajit Singh Nagar, (Punjab) valid till 25-06-2023. ***Data submitted in the dossier has mentioned Saurav Chemical Limited., 370 industrial area Phase II Panchkula, Haryana, India while the provided GMP certificate has mentioned some other address.*** ***Furthermore, validity of the certificate is till 25-06-2023.***
7.	3.2.S.4.1	Specifications of the drug substance by both the drug substance manufacturer and finished product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.2	Justification shall be submitted for the assay test in the analytical procedures	Firm has submitted that drug substance manufacturer used both the methods for analysis

		provided by the drug substance manufacturer wherein assay test is by potentiometry while USP has mentioned HPLC method.	of the drug substance. They also provided analytical procedure from the drug substance manufacturer by HPLC method.
9.	3.2.S.4.3	Verification of analytical procedures of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
10.	3.2.S.4.4	• COA's from both the drug substance and drug product manufacturer with same batch number shall be submitted. • COA of the drug substance from drug product manufacturer has only one identification test while the COA of the finished product manufacturer and USP monograph has three different test. Justification shall be submitted.	Firm has submitted copies of COAs from both the drug substance manufacturer and finished product manufacturer with COA No. KTM200008, mfg. date 01-2020. Firm has submitted they perform all the identification test on drug substance. Tests are also evident from the newly submitted COA.
11.	3.2.S.7.3	• Complete real time stability of all the three batches of the drug substance shall be submitted. • Justification shall be submitted for not conducting most of the test in the stability of the drug substance i.e. Sterility, bacterial endotoxin pH etc.	Firm has submitted real time stability data for three batches the drug substance for 48 months. Firm has submitted that due to Aseptic filling of Biorolac 30mg/ml solution (Ketorolac Tromethamine) the Raw material (Ketorolac Tromethamine) is non sterile powder. That why drug substance manufacturer does not perform Bacterial Endotoxin Test &Sterility test. Other test like pH ,LOD Melting Point, Assay Impurities performed by drug substance manufacturer which are mentioned in the stability summery sheet.
12.	3.2.P.2.2	Details of the comparator product including its manufacturer, batch No. and manufacturing date etc. shall be submitted.	**Product Name:** Toradol 30mg/ml Injection **Registration Number: 108584** **Batch No: 25003** **Mfg. Date**:06/2022 **Exp. Date**:05/2024 **Manufactured by** :Martin Dow Marker LTD
13.	3.2.P.3.3	Scientific justification shall be submitted for not performing the terminal sterilization of the finished product.	Firm has submitted that the Finished Product was Terminally sterilized as recorded on BMR page No. 12 Which could not be mentioned here.
14.	3.2.P.5.2	Complete analytical procedures for all the tests shall be submitted.	Submitted.
15.	3.2.P.5.6	This section has mentioned manufacturer specifications. Justification shall be submitted.	Specification of Biorolac Injection is USP specs however, due to typographical mistake, instead of USP Specifications Manufacturer specifications was mentioned.
16.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Not applicable. Firm has submitted commercial invoice No. SCL/2020-21/138 dated 26-09-2020 mentioning 50gm of ketorolac Tromethamine USP with batch no. KTM200008, mfg. date of 01-01-2020. ***However, invoice is not attested by DRAP.*** Submitted.

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

Decision: Deferred for following;

- **Valid copy of GMP certificate of the applicant shall be submitted.**
- **Clarification regarding the drug substance manufacturer shall be submitted as the submitted GMP certificate has different address than the information submitted in 3.2.S.**
- **Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.**
- **Scientific justification shall be submitted for performing the terminal sterilization of the finished product with reference to innovator drug product literature.**
- **Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.**
- **Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 shall be submitted.**

B. Application of locally manufactured deferred drugs on Form 5F.

758.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34507; dated 29/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.19942923 dated 25/11/2022.
	The proposed proprietary name / brand name	**Pime-4 500mg Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime ….500mg
	Pharmaceutical form of applied drug	Dry powder injection.
	Pharmacotherapeutic Group of (API)	01DE Fourth-generation cephalosporin
	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 (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 500mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030953.
	GMP status of the Finished product	GMP Certificate No.70/2021-

	manufacturer	DRAP(FID/2061717-540) Dated 08-09-21
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) - New section vide No.F.1-10/2012-Lic dated 07-06-2022 is approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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)	Official monograph of Cefepime HCl and L-Arginine is present in USP. Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis (CEIV/B2201004, mfg. date 11-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30°C ± 2°C /65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Cefstar 500mg IV/IM injection by performing quality tests (Identification, Average weight content & 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 Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.		
API Lot No.		CEIV/B2201004.		
Description of Pack (Container closure system)		1x10ml vial containing Cefepime HCl with L-Arginine with reconstituent Diluent (WFI).		
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.		TCH001	TCH002	TCH001
Batch Size		500Vials	500Vials	500Vials
Manufacturing Date		05-2022	05-2022	05-2022
Date of Initiation		06-05-22	07-05-22	08-05-22
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)	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. New-WHO-GMP/Cert/KD/89275/2020/11/33788 dated 20-10-2020 issued on the basis of inspection conducted on 06-03-2020 valid till 19-10-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-897164883689 dated 19-04-2022 for 50Kg of Cefepime HCl and L-Arginine sterile USP having Batch No. CEIV/B2201004 with manufacturing date of 01-11-2021 issued in name of M/s Medisave attested by AD I&E DRAP, Lahore. Firm has also submitted copy of loan letter from M/s Medisave Pharmaceutical for 05kg.		
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 by the Evaluator:				

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Latest GMP certificate/last inspection report conducted within last three years for the Finished Product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021 issued on the basis of inspection conducted on 08-09-2021.
2.	2.3.R	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia with applicable fee.	*Not submitted.*
3.	3.2.S.4.1	Drug Substance manufacturer has mentioned L-arginine quantity (on as is basis) between 34% - 44% while FPP has mentioned 37.1% - 44%. Clarify.	Firm has submitted that it was typographic error and also submitted corrected specification and corrected COA for the drug substance. *However, fee applicable to pre-registration variation is not submitted.*
4.	3.2.S.4.2	Calculation formula for assay of drug substance shall be provided.	Submitted.
5.	3.2.S.4.4	• Justification shall be submitted regarding the COA of the drug substance provided by the drug product manufacturer as assay of Cefepime base on as is basis in the same is 50.19% while the specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5%. • COA of the drug substance by the drug product manufacturer has manufacturing date of 11-2022 while that of the drug substance manufacturer has manufacturing date of 11-2021. Clarify.	Firm has only submitted COA of the drug substance from supplier. *However, initially submitted specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5% while the COA of the finished product manufacturer has assay of Cefepime on as is basis of 50.19 which is out of specifications.* Firm has submitted that it was typo error and they also provided corrected COA.
6.	3.2.P.2.2	• Justification shall be submitted for not performing Pharmaceutical Equivalence against the innovator product. • Details of the reference product used in the Pharmaceutical Equivalence shall be submitted. • pH test is not performed. • Justification shall be submitted for not performing most of the quality test applicable on powder for injection.	Firm has submitted that due to easy availability of market sample Cefstar injection was used in PE. CefStar 500mg Injection, Batch No. C7100, Mfg. date 03-2021 is submitted. Firm has submitted revised results for pharmaceutical equivalence wherein they have added pH test. Not submitted.
7.	3.2.P.8	In use stability data shall be submitted.	Firm has submitted that its ready to use injection.

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

- Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.
- Justification shall be submitted for use of out of specifications drug substance in the trial batches.
- Submission of Pharmaceutical Equivalence against the innovator product.

- Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Reply by the firm:

S. No.	Reason for deferment	Reply submitted by the firm
1.	Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.	Firm has submitted revised table for literature references with correct information.
2.	Justification shall be submitted for use of out of specifications drug substance in the trial batches.	Firm has submitted that it was a typo error and they also submitted raw data sheets for the new calculation wherein the assay on as is basis is 50.60. ***However, they also submitted COA for the drug substance wherein still same value of 50.19% is mentioned.***
3.	Submission of Pharmaceutical Equivalence against the innovator product.	Firm has submitted pharmaceutical equillance with Maxipime 500mg injection by performing quality tests of Description, Identification, clarity of solution, pH, water content, Average weight content, uniformity of dosage units, BET, Sterility & Assay. ***However, no details of the comparator product such as manufacturer, batch number, manufacturing date expiry date etc. are not mentioned.***
4.	Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	Firm has submitted fee of 7500/- vide slip No. 81101392 dated 13-06-2023.

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.**

759.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34508; dated 29/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.63776342 dated 25/11/2022.
	The proposed proprietary name / brand name	**Pime-4 1gm Injection.**

	Strength / concentration of drug of Active Pharmaceuti cal ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime ……..…….1000mg
	Pharmaceutical form of applied drug	Dry powder injection.
	Pharmacotherapeutic Group of (API)	01DE Fourth-generation cephalosporin
	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 (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 1000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030954.
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) - New section vide No.F.1-10/2012-Lic dated 07-06-2022 is approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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)	Official monograph of Cefepime HCl and L-Arginine is present in USP. Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis (CEIV/B2201004, mfg. date 11-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Cefstar 1000mg IV/IM injection by performing quality tests (Identification, Average weight content & 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 Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.		
API Lot No.	CEIV/B2201004.		
Description of Pack (Container closure system)	1x10ml vial containing Cefepime HCl with L-Arginine with reconstituent Diluent (WFI).		
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.	TCP001	TCP002	TCP001
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04-22	29-04-22	30-04-22
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)	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. New-WHO-GMP/Cert/KD/89275/2020/11/33788 dated 20-10-2020 issued on the basis of inspection conducted on 06-03-2020 valid till 19-10-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate No. E-897164883689 dated 19-04-2022 for 50Kg of Cefepime HCl and L-Arginine sterile USP having Batch No. CEIV/B2201004 with manufacturing date of 01-11-2021 issued in name of M/s Medisave attested by AD I&E DRAP, Lahore. Firm has also submitted copy of loan letter from M/s Medisave Pharmaceutical for 05kg.
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 by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Latest GMP certificate/last inspection report conducted within last three years for the Finished Product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021 issued on the basis of inspection conducted on 08-09-2021.
2.	2.3.R	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia with applicable fee.	*Not submitted.*
3.	3.2.S.4.1	Drug Substance manufacturer has mentioned L-arginine quantity (on as is basis) between 34% - 44% while FPP has mentioned 37.1% - 44%. Clarify.	Firm has submitted that it was typographic error and also submitted corrected specification and corrected COA for the drug substance. *However, fee applicable to pre-registration variation is not submitted.*
4.	3.2.S.4.2	Calculation formula for assay of drug substance shall be provided.	Submitted.
5.	3.2.S.4.4	• Justification shall be submitted regarding the COA of the drug substance provided by the drug product manufacturer as assay of Cefepime base on as is basis in the same is 50.19% while the specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5%. • COA of the drug substance by the drug product manufacturer has manufacturing date of 11-2022 while that of the drug substance manufacturer has manufacturing date of 11-2021. Clarify.	Firm has only submitted COA of the drug substance from supplier. *However, initially submitted specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5% while the COA of the finished product manufacturer has assay of Cefepime on as is basis of 50.19 which is out of specifications.* Firm has submitted that it was typo error and they also provided corrected COA.

6.	3.2.P.2.2	• Justification shall be submitted for not performing Pharmaceutical Equivalence against the innovator product. • Details of the reference product used in the Pharmaceutical Equivalence shall be submitted. • pH test is not performed. • Justification shall be submitted for not performing most of the quality test applicable on powder for injection.	Firm has submitted that due to easy availability of market sample Cefstar injection was used in PE. CefStar 500mg Injection, Batch No. C7100, Mfg. date 03-2021 is submitted. Firm has submitted revised results for pharmaceutical equivalence wherein they have added pH test. Not submitted.
7.	3.2.P.8	In use stability data shall be submitted.	Firm has submitted that its ready to use injection.

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

- Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.
- Justification shall be submitted for use of out of specifications drug substance in the trial batches.
- Submission of Pharmaceutical Equivalence against the innovator product.
- Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Reply by the firm:

S. No.	Reason for deferment	Reply submitted by the firm
1.	Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.	Firm has submitted revised table for literature references with correct information.
2.	Justification shall be submitted for use of out of specifications drug substance in the trial batches.	Firm has submitted that it was a typo error and they also submitted raw data sheets for the new calculation wherein the assay on as is basis is 50.60. ***However, they also submitted COA for the drug substance wherein still same value of 50.19% is mentioned.***
3.	Submission of Pharmaceutical Equivalence against the innovator product.	Firm has submitted pharmaceutical equillance with Maxipime 1000mg injection by performing quality tests of Description, Identification, clarity of solution, pH, water content, Average weight content, uniformity of dosage units, BET, Sterility & Assay. ***However, no details of the comparator product such as manufacturer, batch number, manufacturing date expiry date etc. are not mentioned.***
4.	Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	Firm has submitted fee of 7500/- vide slip No. 12428508 dated 13-06-2023.

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.**		
760.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3116; dated 02/02/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.6901084368 dated 01/08/2022.
	The proposed proprietary name / brand name	Invipam 500mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….500mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg & 1gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 500mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030953.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (11C0741702001, 11C0741702002 & 11C0741702003)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Maxipime 500mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, bacterial endotoxin, sterility & Assay).
	Analytical method validation/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 Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.
API Lot No.	11C0742107001.
Description of Pack	Transparent Type II glass vial filled with powder,

(Container closure system)	closed with rubber stopper and 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.	TDI001	TDI002	TDI003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	15-11-2021	15-11-2021	15-11-2021
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

13.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	

6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 327th 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.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	Firm has submitted revised label claim as under; Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime …….500mg. ***Firm has submitted Fee of 7500/- vide slip***

			No. 92213403304 dated 29-05-2023 and differential fee of 22500/- vide slip No. 97100344 dated 13-07-2023.
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	Firm has submitted that it was a typographic error and revised Pharmacotherapeutic group from third generation cephalosporin to 4th generation cephalosporin.
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	Firm has submitted revised table for literature references with correct information regarding both the drug substance and finished product.
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	Firm has submitted new stability data sheets for the same batches of the drug substance with specifications provided by the drug substance manufacturer. Firm has submitted new stability data sheets for the same batches of the drug substance with assay specifications of 34% to 42% of Arginine and NLT 90% NMT 115% of Cefepime calculated on anhydrous and arginine free basis.
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	Firm has submitted USP specifications for the drug product.
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	Submitted.
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size.	Firm has submitted revised stability data sheets for all the three trial batches as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. They also included Identification test, water content tests in the revised stability data sheets. API lot No. 11C0742107001.

		• Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Trial batch size is 500 vials each. 15-11-2021 is the initiation date of stability studies. Firm has submitted commercial invoice No. CI-HXIP201910PK-074 dated 10-09-2021 mentioning 10kg quantity of Cefepime HCL L-Arginine with batch number 11C0742107001, Mfg. date 12-07-2021 attested by Assistant Director I&E, DRAP, Islamabad dated 22-10-2021. Submitted.

Decision: Approved with following label claim;

Each Vial contains:

Cefepime HCl with L-Arginine eq. to Cefepime …….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.**

761.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1853; dated 19/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.0829772894 dated 01/08/2022.
	The proposed proprietary name / brand name	Invipam 1000mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….1000mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.

	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 1000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 030954.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (11C0741702001, 11C0741702002 & 11C0741702003)

	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Maxipime 1000mg IV/IM injection batch No. Y83J, mfg. date 01-2021 manufactured by GSK, Pakistan by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).
	Analytical method validation/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 Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.		
Stability Storage Condition	Real time: 30˚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.	TDI001	TDI002	TCH003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-11-2021	11-11-2021	11-11-2021
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)	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 manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
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:

Sr. No.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	

10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 327th 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.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	Firm has submitted revised label claim as under; Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime ……1000mg. ***Firm has submitted Fee of 7500/- vide slip No. 8750368472 dated 29-05-2023 and differential fee of 22500/- vide slip No. 7672810381 dated 13-07-2023.***
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	Firm has submitted that it was a typographic error and revised Pharmacotherapeutic group from third generation cephalosporin to 4th generation cephalosporin.
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	Firm has submitted revised table for literature references with correct information regarding both the drug substance and finished product.
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted.	Firm has submitted new stability data sheets for the same batches of the drug substance with specifications provided by the drug substance manufacturer.

		• Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	Firm has submitted new stability data sheets for the same batches of the drug substance with assay specifications of 34% to 42% of Arginine and NLT 90% NMT 115% of Cefepime calculated on anhydrous and arginine free basis.
8.	3.2.P.5.1	Specifications provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Clarification shall be submitted.	Firm has submitted USP specifications for the drug product.
9.	3.2.P.5.2	Analytical procedures provided by the finished product manufacturer for the drug product is for Lidocaine HCl instead of Cefepime HCl with L arginine. Signed analytical procedures for the drug product shall be submitted.	Submitted.
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets for all the three trial batches as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. They also included Identification test, water content tests in the revised stability data sheets. API lot No. 11C0742107001. Trial batch size is 500 vials each. 11-11-2021 is the initiation date of stability studies. Firm has submitted commercial invoice No. CI-HXIP201910PK-074 dated 10-09-2021 mentioning 10kg quantity of Cefepime HCL L-Arginine with batch number 11C0742107001, Mfg. date 12-07-2021 attested by Assistant Director I&E, DRAP, Islamabad dated 22-10-2021. Submitted.

Decision: Approved with following label claim;

Each Vial contains:

Cefepime HCl with L-Arginine eq. to Cefepime …….1000mg.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
762.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2384; dated 25/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.91779456 dated 04/08/2022.
	The proposed proprietary name / brand name	Invipam 2000mg Injection IM/IV.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine ……..…….2000mg
	Pharmaceutical form of applied drug	Sterile Powder for injection.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporin. (J01DE)
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	MAXIPIME 500mg, 1gm & 2gm (Cefepime hydrochloride) for injection, USFDA Approved.
	For generic drugs (me-too status)	CefStar for injection 2000mg IV/IM, Barret Hodgson Pakistan (Pvt.) Ltd., Registration No: 089284.
	GMP status of the Finished product manufacturer	Last inspection report conducted on 31-08-2022 is submitted wherein the firm was working at good level of GMP.
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) section vide No.F.1-37/2016-Lic (Vol-I) dated 18-02-2022 is approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China. Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2015. (Raw materials, Sterile raw materials)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (11C0742107001, Mfg. date 12-07-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (11C0741702001, 11C0741702002 & 11C0741702003)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Maxum 2000mg injection batch No. 218006, mfg. date 02-2021 manufactured by M/s Highnoon pharma by performing quality tests (Identification, water content, pH, sterility, bacterial endotoxin & Assay).
	Analytical method validation/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 Group Hengxin Pharmaceutical Co., Ltd., West Side of yanbin Road, Feixian Economic Development Zone, Shandong, China.
API Lot No.	11C0742107001.

Description of Pack (Container closure system)	Transparent Type II glass vial filled with powder, closed with rubber stopper and flip-off seal.		
Stability Storage Condition	Real time: 30˚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.	TDI001	TDI002	TCH003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	23-11-2021	23-11-2021	23-11-2021
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)	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 manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
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:

Sr. No.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product	

		manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	
8.	3.2.P.2.2	Justification shall be submitted for not performing PE against the innovator product.	
9.	3.2.P.5.2	Signed analytical procedures for the drug product shall be submitted.	
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 327th 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.	Section	Observations	Reply by the firm
1.	1.5.2 or 3.2.P.5.1	Label claim of the applied formulation shall be revised as per reference product with submission of full fee.	Firm has submitted revised label claim as under; Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime …….2000mg. ***Firm has submitted Fee of 7500/- vide slip No. 166008087933 dated 29-05-2023 and***

			differential fee of 22500/- vide slip No. 26857018807 dated 13-07-2023.
2.	1.5.5	Pharmacotherapeutic group shall be changed from third generation cephalosporin to 4th generation cephalosporin.	Firm has submitted that it was a typographic error and revised Pharmacotherapeutic group from third generation cephalosporin to 4th generation cephalosporin.
3.	2.3.	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia.	Firm has submitted revised table for literature references with correct information regarding both the drug substance and finished product.
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures for the drug substance used by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Not submitted.
7.	3.2.S.7	• Specifications of the drug substance provided by the drug substance manufacturer are different from the specification of the drug substance in the stability data sheets. Justification shall be submitted. • Specifications of the drug substance has mentioned "Contains NLT 90% and NMT 115% of Cefepime HCl calculated on anhydrous and Arginine free basis" while the stability data sheets for the drug substance has mentioned "NLT 83% of Cefepime calculated on anhydrous and Arginine free basis". Justification shall be submitted.	Firm has submitted new stability data sheets for the same batches of the drug substance with specifications provided by the drug substance manufacturer. Firm has submitted new stability data sheets for the same batches of the drug substance with assay specifications of 34% to 42% of Arginine and NLT 90% NMT 115% of Cefepime calculated on anhydrous and arginine free basis.
8.	3.2.P.2.2	Justification shall be submitted for not performing PE against the innovator product.	Firm has submitted USP specifications for the drug product.
9.	3.2.P.5.2	Signed analytical procedures for the drug product shall be submitted.	Submitted.
10.	3.2.P.8	• Identification test, water content tests are not performed in the stability studies of the drug product. • Stability data sheets shall be as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. • Documents for the procurement of API with approval from DRAP shall be submitted.	Firm has submitted revised stability data sheets for all the three trial batches as per decision of 293rd meeting of Registration Board with inclusion of API lot number, date of initiation of stability studies and total batch size. They also included Identification test, water content tests in the revised stability data sheets. API lot No. 11C0742107001. Trial batch size is 500 vials each. 23-11-2021 is the initiation date of stability studies. Firm has submitted commercial invoice No. CI-HXIP201910PK-074 dated 10-09-2021 mentioning 10kg quantity of Cefepime HCL L-Arginine with batch number 11C0742107001, Mfg. date 12-07-2021 attested by Assistant Director I&E, DRAP, Islamabad dated 22-10-2021. Submitted.

		• Reference of previous approval of applications with stability study data of the firm shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Approved with following label claim;

Each Vial contains:

Cefepime HCl with L-Arginine eq. to Cefepime ……. 2000mg.

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

C: Registration applications of deferred locally manufactured human drugs on Form 5.

763.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemyfenac 100mg Tablet
	Composition	Each Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R & I & fee	Dy. No. 40382; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aceclofenac 100 mg film-coated Tablets. MHRA approved
	Me-too status	Anac 100mg Tablet. Reg. No. 81502
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	The firm has applied for plain tablet. Coating composition are mentioned thereof. However, the manufacturing outlines does not depict coating process. The firm revised the manufacturing outlines. Revision of label claim to film-coated tablet is required.
	Decision of 296th meeting of RB	Deferred for: • Submission of latest GMP inspection report. • Revision of label claim to film-coated tablet along with submission of applicable fee.
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm did not revise the label claim, but resubmitted the master formula. • The firm submitted Rs. 7,500/- fee (Challan: 3050179428)
	Decision of 313th meeting of Reg. Board.	Deferred for revision of label claim.
	Reply submitted by the firm.	Firm has submitted revised label claim as under; **Each film coated tablet Contains:** **Aceclofenac ……..…100mg**
	Evaluation by PEC	
	Decision: Approved with innovator's specifications and following label claim; **Each film coated tablet Contains:** **Aceclofenac ……..…100mg**	
764.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad

	Brand Name + Dosage Form + Strength	Kemsartan Tablet 5mg/160mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…5mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 40384; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; Rs. 340/-
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160mg. USFDA approved
	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• The firm had applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula. • In master formula, the label claim is amlodipine as besilate. However, in Form 5 it is amlodipine. The firm did not clarify the same. • The firm shall submit properly filled enclosure of Form 5. • The firm shall also revise amlodipine as besilate to amlodipine besilate in master formula only.
	Decision of 296th meeting of RB	Deferred for: • Submission of latest GMP inspection report. • Submission of applicable fee for revision of label claim to film-coated tablet. • Revision of amlodipine to amlodipine as besilate in Form 5. • Submission of enclosure of Form 5. • Revision of amlodipine as besilate to amlodipine besilate in master formula only. • Pack size & Demanded Price
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm submitted Rs. 7,500/- fee (Challan: 131899163). • The firm did not adjust the weight of amlodipine besilate in master formula as salt factor.
	Decision of 313th meeting of Reg. Board.	Deferred for adjustment of weight of amlodipine besilate in master formula as salt factor.
	Reply submitted by the firm.	Firm has submitted revised master formula for the applied formulation wherein they have adjusted the weight of amlodipine besylate by applying salt factor.
	Evaluation by PEC	•
	Decision: Approved.	
765.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kemsartan Tablet 10mg/160mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…10mg Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 40383; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	14's; Rs. 448/-
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 10/160. USFDA approved
	Me-too status	VALTAN -M 170 PLUS TABLET. Reg. No. 77207
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	• The firm has applied for film-coated tablet. The firm revised label claim and mentioned the coating composition in master formula. • In master formula, the label claim is amlodipine as besilate. However, in Form 5 it is amlodipine. The firm did not clarify the same. • The firm shall submit properly filled enclosure of Form 5. • The firm shall also revise amlodipine as besilate to amlodipine besilate in master formula only.
	Decision of 296th meeting of RB	Deferred for: • Submission of latest GMP inspection report. • Submission of applicable fee for revision of label claim to film-coated tablet. • Revision of amlodipine to amlodipine as besilate in Form 5. • Submission of enclosure of Form 5. • Revision of amlodipine as besilate to amlodipine besilate in master formula only. • Pack size & Demanded Price
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm submitted Rs. 7,500/- fee (Challan: 17055425) • The firm did not adjust the weight of amlodipine besilate in master formula as salt factor.
	Decision of 313th meeting of Reg. Board.	Deferred for adjustment of weight of amlodipine besilate in master formula as salt factor.
	Reply submitted by the firm.	Firm has submitted revised master formula for the applied formulation wherein they have adjusted the weight of amlodipine besylate by applying salt factor.
	Evaluation by PEC	•
	Decision: Approved.	
766.	Name and address of manufacturer/ Applicant	M/s Alkemy Pharmaceuticals Labs Pvt Ltd, P/9, SITE, Hyderabad
	Brand Name + Dosage Form + Strength	Kem- Mont 5mg Tablet
	Composition	Each chewable tablet Contains: Montelukast (as sodium)…….5mg
	Diary No. Date of R & I & fee	Dy. No. 40387; 05.12.2018 PKR. 20,000/-; 05.12.2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 30's, 40's, 50's,60's, 70's, 80's, 90's, 100; Rs. 100 per tablet
	Approval status of product in Reference Regulatory Authorities.	SINGULAIR® (montelukast sodium) Chewable Tablets. USFDA approved
	Me-too status	Nohist Chewable Tablet 5mg. Reg. No. 85712
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator(IX)	Revise "Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.
	Decision of 296th meeting of RB	Deferred for: • Submission of latest GMP inspection report.

		• Revision of Montelukast sodium eq. to. Montelukast" to "Montelukast sodium" in master formula only.
	Evaluation by PEC	• The firm was inspected on 06.10.2021, wherein acceptable level of GMP compliance was reported. • The firm submitted Rs. 7,500/- fee (Challan: 126310600433) • The firm did not adjust the weight of montelukast sodium in master formula as salt factor.
	Decision of 313th meeting of Reg. Board.	Deferred for adjustment of the weight of montelukast sodium as salt factor in master formula.
	Reply submitted by the firm.	Firm has submitted revised master formula for the applied formulation wherein they have adjusted the weight of montelukast sodium in the master formula.
	Evaluation by PEC	•
	Decision: Approved.	

Agenda of Evaluator PEC-XV

Cases of New sections & New licenses received on form 5-F:

767.	**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 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	Firm replied that Pharmaceutical

		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.	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: 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.**

768.	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, general properties, solubilities, physical form, manufacturers, description of manufacturing process and 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	Firm has submitted analytical record for product testing.

	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:

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: 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.**

769.	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.8958 dated 03-04-2023
	Details of fee submitted	PKR 30,000/- Dated 16-03-2023
	The proposed proprietary name / brand name	**Flepicin 250 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Phenoxy methyl penicillin potassium eq. to Phenoxy methyl penicillin…… 250mg
	Pharmacotherapeutic Group of (API)	penicillin antibiotics
	Pharmaceutical form of applied drug	White colored oblong Film coated tablets scored from both sides blistered and packed as 1 x 14's in unit carton with insertion of leaflet.
	Reference to Finished product specifications	BP
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Phenoxymethylpenicillin 250 mg Tablet (MHRA Approved)
	For generic drugs (me-too status)	Penicillin V Tablets of M/s Lisko Pharma, Karachi. Reg.no. 011959
	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 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 Innovator product Penicillin VK 250 mg manufactured by Sandoz GMBH., Austria.
	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 Alu- PVC packaging that is further packed in cardboard 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	3000 Tablets	3000 Tablets	3000 Tablets
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	Response of the Firm
1.	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 has only submitted the one sided picture of outer carton which did not reflect the batch number, mfg. date , expiry date of comparator product against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
2.	3.2.P.8	BP monograph of phenoxymethyl penicillin potassium tablet recommend to calculate the assay content of phenoxymethyl penicillin, justify how you had calculate the content of phenoxymethyl penicillin by considering the peak of phenoxymethyl penicillin potassium, as chromatograms of assay revealed that main peak achieved at around 10 min was of phenoxymethyl penicillin potassium.	Firm replied that they have used Phenoxymethyl Penicillin Potassium in reference standard and in sample that's why peak naming was given as Phenoxymethyl penicillin potassium. While calculating the assay as we have taken weight equivalent to phenoxymethyl penicillin and thus assay calculated is of phenoxymethyl penicillin.

Decision: Approved.

The registration letter will be oisssued after submission of the details of the inovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.

770.	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.8959 dated 03-04-2023
	Details of fee submitted	PKR 30,000/- Dated 16-03-2023
	The proposed proprietary name / brand name	**Flepicin 500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Phenoxy methyl penicillin potassium eq to Phenoxy methyl penicillin…… 500mg
	Pharmacotherapeutic Group of (API)	penicillin antibiotics
	Pharmaceutical form of applied drug	White colored oblong Film coated tablets scored from both sides blistered and packed as 1 x 14's in unit carton with insertion of leaflet.
	Reference to Finished product specifications	BP
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Phenoxymethylpenicillin 500 mg Tablet (MHRA Approved)
	For generic drugs (me-too status)	Penicillin V Tablets of M/s Lisko Pharma, Karachi.
	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 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 Innovator product Penicillin VK 500 mg manufactured by Sandoz GMBH, Austria
	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 Alu- PVC packaging that is further packed in cardboard 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	3000 Tablets	3000 Tablets	3000 Tablets
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	Response of the Firm
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.	Firm has only submitted the one sided picture of outer carton which did not reflect the batch number, mfg. date , expiry date of comparator product against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
4.	3.2.P.8	BP monograph of phenoxymethyl penicillin potassium tablet recommend to calculate the assay content of phenoxymethyl penicillin, justify how you had calculate the content of phenoxymethyl penicillin by considering the peak of phenoxymethyl penicillin potassium, as chromatograms of assay revealed that main peak achieved at around 10 min was of phenoxymethyl penicillin potassium.	Firm replied that they have used Phenoxymethyl Penicillin Potassium in reference standard and in sample that's why peak naming was given as Phenoxymethyl penicillin potassium. While calculating the assay as we have taken weight equivalent to phenoxymethyl penicillin and thus assay calculated is of phenoxymethyl penicillin.

Decision: Approved.

The registration letter will be oisssued after submission of the details of the inovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.

771.	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	☐ 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. 8827 dated 31-03-2023
	Details of fee submitted	PKR 30,000/- Dated 16-03-2023
	The proposed proprietary name / brand name	**Bi-penem 300 mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Bi-penem……. 300mg
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotics
	Pharmaceutical form of applied drug	White or almost yellow crystalline 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	Omegacin 300 mg Injection (PMDA Japan Approved)
	For generic drugs (me-too status)	No generic is available in Pakistan.
	Name and address of API manufacturer.	Shandong Anhong Pharmaceutical Co., Ltd. No. 29 Huayuan Street Linyi County, Dezhou, Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 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	Firm has submitted pharmaceutical equivalence of their product against the Generic product Biapen 300 mg injection manufactured by BDR Pharma International pvt LTD (India). Batch no. ABIBF0122, Mfg date 11-2021, Exp date: 10-2023.
	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	Shandong Anhong Pharmaceutical Co., Ltd.		
API Lot No.	1010L91M		
Description of Pack (Container closure system)	FPP is packed in glass vial and properly sealed labelled and packed in white colored unit cardboard box with insertion of 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.	T01	T02	T03
Batch Size	544 Vials	544 Vials	544 Vials
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	18-06-2022	18-06-2022	18-06-2022
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)	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. LY 2021001) dated 15-12-2021 issued by Linyi country administration for market regulation. 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 30-05-2022 specifying 0.50 Kg of Biapenem. 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	Response of the Firm
1.	3.2.S.4.3	Firm has submitted analytical method validation reports in which they have not determined limit of detection and quantification in the validation of analytical procedures section 3.2.P.4.3, submit complete validation report including all the parameters in accordance with ICH guidelines.	Firm has not submitted the requisite document.
2.	3.2.P.1	Submit information in section 3.2.P.1 c) Description of accompanying reconstitution diluent(s) as per the guidance document approved by Registration Board which specifies 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".	Firm replied that the Diluent used for reconstitution is 0.9% sodium chloride injection and must be reconstituted in 100ml of 0.9% sodium chloride before reconstitution.
3.	3.2.P.2.2.1	Justify for not performing the pharmaceutical equivalence against the innovator product, since you have performed the equivalence study against the comparator product	Firm replied that due to unavailability of innovator product, Pharmaceutical equivalence was performed against comparator product.
4.	3.2.P.2.6	Submit data of compatibility of the drug product along with reconstitution solvent in section 3.2.P.2.6.	Firm submitted the compatibility data of drug product along with its reconstitution diluent.
5.	3.2.P.3	According to the manufacturing procedure given in section 3.2.P.3.3 filled vials are packed with WFI in unit carton, how can WFI will be used for reconstitution when the literature of innovator product revealed that "*do not use water for injection as the solution does not become isotonic."*	Firm replied that it was a clerical mistake, they used 0.9% sodium chloride injection for reconstitution.
6.	3.2.P.5.2	Justify, how you had achieved the complies result of test of *COMPLETENESS AND CLARITY OF SOLUTIONS* while using the water, since the product is sparingly soluble in water	Firm replied that in the test method it was written because of clerical error.

		according to the physicochemical properties of innovator product approved in PMDA Japan.	
7.	3.2.P.8	Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided".	Firm submitted the in-use stability data of Bi-penem injection till 24 hours.

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.**

772.	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.
	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. 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	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.

		dissolution on HPLC.	
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 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 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 equivalence of the applied drug with the innovator / reference/ comparator product and results of all the quality tests	Firm did not submit the reply of this query.

		(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".	
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: 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.**		
773.	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.
	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.
	Staspecificatintus 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 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*	Firm submitted the Batch analysis report of drug substance.

		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.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
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	Firm replied that the Higher conc. Was taken to minimize errors in readings and graphs and for better resolution.

		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: 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.**

774.		
	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 grant dated 28-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Oral Dry Powder Suspension (General), Capsule (General), Sachet (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. 7092 dated 10-03-2023
	Details of fee submitted	PKR 30,000/- Dated 08-03-2023
	The proposed proprietary name / brand name	**Privo 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: - Levosulpiride……..25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Pharmaceutical form of applied drug	White colour round biconvex tablet having plain on both sides.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x10's, 2x7's 2x10's, 3x10's, 5x10's, 10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved
	For generic drugs (me-too status)	Levopiride 25 mg Tablet of M/s Medera Pharmaceuticals (Pvt.) Ltd. Islamabad (Reg.No. 066294)
	Name and address of API manufacturer.	Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 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 manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 the comparator product Scipride 25mg Tablet manufactured by Scilife Pharma Pvt. Ltd. (Reg.no.057902) Firm has submitted CDP results of their product against the comparator product Scipride 25mg 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	Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India		
API Lot No.	KB/LSD/MC/22/001		
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.	TT007	TT008	TT009
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	27-07-2022	27-07-2022	27-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Two products were approved in 326th DRB Meeting and Registration letter was issued on 31st May, 2023. CPX 250mg Reg. No.116595 & CPX 500mg Reg. No.116596.
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. 4-138-I Drug 1-2019-8359) dated 18-11-19 issued by Food and Drugs Control Administration Haryana India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of loan letter from DeMont research Laboratories Pvt. Ltd. Borrowing Material qty. is 400g of Kimia Biosciences Limited India. Copy of Form 5 and ADC clearance Certificate issued by DRAP Lahore. ADC Clearance Certificate No. E-1725322807958 Dated 24-June, 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 Applicable
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	Response of the Firm
1.	3.2.S.4.1	Drug substance manufacturer performed assay via potentiometric titration while the drug product manufacturer has performed assay of drug substance on UV-Vis spectrophotometer, justification is required in this regard.	Firm replied that "We perform the assay of drug substance by manual titration and UV-Vis Spectrophotometric method. But we mentioned the results in COA only UV-Vis Spectrophotometric."
2.	3.2.S.4.2	Submit Analytical procedure of drug substance by drug substance manufacturer , since you have only submitted the analytical procedure by drug product manufacturer.	Firm in their reply submitted the analytical procedure of drug substance by drug product manufacturer only. While, the query is related to the submission of analytical procedure of drug substance by drug substance manufacturer.
3.	3.2.P.2.2.1	Justify, why the pharmaceutical equivalence and comparative dissolution profile was studied against comparator product instead of using innovator product/brand leader.	• Firm replied that Comparative product sample was easily available at the time of trial batches manufacturing so we use that sample for Pharmaceutical equivalent study. • Now they perform pharmaceutical equivalence against innovator product Levopraid 25mg & 50mg Tablet of Pacific Pharma and accordingly revised Pharmaceutical equivalence report has submitted.
4.	3.2.P.2.2.1	Justify the submitted CDP data comparing the statement specify in the available public assessment report of reference product i.e. "*The active substance exhibits high solubility in the proposed dissolution medium, HCl 0.1N, as well as in the pH 4.5 and pH 6.8 medium, since the percentage dissolved is higher than 85% at 15 minutes (very rapidly dissolving scenario)".*	Firm has not submitted the reply against this query.
5.	3.2.P.5.2	Please specify the reference of acceptance criteria adopted for dissolution test and submit along with evidence of literature of innovator product.	Not submitted the reply of this query.
6.		Justify for adopting 0.06N HCl as a dissolution medium comparing the CDP report in which it was clearly revealed that drug is poorly dissolved in acidic medium, further justify the adopted dissolution medium considering the absorption window of drug in the physiological medium.	Not submitted the reply of this query.
7.		Justify for performing the assay of drug product via UV-Vis spectrophotometer instead of adopting HPLC method.	Firm replied that product monograph is not available in any pharmacopeia, so we adopted UV-Vis spectrophotometer method for stability study purpose and also performed validation of UV-Vis spectrophotometer method. Once the product is registered we will adopted HPLC method and also validate it.
8.	3.2.P.5.3	Firm has submitted analytical method validation reports in which they have	Firm submitted the Revised analytical method validation protocol and report.

		not determined limit of detection and quantification in the validation of analytical procedures, submit complete validation report including all the parameters in accordance with ICH guidelines. Further, repeatability of precision has been performed using 5 determinants while the ICH guideline/general chapter of USP recommends *"a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each); OR a minimum of 6 determinations at 100% of the test concentration",* so scientific justification is required in this regard.	
9.	3.2. P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Firm submitted the COA of working standard of ATLAS Life Science, Ahmedabad, Gujarat, India. While the API is imported from Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India
10.	3.2.P.8	Submit valid GMP certificate of API manufacturer.	Firm has submitted the same INVALID GMP certificate of API Manufacturer (Valid from 18-11-2019 to 17-11-2022)

Decision: Deferred for submission of following shortcomings:

- **Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.**
- **Justify the submitted CDP data comparing the statement specify in the available public assessment report of reference product i.e. "*The active substance exhibits high solubility in the proposed dissolution medium, HCl 0.1N, as well as in the pH 4.5 and pH 6.8 medium, since the percentage dissolved is higher than 85% at 15 minutes (very rapidly dissolving scenario)".***
- **Specify the reference of acceptance criteria adopted for dissolution test and submit along with evidence of literature of innovator product.**
- **Justify for adopting 0.06N HCl as a dissolution medium comparing the CDP report in which it was clearly revealed that drug is poorly dissolved in acidic medium.**
- **Submit valid GMP certificate of API manufacturer.**

775.	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 grant dated 28-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Oral Dry Powder Suspension (General), Capsule (General), Sachet (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.7093 dated 10-03-2023
	Details of fee submitted	PKR 30,000/- Dated 08-03-2023
	The proposed proprietary name / brand name	**Privo 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: - Levosulpride……..50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Pharmaceutical form of applied drug	White colour round biconvex tablet having plain on both sides.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x10's, 2x7's 2x10's, 3x10's, 5x10's, 10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved
	For generic drugs (me-too status)	Levopiride 50 mg Tablet of M/s Medera Pharmaceuticals (Pvt.) Ltd. Islamabad (Reg.No. 066397)
	Name and address of API manufacturer.	Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 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 manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 the innovator's product Scipride 50mg Tablet manufactured by Scilife Pharma Pvt. Ltd.(Reg.no. 057903) Firm has submitted CDP results of their product against the innovator's product Scipride 50mg 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	Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India		
API Lot No.	KB/LSD/MC/22/001		
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.	TT010	TT011	TT012
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	29-07-2022	29-07-2022	29-07-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Two products were approved in 326th DRB Meeting and Registration letter was issued on 31th may, 2023. CPX 250mg Reg. No.116595 & CPX 500mg Reg. No.116596.
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. 4-138-I Drug 1-2019-8359) dated 18-11-19 issued by Food and Drugs Control Administration Haryana India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of loan letter from DeMont research Laboratories Pvt. Ltd. Borrowing Material qty. is 400g of Kimia Biosciences Limited India. Copy of Form 5 and ADC clearance Certificate issued by DRAP Lahore. ADC Clearance Certificate No. E-1725322807958 Dated 24-June, 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 Applicable

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	Response of the Firm
1.	3.2.S.4.1	Drug substance manufacturer performed assay via potentiometric titration while the drug product manufacturer has performed assay of drug substance on UV-Vis spectrophotometer, justification is required in this regard.	Firm replied that "We perform the assay of drug substance by manual titration and UV-Vis Spectrophotometric method. But we mentioned the results in COA only UV-Vis Spectrophotometric."
2.	3.2.S.4.2	Submit Analytical procedure of drug substance by drug substance manufacturer , since you have only submitted the analytical procedure by drug product manufacturer.	Firm in their reply submitted the analytical procedure of drug substance by drug product manufacturer only. While, the query is related to the submission of analytical procedure of drug substance by drug substance manufacturer.
3.	3.2.P.2.2.1	Justify, why the pharmaceutical equivalence and comparative dissolution profile was studied against comparator product instead of using innovator product/brand leader.	• Firm replied that Comparative product sample was easily available at the time of trial batches manufacturing so we use that sample for Pharmaceutical equivalent study. • Now they perform pharmaceutical equivalence against innovator product Levopraid 25mg & 50mg Tablet of Pacific Pharma and accordingly revised Pharmaceutical equivalence report has submitted.
4.	3.2.P.2.2.1	Justify the submitted CDP data comparing the statement specify in the available public assessment report of reference product i.e. "*The active substance exhibits high solubility in the proposed dissolution medium, HCl 0.1N, as well as in the pH 4.5 and pH 6.8 medium, since the percentage dissolved is higher than 85% at 15 minutes (very rapidly dissolving scenario)".*	Firm has not submitted the reply against this query.
5.	3.2.P.5.2	Please specify the reference of acceptance criteria adopted for dissolution test and submit along with evidence of literature of innovator product.	Not submitted the reply of this query.
6.		Justify for adopting 0.06N HCl as a dissolution medium comparing the CDP report in which it was clearly revealed that drug is poorly dissolved in acidic medium, further justify the adopted dissolution medium considering the absorption window of drug in the physiological medium.	Not submitted the reply of this query.
7.		Justify for performing the assay of drug product via UV-Vis spectrophotometer instead of adopting HPLC method.	Firm replied that product monograph is not available in any pharmacopeia, so we adopted UV-Vis spectrophotometer method for stability study purpose and also performed validation of UV-Vis spectrophotometer method. Once the product is registered we will adopted HPLC

			method and also validate it.
8.	3.2.P.5.3	Firm has submitted analytical method validation reports in which they have not determined limit of detection and quantification in the validation of analytical procedures, submit complete validation report including all the parameters in accordance with ICH guidelines.Further,repeatability of precision has been performed using 5 determinants while the ICH guideline/general chapter of USP recommends *"a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each); OR a minimum of 6 determinations at 100% of the test concentration",* so scientific justification is required in this regard.	Firm submitted the Revised analytical method validation protocol and report.
9.	3.2. P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Firm submitted the COA of working standard of ATLAS Life Science, Ahmedabad, Gujarat, India. While the API is imported from Kimia Biosciences Limited Formerly known as Laurel Organics Limited) Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India
10.	3.2.P.8	Submit valid GMP certificate of API manufacturer.	Firm has submitted the same INVALID GMP certificate of API Manufacturer (Valid from 18-11-2019 to 17-11-2022)

Decision: Deferred for submission of following shortcomings:

- **Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.**
- **Justify the submitted CDP data comparing the statement specify in the available public assessment report of reference product i.e. "*The active substance exhibits high solubility in the proposed dissolution medium, HCl 0.1N, as well as in the pH 4.5 and pH 6.8 medium, since the percentage dissolved is higher than 85% at 15 minutes (very rapidly dissolving scenario)".***
- **Specify the reference of acceptance criteria adopted for dissolution test and submit along with evidence of literature of innovator product.**
- **Justify for adopting 0.06N HCl as a dissolution medium comparing the CDP report in which it was clearly revealed that drug is poorly dissolved in acidic medium.**
- **Submit valid GMP certificate of API manufacturer.**

776.	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 grant dated 28-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Oral Dry Powder Suspension (General), Capsule (General), Sachet

		(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.9669 dated 11-04-2023
	Details of fee submitted	PKR 30,000/- Dated 31-03-2023
	The proposed proprietary name / brand name	Thinvo 250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Azithromycin Dihydrate Eq. to Azithromycin ……250mg
	Pharmacotherapeutic Group of (API)	Macrolides
	Pharmaceutical form of applied drug	White colour film coated round biconvex tablet having plain on both side.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1x6's, 1x10's 2x10's,10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azithromycin 250mg film coated tablet USFDA approved
	For generic drugs (me-too status)	Azitma 250mg Tablet of M/s Sami Pharmaceuticals Karachi (Reg.No. 074899)
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Azitma 250mg Tablet manufactured by Sami Pharmaceuticals. Pvt Ltd.(Reg.no.074899) Firm has submitted CDP results of their product against the innovator's product Azitma 250mg in 3 dissolution medias. 1.2pH, 4.5pH & 6.8pH
	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	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur.		
API Lot No.	AZM2207001		
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.	TT013	TT014	TT015
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	22-08-2022	22-08-2022	22-08-2022
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)	Two products were approved in 326th DRB Meeting and Registration letter was issued on 31th may, 2023. CPX 250mg Reg. No.116595 & CPX 500mg Reg. No.116596.
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. 01/2021-DRAP(FID-2036001-5101 dated 06-01-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API Received from Local manufacturer as 4 kg sample for trail Purpose only.
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 the audit trail 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.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-	Response of the Firm

		comings	
1.	3.2.S.4.2	Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.	Firm submitted the analytical procedure of drug substance again by the drug product manufacturer instead of submitting the analytical procedure of drug substance by drug substance manufacturer.
2.	3.2.S.4.2	Justify for adopting the assay procedure different from that recommended by USP for Azithromycin Dihydrate raw material.	Firm submitted the revised analytical procedure of drug substance in accordance with USP monograph of Azithromycin.
3.	3.2.S.4.4	Justify for adopting the acceptance criteria of assay different from that recommended criteria by USP, since you have mentioned the results of assay in percentage on the COA of API while USP specify the limits in µg/mg.	Firm submitted the revised COA of API in which the result of assay is in accordance with USP monograph.
4.	3.2.S.7	Specification of water content test mentioned on the stability data sheet is not the recommended criteria for the dihydrate labelled Azithromycin according to USP, justification is required in this regard.	Firm submitted the revised stability data of drug substance in which the specifications are in accordance with Azithromycin Dihydrate labelled API.
5.	3.2. P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Firm submitted the COA working standard supplied by API Manufacturer M/s. Citi Pharma.

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.**

777.	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 grant dated 28-04-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Oral Dry Powder Suspension (General), Capsule (General), Sachet (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.9670 dated 11-04-2023
	Details of fee submitted	PKR 30,000/- Dated 31-03-2023
	The proposed proprietary name / brand name	Thinvo 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)	Macrolides
	Pharmaceutical form of applied drug	White colour film coated oval shape tablet having plain on both side.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1x6's, 1x10's 2x10's,10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azithromycin 500mg film coated tablet USFDA approved
	For generic drugs (me-too status)	Zetro 500mg Tablet of M/s Getz Pharma Karachi (Reg.No. 053120)
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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 Zetro 500mg

		Tablet manufactured by Getz Pharma (Reg.no.053120) Firm has submitted CDP results of their product against the innovator's product Zetro 500mg tablet in 3 dissolution medias. 1.2pH, 4.5pH & 6.8pH
	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	Citi Pharma (Pvt.) Ltd. 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur.		
API Lot No.	AZM2207001		
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.	TT016	TT017	TT018
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	25-08-2022	25-08-2022	25-08-2022
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)	Two products were approved in 326th DRB Meeting and Registration letter was issued on 31th may, 2023. CPX 250mg Reg. No.116595 & CPX 500mg Reg. No.116596.
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. 01/2021-DRAP(FID-2036001-5101 dated 06-01-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API Received from Local manufacturer as 4 kg sample for trail Purpose only.
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 the audit trail 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.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.	Firm submitted the analytical procedure of drug substance again by the drug product manufacturer instead of submitting the analytical procedure of drug substance by drug substance manufacturer.
2.	3.2.S.4.2	Justify for adopting the assay procedure different from that	Firm submitted the revised analytical procedure of drug substance in accordance with USP

		recommended by USP for Azithromycin Dihydrate raw material.	monograph of Azithromycin.
3.	3.2.S.4.4	Justify for adopting the acceptance criteria of assay different from that recommended criteria by USP, since you have mentioned the results of assay in percentage on the COA of API while USP specify the limits in µg/mg.	Firm submitted the revised COA of API in which the result of assay is in accordance with USP monograph.
4.	3.2.S.7	Specification of water content test mentioned on the stability data sheet is not the recommended criteria for the dihydrate labelled Azithromycin according to USP, justification is required in this regard.	Firm submitted the revised stability data of drug substance in which the specifications are in accordance with Azithromycin Dihydrate labelled API.
5.	3.2. P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Firm submitted the COA working standard supplied by API Manufacturer M/s. Citi Pharma.

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.**

778.	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
	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 9671 dated 11-04-2023
	Details of fee submitted	PKR 30,000/- Dated 31-03-2023
	The proposed proprietary name / brand name	P-Dext 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)	Anti-inflammatory
	Pharmaceutical form of applied drug	Light yellow colour round biconvex tablet having plain on both side.

	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x10's, 2x7's 2x10's, 3x10's, 5x10's, 10x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Brexin 20mg Tablet AIFA Italy approved
	For generic drugs (me-too status)	Woxicam 20mg Tablet of M/s Warafana Pharmaceuticals (Reg.No. 072300)
	Name and address of API manufacturer.	Nantong Jinghua Pharmaceutical Co., Ltd. No.20,3 Haibin Road, Yanhai Economic Development Zone,Rudong, Nantong, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (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 Felbex 20mg Tablet manufactured by Martin Dow Pharma Pvt. Ltd. Firm has submitted CDP results of their product against the innovator's product Felbex 20mg 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	Nantong Jinghua Pharmaceutical Co., Ltd. No.20,3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.
API Lot No.	20211206

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.	TT019	TT020	TT021
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	30-08-2022	30-08-2022	30-08-2022
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)	Two products were approved in 326th DRB Meeting and Registration letter was issued on 31th may, 2023. CPX 250mg Reg. No.116595 & CPX 500mg Reg. No.116596.
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. JS20180829 dated 01-06-2018 valid till 31-05-2023 issued by China Food and Drugs Administration china
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of loan letter from DeMont research Laboratories Pvt. Ltd. Borrowing Material qty. is 1kg of Nantong Jinghua Pharmaceutical Co., Ltd. Copy of Form 5 and ADC clearance Certificate issued by DRAP Lahore. ADC Clearance Certificate No. E-1582822802698 Dated 12-June, 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)	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	Response of the Firm
1.	3.2.S.4.2	Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.	Firm submitted the analytical procedure of drug substance again by the drug product manufacturer instead of submitting the analytical procedure of drug substance by drug substance manufacturer.
2.	3.2.S.4.3	Firm has submitted analytical method validation reports in which they have not determined limit of detection and quantification in the validation of analytical procedures, submit complete validation report including all	Firm submitted revised complete method validation as per ICH guideline is attached.

		the parameters in accordance with ICH guidelines. Further, repeatability of precision has been performed using 5 determinants while the ICH guideline/general chapter of USP recommends *"a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each); OR a minimum of 6 determinations at 100% of the test concentration",* so scientific justification is required in this regard.	
3.	3.2.P.2.1	Justify the quantity of Piroxicam Beta cyclodextrin i.e. 212.31mg used per tablet comparing the claim of innovator product i.e. Piroxicam Beta cyclodextrin 191.2 mg eq. to piroxicam 20mg.	Firm replied that "as per API assay results i.e. 9.42%, quantity of API per tablet is 212.31mg: 100/9.42x20=212.31mg per tablet.
4.	3.2.P.2.2.1	Justify, why the pharmaceutical equivalence and comparative dissolution profile was studied against comparator product instead of using innovator product/brand leader.	Firm replied that Comparative product sample was easily available at the time of trial batches manufacturing so we use that sample for Pharmaceutical equivalent study
5.	3.2.P.5.2	Justify how UV-Vis spectrophotometer method was adopted for the testing of drug product, since the testing method of drug substance manufacturer for assay of Piroxicam Beta cyclodextrin was based on HPLC.	Firm replied that "As product monograph is not available in any pharmacopeia, so we adopted UV-Vis spectrophotometer method for stability study purpose and also performed validation of UV-Vis spectrophotometer method. Once the product is registered we will adopted HPLC method and also validate it".
6.	3.2.P.5.2	Submit the detailed procedure of dissolution testing, since you have not submitted the method of dissolution.	Firm replied that "As product is innovator specification and product monograph is not available in any pharmacopeia and dissolution test is not available in FDA dissolution method, so we performed only disintegration test. Once the product is registered we will developed the dissolution method and will performed it on commercial scale product stability batched".
7.	3.2.P.5.2	Scientific justification is required for calculation of assay content of piroxicam Beta cyclodextrin instead of only piroxicam comparing the label claim of applied formulation.	Firm replied We claimed Piroxicam as beta cyclodextrin, so Piroxicam content is required for calculation purpose.

8.	3.2.P.5.2	Justify why water content test is not included in the finished product specification, further justify why water content test was not performed during the stability studies.	Firm replied that The water content test is performed during the raw material testing stage, while the bulk manufacturing test performed is LOD (Loss on Drying). Additionally, when analysing the finished product sample containing multiple inactive materials, conducting a water content test on Piroxicam beta cyclodextrin is not feasible. Also testing record is attached in BMR record.
9.	3.2.P.5.2	Justify why dissolution is not included in the finished product specification, further justify why dissolution test was not performed during the stability studies.	Firm in their reply stated that "As product is innovator specification and product monograph is not available in any pharmacopeia and dissolution test is not available in FDA dissolution method, so we performed only disintegration test. Once the product is registered we will developed the dissolution method and will performed it on commercial scale product stability batched".
10	3.2.P.5.2	Justify why content uniformity test is not included in the finished product specification, further justify why content uniformity test was not performed during the stability studies	Firm replied that "Revised finished product specification is attached. Further we adopted uniformity of dosage units by weight variation test, Once the product is registered we will adopt the content uniformity as per described in USP general chapter".Revised Finished product specification & certificate of analysis of finished product is attached.
11	3.2.P.5.3	Firm has submitted analytical method validation reports in which they have not determined limit of detection and quantification in the validation of analytical procedures, submit complete validation report including all the parameters in accordance with ICH guidelines. Further, repeatability of precision has been performed using 5 determinants while the ICH guideline/general chapter of USP recommends *"a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each); OR a minimum of 6 determinations at 100% of the test concentration",* so scientific justification is required in this regard.	Firm submitted revised complete method validation as per ICH guideline.
12	3.2. P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Firm submitted the COA of working standard from M/s. Kaifeng Pharmaceuticals (Group) Co. Ltd. Henan, China while the API is imported from Nantong Jinghua Pharmaceutical

			Co., Ltd. No.20,3 Haibin Road, Yanhai Economic Development Zone,Rudong, Nantong, Jiangsu, China.

Decision: Deferred for submission of following shortcomings:

- **Submit Analytical procedure of drug substance by drug substance manufacturer, since you have only submitted the analytical procedure by drug product manufacturer.**
- **Firm should include the dissolution test in the finished product analysis, accordingly submit the detailed analytical procedure of dissolution test and submit Performance of dissolution test at next time point of long term stability studies and CDP studies against the innovator/reference product using the same newly developed dissolution method.**

779.	Name, address of Applicant / Marketing Authorization Holder	M/s. TriVista Pharmaceuticals
	Name, address of Manufacturing site.	M/s. TriVista Pharmaceuticals 8-KM, Taxila Khanpur Road, District Haripur, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New License grant dated 28-04-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section and Capsule (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14388 dated 08-06-2023
	Details of fee submitted	PKR 30,000/- Dated 30-05-2023
	The proposed proprietary name / brand name	**Moxivista 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: - Moxifloxacin as HCl…..400mg
	Pharmacotherapeutic Group of (API)	Quinolone broad spectrum Antibiotic
	Pharmaceutical form of applied drug	Tablet.
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi Reg.no. 047117
	Name and address of API manufacturer.	M/s. SAAKH Pharma Plot no. C-7/1, North Westren Industrial Zone Port Qasim, 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, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system 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.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi. Batch no. 239F31 Firm has submitted CDP results of their product against Comparator product Moxiget 400mg Tablet of M/s. Getz Pharma, Karachi. Batch no. 239F31 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. SAAKH Pharma Plot no. C-7/1, North Westren Industrial Zone Port Qasim, Karachi.		
API Lot No.	22GN30-10012		
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.	PFT22E007	PFT22E008	PFT22E009
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	26-05-2022	26-05-2022	26-05-2022
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	NA

	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. 83/2020-DRAP (K) dated 23-06-2020 valid for 2 years.
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 Raw data sheets, COA, summary data sheets.
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:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit Analytical procedure and specification of drug substance by drug product manufacturer, since you have only submitted the analytical procedure by drug substance manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.5	Reference Standards or Materials Provide certificate of analysis of reference standard /working standard used for testing of the drug substance.
4.	3.2.S.7	The stability study data of drug substance submitted in section 3.2.S.7.3 is tested on completely different specifications as provided in section 3.2. S.4. Justification is required in this regard how this stability study data represents the same drug substance for which the data in module 3.2.S is submitted. Further, justify for not performing the test of pH, water determination test ,chloride and sulphate test during the stability studies.
5.	3.2.P.2.2.1	Justify, why the pharmaceutical equivalence and comparative dissolution profile was studied against comparator product instead of using innovator product/brand leader.
6.	3.2.P.5.4	Provide batch analysis report of the stability batches in section 3.2.P.5.4.
7.	2.3.R.1.1	Please provide complete calculation of dispensed weight of drug substance per tablet considering the water content and salt factor of active material.

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

New Cases of Form 5-F (Import Finished Product)

780.	Name, address of Applicant / Importer	M/s. Hospital Supply Corporation
	Details of Drug Sale License of importer	License No:0013 Address: 42, Darul Aman Housing Society, Karachi Address of Godown: 46-E-2, Block-6, PECHS, Karachi Validity: 29-06-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey
	Name, address of manufacturer(s)	Mefar Ilac San A.S. Ramazanoglu Mahalles Ensar Caddesi No.2 Istanbul Turkey
	Name of exporting country	Turkey

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.2021/3007) dated 01-10-2021 issued by Turkish Medicines and Medical Devices Agency. 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. Furthermore the CoPP was valid till 01-10-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey. The letter species that the manufacturer appoints M/s. Hospital Supply Corporation to register their products in Pakistan. The authorization letter is valid till 31-12-2024.
	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.3416 Date: 04-02-2022
	Details of fee submitted	PKR 150,000/ dated: 28-09-2021
	The proposed proprietary name / brand name	Biemexol 350mgI/ml vial (100ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	X-Ray Contrast Media
	Reference to Finished product specifications	In-house specification/USP
	Proposed Pack size	100ml vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Omnipaque 350mgI/ML Vial (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	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province

		Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 36 months. Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province Batch no. H18920080501, H18920080502, H18920080503 Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China Batch no. C006-0802003, C006-0802004, C006-0802005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 established against Omnipaque 350mgI/ML Vial (100ml)
	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 type I Glass vial (100ml), bromobutyl closure, blue tear off cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 2 batches of 50ml.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 24 month has submitted.

INDICATIONS AND USAGE:
OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen.
DOSAGE AND ADMINISTRATION:
The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information.
Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings along with Response of the Firm
1.	Submit valid drug sale license of importer Hospital supply corporation, since the submitted DSL was expired on 29-06-2022. Firm submitted the copy of valid DSL issued in the name of M/s. Hospital Supply Corporation 42, Darul Aman Housing Society, Karachi (DSL no. 0237) and validity granted till 29/06/2024.	

2.	According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard. Firm submit the explanation letter from Product License holder i.e. BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey, in which it is stated that "during pharmaceutical development and first application in country of origin, first DMF of API supplier Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China was in compliance of USP. Accordingly, batch formula was established according to USP specifications. Lately, starry pharmaceutical has update their specifications according to EP specifications and get approval for CEP. Biem has applied for CEP submission variation in 03-08-2016 and get approval for variation in 10.10.2016. Firm submitted the copy of variation letter issued from Turkish Medicines and Medical Agency for the approval of updated European Pharmacopeia certificate of conformity. However, the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.	
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer 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 table of drug substance which did not include the test of related substance, test of free aromatic amine, test of iodide and test of ionic compounds as per BP monograph. Further, firm submitted the analytical procedure used for routine testing of drug substance.
4.	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".* Since you have submitted the validation report of drug substance manufacturer. Not submitted the requisite information instead submit the verification report of Bacterial Endotoxin test..
5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers. Firm replied that the parameter such as ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test are not susceptible to change during storage and are not likely to influence quality, safety and efficacy of iohexol, so they did not perform them in stability study. However, these test are included in the specification of API and also the part of BP monograph of API iohexol , further the shelf life specification may related to widened the limit of specifications but the critical test may remain same both in release specification and shelf life specification.
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product. • Product license holder replied that Product was developmental batches manufactured in non-sterile R&D Laboratory, because of this sterility test and bacterial endotoxin test was not performed. • Further, excipients used for manufacturing of Biemexol are standard excipient used in injectable solutions. Iohexol is very soluble in water. Trometamine dissolves in

<table>
<tr><td></td><td></td><td>water and it is used for increasing solubility in our formulation. Therefore, particulate matter test was not performed in the developmental phase.
• In the formulation of the drug product, the only source for free iodine is the API Iohexol. According to the analysis results (lower than 10 PPM) obtained from CoA of API, the free iodine was evaluated as low risk for effecting of product quality. Therefore, free iodine was not performed during the development phase. Also, it is confirmed by stability data that active ingredient has not got negative effects on free iodine and stability.
However, test of free iodine, particulate matter, sterility and bacterial endotoxin test are the part of both BP and USP monograph.</td></tr>
<tr><td>7.</td><td>3.2.P.5.1</td><td>Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.
Firm replied that for specifications which limits given In-house methods as related substances, assay and density-analysis methods are established following the USP monographs.
Firm replied that for assay release and shelf life specification of Biemexol 350mg I/ml vial containing solution for IA, IV injection are proposed as 90%-110% according to the results obtained from analytical results of development batches, validation batches and reference product.
However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.</td></tr>
<tr><td>8.</td><td>3.2.P.5.1</td><td>Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
Firm replied that the assay release and shelf life specifications of Biemexol 350mgI/ml vial containing solution for IA, IV Injection are proposed as 90.0%-110% according to the results obtained from analytical results of developmental batches, validation batches and reference product.
However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.</td></tr>
<tr><td>9.</td><td>3.2.P.8</td><td>Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8.
Submit the stability data of drug product of 100ml filled volume vials since you have submitted the data of 50ml and 200ml only.

Firm claimed that they applied bracketing for BIEMEXOL 350mgI/100ml SOLUTION FOR Injection. The applied Bracketing Plan is as under:

<table>
<tr><td colspan="2">Strength</td><td colspan="3">BIEMEXOL 350mgI/ml solution for Injection</td></tr>
<tr><td colspan="2">Batch</td><td>1</td><td>2</td><td>3</td></tr>
<tr><td rowspan="3">Ambalage</td><td>50ml</td><td>T</td><td>T</td><td>T</td></tr>
<tr><td>100ml</td><td></td><td></td><td></td></tr>
<tr><td>200ml</td><td>T</td><td>T</td><td>T</td></tr>
</table>
<table>
<tr><th>Batch no.</th><th>Batch size (Litre)</th><th>Batch size (vials)</th><th>Submitted data</th></tr>
<tr><td>711001 (50ml)</td><td>80L</td><td>1,584</td><td>36-month real time
6 month accelerated</td></tr>
<tr><td>712002 (50ml)</td><td>80L</td><td>1,584</td><td>36-month real time
6 month accelerated</td></tr>
<tr><td>711001 (200ml)</td><td></td><td></td><td>36-month real time
6 month accelerated</td></tr>
<tr><td>712002 (200ml)</td><td></td><td></td><td>36-month real time
6 month accelerated</td></tr>
</table>
However, the firm submit only the data of 2 batches of both volumes, while the Bracketing plan given by manufacturer is consisting of stability data of three batches of both volumes of 50ml and 200ml. Further, the Justification of application of bracketing may be required in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.</td></tr>
</table>

Decision: Deferred for the submission of following shortcomings/justifications:

- **Justify, how the CoPP issued in 2021 did not specify the post registration variation approved in 2016 related to the change of specification of API from USP to EP.**
- **Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.**
- **Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.**
- **Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.**
- **Justification for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.**
- **Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.**
- **Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.**
- **Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board. Further, submit the stability data of both 50ml and 200ml volumes in accordance with the given bracketing plan and Justification the bracketing plan in context of container closure size and/or Fills as described in ICH guidelines, which the manufacturer has not discussed in their bracketing plan.**

781.	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 not include the test of Iron, test of particulate matter in injection and Bacterial Endotoxin test as per USP monograph.

Decision: Deferred for submission of details of Reference Listed product including name, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted

CASE OF EXPORT FACILITATION:

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD) dated 02-06-2023. "M/s Vision Pharmaceuticals (Pvt.) Ltd. have achieved benchmark OF USD 756,000 as defined in the Board's decision during fiscal year 2021-2022. In this regard, please find the (1 molecule) 01 products applications submitted by the firm."

782.	Name, address of Applicant / Marketing Authorization Holder	M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot # 22-23 Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt. Ltd Plot # 204-205, Industrial 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. 30455 dated 27-10-2022
	Details of fee submitted	PKR 75,000/-: dated 17-10-2022 (6903530207)
	The proposed proprietary name / brand name	Visotol 200mcg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Misoprostol Dispersion USP eq. to Misoprostol……200 mcg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Gastrointestinal Agents (Synthetic Prostaglandins)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack Size: 10's , 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cytotec 200mcg Tablets (MHRA)
	For generic drugs (me-too status)	Brand Name: Breeky 200mcg Tablet Registration No: 073698 Manufacturer: Sami Pharmaceuticals
	GMP status of the Finished product manufacturer	New license granted on 03/01/2022 Tablet Section Approved.
	Name and address of API manufacturer.	<u>MISOPROSTOL 1% DISPERSION:</u> Manufacturer: Vision Pharmaceuticals (Pvt.) Limited Manufacturing Site: Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Accelerated: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Real Time: 5˚C ± 3˚C for 36 months Batches: (MPD002T, MPD003T, MPD001T)
	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 Innovator's product Cytotec Tablets 200mcg by Pfizer (Pvt) Ltd

		Batch no. B16530) by performing quality tests (Physical Appearance, Identification, Assay, Average Weight, Dissolution, uniformity of dosage unit).	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API		<u>MISOPROSTOL 1% DISPERSION:</u> Manufacturer: Vision Pharmaceuticals (Pvt.) Limited Manufacturing Site: Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad, Pakistan.	
API Lot No.		2110R0021	
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, 24,36 (Months)	
Batch No.		21M147	21M148
Batch Size		300,000 Tablets	300,000 Tablets
Manufacturing Date		12-2021	12-2021
Date of Initiation		05-2023	05-2023
No. of Batches		02	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Attached	
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 Vision Pharmaceuticals (Pvt.) Limited The certificate is valid till 02-01-2024	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable as API source is a local 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 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:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm

<table>
<tr><td>1.</td><td>1.5.6</td><td>Justify for adopting innovator’s specification for finished product when the official monograph of misoprostol tablet is present in international pharmacopeia.</td><td>Firm replied that Innovator's Specs were found equivalent to IP Specs, comparison between Innovator's and IP Specs is as under:
<table><tr><td>Parameter</td><td>Innovator’s</td><td>IP</td></tr><tr><td>Identification</td><td>By HPLC</td><td>By HPLC
By TLC</td></tr><tr><td>Uniformity of content</td><td>L1-max 15</td><td>L1-max 15</td></tr><tr><td>Assay</td><td>90-110%</td><td>90-110%</td></tr><tr><td>Dissolution</td><td>NLT 80% (Q)</td><td>NLT 80% (Q)</td></tr><tr><td>Related Substances</td><td>Unknown impurities</td><td>Impurity A,B,C,D&E</td></tr></table>However, the applied product did not comply IP monograph for analysis of finished product.</td></tr>
<tr><td>2.</td><td>1.6.5</td><td>According to the GMP certificate (semi basic) of API manufacturer, they have the facility of palletization and lyophilisation, then provide the evidence of approval for manufacturing facility of misoprostol dispersion along with the details of equipment required for its manufacturing.</td><td>Firm submitted the additional section approval letter issued by Licensing Division vide letter no.F1-26/2009-Lic (Vol-II) dated 4th December, 2018 in which under three main section 13 API has approved and under section Micro-pellet Dispersion API Misoprostol dispersion has approved.</td></tr>
<tr><td>3.</td><td>3.2.S.7</td><td>Justify for performing the accelerated studies at 30°C±2°C,65 ±5%RH, comparing the ICH guidelines recommended condition for API intended for storage at refrigerated conditions.</td><td>Firm replied that actual accelerated condition is 25°C±2°C,60 ±5%RH, while preparing stability summary sheets it’s a typo mistake and correct summary sheets are submitted.</td></tr>
<tr><td>4.</td><td>3.2.P.6</td><td>Reference/working standard used for analysis of API is Misoprostol oil (as per the COA submitted in requisite section) while the working standard used for analysis of drug product is Misoprostol powder, clarify the physical form of reference standard/ primary standard used for standardization of working standard along with justification of using misoprostol oil reference standard for analysis of API.</td><td>Primary standard used for standardization of working standard is in oil form. In analysis of API, misoprostol in oil form is use as per USP monograph that is mentioned Misoprostol in standard preparations and as per USP Description and Relative Solubility, "Misoprostol: Clear, colorless or light yellow viscous liquid. Very slightly soluble in water. USP Monograph of Misoprostol, Misoprostol Dispersion, Description, and relative Solubility is submitted.</td></tr>
<tr><td colspan="4">Decision: Deferred for submission of following shortcomings:
Revised analytical procedure used for analysis of drug product in accordance with monograph of Internation pharmacopoeia (IP) and accordingly submit the Performance report at next time point of long term stability studies.
Clarify the physical form of Reference/ working standard actually used for the analysis of finished product and submit the details of primary reference standard, against which the working standard has been standardized.</td></tr>
</table>

PREVIOUSLY DEFERRED CASES OF FORM-5F:

FINISHED IMPORT:

783.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0058-066904D 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)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name, address of manufacturer(s)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei 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. 20210368) dated 08-2021 issued by CCPIT for compound alpha ketoacid tablet. 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 01-08-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Hebei tiancheng pharmaceutical Co. Ltd. The letter species that the manufacturer appoints M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan to register their products in Pakistan. The authorization letter is valid till 08-2026.
	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.3529 dated 07-02-2022
	Details of fee submitted	PKR 150,030/-: 02-11-2021
	The proposed proprietary name / brand name	**Ketogen tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Compound α- Ketoacid …….0.63g
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	amino acid , including combination with polypeptide
	Reference to Finished product specifications	In house

	Proposed Pack size	20 tablets/blister, 5 blisters/box
	Proposed unit price	Rs. 3450/- box
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Not 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.
	Name, address of drug substance manufacturer	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou 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 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	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	
	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 2 batches is for 12 months while the stability study data for 3rd batch is for 9 months only.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.

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.

Reply of the Firm:
Firm submitted the evidence of approval status of applied formulations in the following in reference regulatory agencies:

No.	Brand name	Country	MA Holder / Manufacturer	Formulation
I	Ketosteril	RMS Portugal CMS Belgium (BE), Denmark (DK), Spain (ES), Finland (FI), Croatia (HR), Italy (IT), Netherlands (NL), Norway (NO), Sweden (SE), Slovenia (SI)	Fresenius Kabi Deutschland GmbH	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg Phenylalanine Calcium, Alfa-Keto- 68 mg Hydroxymethionine Calcium, Alfa - 59 mg Tyrosine 30 mg
2	KETOSTERIL	Romania	FRESENIUS KABI DEUTSCHLAND GMBH - GERMANIA	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg
3	Ketosteril Tabletten	Germany	FRESENIUS KABI DEUTSCHLAND GMBH - GERMANIA	Ketovaline Calcium 86 mg Lysine Acetate 105 mg Histidine 38 mg Threonine 53 mg Tryptophan 23 mg Isoleucine Calcium, Alfa-, Keto- 67 mg Leucine Calcium, Alfa-, Keto- 101 mg Phenylalanine Calcium, Alfa-Keto- 68 mg Hydroxymethionine Calcium, Alfa - 59 mg Tyrosine 30 mg

After the confirmation of approval status of applied formulation in the above given reference agencies, complete dossier has been evaluated and accordingly shortcoming letter has communicated to the firm. Firm submitted following reply in response of the shortcoming letter:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm

Clarification is required related to the strength of tablet i.e. 0.63g mentioned in the relevant section, since the innovator product do not mention the strength of tablet as it is a combination product.

In the response of above query firm submitted the clarification letter from the Finished Product Importer i.e. Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china, in which they stated that "The Applied Product (Compound α-Ketoacid Tablets, manufactured by Hebei Tiancheng Pharmaceutical Co., Ltd.) contains ten active substances the formulation of which is consistent with that of the Innovator Drug (Ketosteril). The formulation of Applied Product and Ketosteril are shown in the table below.

No.	Ingredients	Each tablet contains:	
		Applied Product	Ketosteril
1	α-Ketoleucine calcium	101mg	101mg
2	α-Ketovaline calcium	86mg	86mg
3	α-ketophenylalanine calcium	68mg	68mg
4	D L-α-ketoisoleucine calcium	67mg	67mg
5	D L-α-hydroxymethionine calcium	59mg	59mg
6	L-lysine acetate	105mg	105mg
7	L-threonine	53mg	53mg
8	L-tryptophan	23mg	23mg
9	L-histidine	38mg	38mg
10	L-tyrosine	30mg	30mg
Total		630mg	630mg

The strength of the finished product is specified as the weight (or potency) or content of the active substances as per the regulation of NMPA (National Medical Product Administration, China). Due to the Applied Product contains more active substances, the strength is specified as the weight of the active substances, 0.63g, in the dossier.

1.	1.5.6	Justify how you have claimed USP specification for the applied formulation when the official monograph is not present in USP.	Firm replied that the specification of applied is in-House standard.

Lysine Acetate

Justify for using API complying in-house specification when the official monograph of lysine acetate is present in USP.

Firm replied that The specifications of Lysine Acetate are ChP. For the amino acids such as Lysine Acetate, Chinese manufacturer can only purchase the APIs complied with ChP. Based on the stability results, the APIs complied with ChP can ensure the quality of the finished product.

Applied specification of L-Lysine Acetate	USP specification of L-Lysine acetate
Identification Infrared Absorption IR spectrum of the sample should be concordant with standard.	Identification Infrared Absorption IR spectrum of the sample should be concordant with standard.
Specific Rotation Between +8.5° and +10.0°.	Optical Rotation: Acceptance criteria: +8.4° to +9.9°
Transmittance T430 Clear and colourless. Not less than 98.0 %	NA
Chloride Not more than 0.02 %	Chloride: NMT 0.05%
Ammonium Not more than 0.02 %	NA
Sulfate Not more than 0.02 %	Sulphate : NMT 0.03%
Iron Not more than 10 ppm	Iron: NMT 30 ppm
Heavy metals Not more than 10 ppm	NA
Arsenic Not more than 1.0 ppm	NA
Loss on drying Not more than 0.20 %	LOSS ON DRYING: it loses NMT 0.2% of its weight.
Residue on ignition Not more than 0.10 %	Residue on Ignition: NMT 0.4%

Chromatographic Purity i) Any individual impurity ii) Total impurities Not more than 0.5 % Not more than 2.0 %	Related Compounds: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*. Individual impurities: NMT 0.5% Total impurities: NMT 2.0%
Assay (on anhydrous basis) 98.5 to 101.0 %	Assay: Acceptance criteria: 98.0%–102.0% on the dried basis (Direct Titration)
Residual Solvent	NA

2.	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 submitted the pharmaceutical equivalence report in which all the quality parameters are included as per the specification of finished product. Further, the applied product (Compound α, -ketoacid Tablets) is a generic drug, the reference product is Ketosteril from Fresenius. The dosage forms, route of administration and active substances of applied product (Compound α, -ketoacid Tablets) is identical with those of Innovator drug. The quality between the applied product and reference product is comparable.
3.	3.2.P.2.2.1	Justify for not performing the comparative dissolution profiling study of individual amino acids.	Firm replied that "According to the specification for Compound Alpha-Ketoacid Tablets published by the Chinese NMPA, only the dissolution test for ketoanalogue calcium is required. Therefore, manufacturer instead of carrying out dissolution study of individual amino acid, performed comparative dissolution study of each ketoanalogue calcium".
4.	3.2.P.5.2	Justify for not including the dissolution profiling of individual amino acids in the release specification of finished drug product.	Firm replied that "According to the specification for Compound Alpha-Ketoacid Tablets published by the Chinese NMPA, only the dissolution test for ketoanalogue calcium is required, dissolution for each amino acid is not required".
5.	3.2.P.8	Submit complete stability data of drug product till the claimed shelf , since you have only submitted the detail of stability batches.	Firm submitted the stability data of batches 11101401,11101402,1110140 performed both at accelerated and long term conditions. However, the stability data is not on the letter head of manufacturer, without owned/signed by any technical personnel neither the stability conditions were mentioned on individual stability table of each batches.

Decision: Deferred for submission of

1. **detailed analytical procedure of dissolution testing of individual amino acid used in the formulation**
2. **the stability data of drug product which includes the result of dissolution testing of each amino acid included in the applied formulation.**
3. **Comparative dissolution profiling data which includes the release profiling study of all the amino acids used in the applied formulation.**

784.	Name, address of Applicant / Importer	M/s. Medical Equipment & Systems
	Details of Drug Sale License of importer	Address: 60/61 F.C.C. Syed Maratib Ali Road, Gulberg IV, Lahore Validity: Status: License to sell drugs as distributor

	Name and address of marketing authorization holder (abroad)	M/s. GUERBET BP-57400 F-95943 ROISSY CdG CEDEX
	Name, address of manufacturer(s)	M/s. GUERBET 16-24 rue Jean Chaptal 93600 Aulnay-sous-Bois
	Name of exporting country	France
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted copy of legalized CoPP certificate (No.034154) dated October,2015 issued by chamber and Commerce Industrial Region Paris, France for Xenetix 350, Solution for injection (350mg Iodine/ml). 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. Copy of Certificate of Good Manufacturing Practices of M/s. GUERBET 16-24 rue Jean Chaptal, AULNAY SOUS BOIS,93600, France certificate no. 2019/HPF/FR/111 DATED 10-04-2019.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Authorization from M/s. GUERBET 15 rue des Vanesses, VILLEPINTE,93420, France authorize to M/s. Medical Equipment a sole agent and distributor of Xenetix 300mg Pack size 50ml. The releasing site of contrast media drugs for Pakistan is M/s. Guerbet and contrast media will be exported to Pakistan from Hong Kong.
	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. 30261 dated 25-10-2022
	Details of fee submitted	PKR 75,000/-: dated 25-07-2022 slip no.3678562376
	The proposed proprietary name / brand name	Xenetix 300mg/50ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Xenetix is a 300/ml aqueous injectable solution of Iobitridol. Xenetix 300 in 50ml vial contains 32.905g of Iobitridol.
	Pharmaceutical form of applied drug	Contrast Media (Solution for Injection)
	Pharmacotherapeutic Group of (API)	ATC Code V08AB11 Iodinated contrast media
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's (50ml)
	Proposed unit price	As per policy
	The status in reference regulatory authorities	MHRA Approved, ANSM France approved
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm

<table>
<tr><td></td><td></td><td>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.</td></tr>
<tr><td></td><td>Name, address of drug substance manufacturer</td><td>M/s. GUERBET Rue Denis PAPIN ZI Kerpont 56600 Lanester France (Manufacturing ,QC testing and Batch release)</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>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.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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°C±2°C,60%±5% RH (36 months) and accelerated time stability study conducted at 40°C±2°C,75%±5% RH (6 months) of following batches:
At Accelerated storage condition:
L001, L002, L003
At Real time storage condition:
97L2676,98L0987,99L0603.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>NA (innovator brand)</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>The drug product is packaged in type II clear glass vials, closed with a type I elastomeric rubber stopper and crimped with aluminium cap.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of 3 following batches. The accelerated stability study is conducted at 40°C/75%RH and data of 6 months has submitted. The real time stability study is conducted at 30°C±2°C/65%±5%RH and data of 36month has submitted.
<table>
<tr><th>Batch no.</th><th>Date of Manufacture</th><th>Packaging</th><th>Batch size (Litre)</th></tr>
<tr><td>04WC021A</td><td>01/06/2004</td><td rowspan="3">Type II colourless glass bottle, closed by an elastomeric (chlorobutyl rubber) stopper</td><td>768</td></tr>
<tr><td>04WC022A</td><td>01/06/2004</td><td>1020</td></tr>
<tr><td>04WC023A</td><td>01/06/2004</td><td>2400</td></tr>
</table></td></tr>
</table>

S.no.	Observations/Deficiencies/ Short-comings
1.	Submit original legalized CoPP of Xenetix 300mg Iodine/ml (50ml),since you have submitted the copy of CoPP of product Xenetin 350mg Iodine /ml Injection.
2.	Submit original legalized letter of authorization from Guerbet, France mentioning the product alongwith the applied volume, since you have submitted the copy of letter without any details of applied product.
3.	Submit the legal agreement letter between Hong Kong site and the Guerbet, France since you have mentioned that the product will be exported from Hong Kong to Pakistan. Further,you have mentioned in Form-5F that secondary packaging of applied product will be performed in Pharmtech(HongKong Limited) for Pakistan, so, please clarify the final QC release site of applied product for Pakistan and why the secondary packaging site has not mentioned in the submitted copy of CoPP.

Decision of 324th meeting of Registration Board:
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.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit original legalized CoPP of Xenetix 300mg Iodine/ml (50ml), since you have submitted the copy of CoPP of product Xenetin 350mg Iodine /ml Injection. Firm submitted the copy of CoPP in which following disparities have been observed: • Name and Pharmaceutical Form of the medicinal Product: In French it was mentioned that "*Xenetix 300, solution injectable (300mg d'Iode/ml)100ml*" In English it was written as "*Xenetix 300, solution injectable (300mg Iodine/ml)50ml".* • Status of Marketing Authorisation Holder: In French language a response is encircled which means that "*MAH is the Manufacturer in France, responsible for batch release*" In English translation b response is encircles which means that "MAH *is involved in one of the steps of the finished product manufacturing without being the manufacturer or the importer in France in charge of the batch release*." Further, the auxiliary document along with CoPP i.e. the product characteristics resume is of Xenetix 350mg d'Iode/ml instead of Xenetix 300, solution injectable (300mg Iodine/ml)50ml.	
2.	Submit original legalized letter of authorization from Guerbet, France mentioning the product along with the applied volume, since you have submitted the copy of letter without any details of applied product.	Firm submit the letter of authorisation from M/s. Guerbet Asia Pacific located at Units 1502-03,15/F, Tower A, Cheung Kei Center, 18 Hung Luen Road, Hung Hom, Kowloon, Hong Kong ("GAP") in which they certify that M/s. Medical Equipment & Systems 60/61 F.C.C. Syed Maratib Ali Road, Gulberg IV, Lahore is appointed as the sole distributor for GAP in Pakistan. List of product given in the letter includes Xenetix 300mg/ml (50ml).
3.	Submit the legal agreement letter between Hong Kong site and the Guerbet, France since you have mentioned that the product will be exported from Hong Kong to Pakistan. Further, you have mentioned in Form-5F that secondary packaging of applied product will be performed in Partech (Hong Kong Limited) for Pakistan, so, please clarify the final QC release site of applied product for Pakistan and why the secondary packaging site has not mentioned in the submitted copy of CoPP.	Firm submit the letter with reference to products Xenetix 350mg/ml Solution for Injection 100ml and Dotarem Solution for Injection 15ml from Guerbet Boite Postale 57400 95943 Roissy CdG Cedex France in which it is confirm that /s. Guerbet Asia Pacific located at Units 1502-03,15/F, Tower A, Cheung Kei Center, 18 Hung Luen Road, Hung Hom, Kowloon, Hong Kong is a subsidiary of Geurbet in Hong Kong. Further, it is stated that Guerbet Asia Pacific Ltd. Is responsible for arranging the shipments to Pakistan and is not taking part in any manufacturing or packaging process of the captioned product.

Decision: Aproved as policy for inspection of manufacturer abroad. Firm shall submit legalized CoPP from the concerned regulatory authority before issuance of registration letter.

785.	Name, address of Applicant / Importer	M/s. Medical Equipment & Systems
	Details of Drug Sale License of importer	Address: 60/61 F.C.C. Syed Maratib Ali Road, Gulberg IV,

		Lahore Validity: Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s. GUERBET BP-57400 F-95943 ROISSY CdG CEDEX
	Name, address of manufacturer(s)	M/s. GUERBET 16-24 rue Jean Chaptal 93600 Aulnay-sous-Bois
	Name of exporting country	France
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted copy of legalized CoPP certificate (No.034529) dated 27 May,2020 issued by chamber and Commerce Industrial Region Paris, France 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. Copy of Certificate of Good Manufacturing Practices of M/s. GUERBET 16-24 rue Jean Chaptal, AULNAY SOUS BOIS,93600, France certificate no. 2019/HPF/FR/111 DATED 10-04-2019.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Authorization from M/s. GUERBET 15 rue des Vanesses, VILLEPINTE,93420, France authorize to M/s. Medical Equipment a sole agent and distributor of Xenetix 300mg Pack size 50ml. The releasing site of contrast media drugs for Pakistan is M/s. Guerbet and contrast media will be exported to Pakistan from Hong Kong.
	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. 30259 dated 25-10-2022
	Details of fee submitted	PKR 150,000/-: dated 25-07-2022 slip no.00194398
	The proposed proprietary name / brand name	Dotarem Injection 20ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dotarem is a 0.5mmol/mL The composition per 100ml is as follows: Gadoteric Acid…27.932g Corresponding to Dota…. 20.246g Corresponding to gadolinium oxide….9.062g Gadoteric acid: complex of gadolinium with 1,4,7,10-tetraazacyclododecane-N,N',N'',N''' tetraacetic acid
	Pharmaceutical form of applied drug	Contrast Media (Solution for Injection)
	Pharmacotherapeutic Group of (API)	Paramagnetic Contrast media for MRI ATC CODE :V08CA02
	Reference to Finished product specifications	Manufacturer's Specification

<table>
<tr><td></td><td>Proposed Pack size</td><td>1’s (20ML)</td></tr>
<tr><td></td><td>Proposed unit price</td><td>As per policy</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>USFDA Approved</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>NA (NEW DRUG ,INNOVATOR BRAND)</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>Firm has submitted QOS as per 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.</td></tr>
<tr><td></td><td>Name, address of drug substance manufacturer</td><td>M/s. SIMAFEX 16, Avenue des Fours a´Chaux 17230 MARANS France (Manufacturing, QC testing and Batch release)
M/s. PCAS Finland, O.y Messukentankatu,8 20210 TURKU,Finland ((Manufacturing, QC testing and Batch release)</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>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.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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°C±2ºC,60%±5% RH (36 months) and accelerated time stability study conducted at 40°C±2°C,75%±5% RH (6 months) of following batches:
<table>
<tr><th>Batches</th><th>Manufacturing Date</th><th>Manufacturing site</th></tr>
<tr><td>6113</td><td>Nov 2006</td><td>SIMAFEX</td></tr>
<tr><td>7105</td><td>Oct 2007</td><td>SIMAFEX</td></tr>
<tr><td>11002E</td><td>Mar 2011</td><td>SIMAFEX</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>NA (innovator brand)</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>The drug product is packaged in type II clear glass vials, closed with a type I elastomeric rubber stopper and crimped with aluminium cap.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of 3 following batches of DOTA 15ml. The accelerated stability study is conducted at 40°C/75%RH and data of 6 months has submitted. The real</td></tr>
</table>

time stability study is conducted at 30°C±2°C/65%±5%RH and data of 36month has submitted.

Batch no.	Date of Manufacture	Packaging	Batch size (Litre)
Accelerated Stability study			
08GD021A	March,2008	Type I clear glass vials	400
11GD076B	September 2011		600
15GD040B	May 2015		600
Long term stability study			
15GD040B	May 2015	Type I clear glass vials	600
16GD170B	Dec 2016		900
10GD035B	April 2010		600

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.		Submit original legalized CoPP for 20ml volume of injection, since you have submitted the copy of CoPP, which was previously considered for 15ml injection.
2.		Submit original legalized letter of authorization from Guerbet, France mentioning the product alongwith the applied volume, since you have submitted the copy of letter without any details of applied product.
3.		Submit the legal agreement letter between Hong Kong site and the Guerbet, France since you have mentioned that the product will be exported from Hong Kong to Pakistan. Further,you have mentioned in Form-5F that secondary packaging of applied product will be performed in Pharmtech(HongKong Limited) for Pakistan, so, please clarify the final QC release site of applied product for Pakistan and why the secondary packaging site has not mentioned in the submitted copy of CoPP.
4.	3.2.P.8	Submit the stability data of 20ml filled volume vials as per zone-IV-a conditions till the claimed shelf life, since you have submitted the stability data of Dotarem Injection of 15ml filled volume.

Decision of 324th meeting of Registration Board:
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.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit original legalized CoPP for 20ml volume of injection, since you have submitted the copy of CoPP, which was previously considered for 15ml injection.	Firm submitted the original Legalized CoPP (certificate no.054552 dated 11May,2023) of product DOTAREM 0.5mmol/ml, solution for injection specifying the composition per 100ml. Further, Point 2A.1 of CoPP related to the Marketing Authorisation Number and date of issue mentioning the initial marketing authorization date of 20ml vial(glass), box of 1. The composition mentioned on Resume of product Characteristic attached with CoPP is of 100ml solution, Marketing Authorisation Details enlisted 20ml glass vial injection.
2.	Submit original legalized letter of authorization from Guerbet, France mentioning the product along with the applied volume, since you have submitted the copy of letter without any details of applied product.	Firm submit the letter of authorisation from M/s. Guerbet Asia Pacific located at Units 1502-03,15/F, Tower A, Cheung Kei Center, 18 Hung Luen Road, Hung Hom, Kowloon, Hong Kong ("GAP") instead of Guerbet, France, in which they certify that M/s. Medical Equipment & Systems 60/61 F.C.C. Syed Maratib Ali Road, Gulberg IV, Lahore is appointed as the sole distributor for GAP in Pakistan. List of product given in the letter includes Dotarem Solution for Injection 20ml.
3.	Submit the legal agreement letter between Hong Kong site and the Guerbet, France since you have mentioned that the product will be exported from Hong Kong to	Firm submit the letter with reference to products Xenetix 350mg/ml Solution for Injection 100ml and Dotarem Solution for Injection 15ml from Guerbet Boite Postale 57400 95943 Roissy CdG Cedex France in which it is

	Pakistan. Further,you have mentioned in Form-5F that secondary packaging of applied product will be performed in Pharmtech (HongKong Limited) for Pakistan, so, please clarify the final QC release site of applied product for Pakistan and why the secondary packaging site has not mentioned in the submitted copy of CoPP.	confirm that /s. Guerbet Asia Pacific located at Units 1502-03,15/F, Tower A, Cheung Kei Center, 18 Hung Luen Road, Hung Hom, Kowloon, Hong Kong is a subsidiary of Geurbet in Hong Kong. Further, it is stated that Guerbet Asia Pacific Ltd. Is responsible for arranging the shipments to Pakistan and is not taking part in any manufacturing or packaging process of the captioned product.

4. Submit the stability data of 20ml filled volume vials as per zone-IV-a conditions till the claimed shelf life, since you have submitted the stability data of Dotarem Injection of 15ml filled volume.
Firm submitted the stability data of three batches in which following disparities has been observed:

Sr. No.	Batch details	Accelerated Data (40°C±2°C/75%±5%RH)	Real time data 30°C±2°C/65%±5%RH
1	13GD061A Batch size 600L Primary Packaging: 20ml Vials Manufacturing site: GUERBET Aulnay Manufacturing Date: Apr 2012	Not submitted	36 months data submitted
2	16GD170B Batch size: 900L Primary Packaging: 20ml Filled in 10 ml vials Manufacturing site: GUERBET Manufacturing Date: Dec 2016	Data of 6 month submitted of same batch with different batch details: 16GD170B Batch size: 600L Primary Packaging: 20ml vials Manufacturing site: GUERBET Manufacturing Date: Sep,2011	36 months data submitted
	15GD040B Batch size: 600L Primary Packaging: 20ml Filled in 20 ml vials Manufacturing site: GUERBET Manufacturing Date: May 2015 Gadolinium Oxide Manufacturer: TIAG	6 months data has submitted.	36 months data submitted
	12GD037A Batch size: 600L Primary Packaging: 20 ml vials Manufacturing site: GUERBET Aulnay Manufacturing Date: April 2012	6 months data has submitted. Further, 6 months data of same batch has submitted with different manufacturing date i.e. Sep,2011.	

Decision: Aproved as policy for inspection of manufacturer abroad. Firm shall submit following before ssunace of registration letter:

- **Legalized CoPP from the concerned regulatory authority.**
- **Stability data of 20ml filled volume vials as per zone-IV-a conditions till the claimed shelf life.**

Application of Locally Manufacturing Product on Form5-F

786.	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	Submitted

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

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.

787.	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
	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 and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%. / 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)".
2.	3.2. S.4.3	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.

<table>
<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><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></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>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>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.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>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.</td></tr>
<tr><td>12.</td><td>3.2.R</td><td>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.</td></tr>
</table>

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: Deferred for verification of DRAP attested documents related to the procurement of API.

788.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road,

	site.	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	Submitted		

	(real time and accelerated)	

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.

789.	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	Dry Powder for Injection

	drug	
	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:

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 and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%. / 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)".
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

<table>
<tr><td></td><td></td><td>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><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></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>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>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.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>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.</td></tr>
<tr><td>12.</td><td>3.2.R</td><td>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.</td></tr>
</table>

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	Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s.

	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.	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: Deferred for verification of DRAP attested documents related to the procurement of API.		
Central Licensing Board in 278th meeting held on 10th &11th December,2020 has considered and approved additional section "Liquid Ampoule (SVP) General Section" of M/s Islam Pharmaceuticals, Sialkot.		
790.	Name, address of Applicant / Marketing Authorization Holder	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New Section for liquid ampoule (SVP) General was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020
	Evidence of approval of manufacturing facility	New Section for liquid ampoule (SVP) General was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 18/12/2020
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22726 Dated: 11/08/2022
	Details of fee submitted	PKR 30,000/- Dated: 02/12/2021
	The proposed proprietary name / brand name	Diflo 75mg/3ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Diclofenac Sodium …….75mg
	Pharmacotherapeutic Group of (API)	Clear and colorless solution filled in clear glass ampoules
	Pharmaceutical form of applied drug	Non-steroidal anti-inflammatory drug (NSAID)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	3ml×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Econac Injection 75mg/3ml, MHRA Approved.
	For generic drugs (me-too status)	Voren injection 75mg/3ml by Asian Continental (Pvt.) Ltd. Reg. No. 007737
	Name and address of API manufacturer.	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, 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. 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 Batches:(1702201,1702202, 1702203)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 comparator product that is Voren injection 75mg/3ml injection by Asian Continental Pvt. Ltd. by performing quality tests (Appearance, Identification, Assay, pH and Volume Variation). All parameters results 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	Shaanxi Xiyue Pharmaceutical Co., Ltd. Huashan town, huayin city, veinan city, shaanxi province 714200, china.		
API Lot No.	2010205		
Description of Pack (Container closure system)	USP Type-I Clear Glass ampoules in PVC Tray, packed in unit carton (3ml×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: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21ARn048	21ARn048	21ARn048
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	24-05-2021	24-05-2021	24-05-2021
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)	The firm has not submitted any document. (New Section)
2.	Approval of API/ DML/GMP certificate	Copy of GMP certificate No. SN20190340 issued by CFDA

	of API manufacturer issued by concerned regulatory authority of country of origin.	valid till 24/02/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.14850/2020/DRAP-AD-VIII (I&E) dated 16/10/2020 is submitted wherein the permission to import different APIs including Diclofenac sodium for the purpose of test/analysis and stability studies is granted. • AirWay Bill No.607PVG91267326 Dated 22/12/2020
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)	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.S.4.4	Justify for not importing/using the sterile API for manufacturing of injection, since the results of sterility test and Bacterial Endotoxin test is not included in the COA of drug substance by both drug substance manufacturer and drug product manufacturer.
2.	3.2.P.1	• Clarify the role of benzyl alcohol in the applied formulation. • According to the literature of innovator brand the recommended quantity of Sodium metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the quantity of both excipients used in the applied formulation is different from the recommended quantity by the innovator, scientifically rationalize the quantity of both excipients used in the applied formulation.
3.	3.2.P.2.2.1	Justify for not performing the test of osmolality, particulate matter,sterility and Bacterial Endotoxin test while establishing the pharmaceutical equivalence against the reference product.
4.	3.2.P.3.3	Justify for prefering the aseptic filling procedure over terminal sterilization in the manufacturing procedure of drug product.
5.	3.2.P.5.1	• Submit reference of specification of pH test. • Justify for not including the test of osmolality in the finished product specification since it is the critical parameter in the injectable formulation.
6.	3.2.P.8	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Clarify the volume of glass ampoule use for primary packaging of drug product, since it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.
7.	2.3.R.1.1	Submit minimum handling capacity of the equipment used in the formulation of trail batches.

Decision of 327th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
8.	Justify for not importing/using the sterile API for manufacturing of injection, since the results of sterility test and Bacterial Endotoxin test is not included in the COA of drug substance by both drug substance manufacturer and drug product manufacturer. Firm replied that "since applied product is liquid injection and to be manufactured through aseptic filling procedure (sterilization through filtration method) so it is not necessary to use sterile API. However, Reference of USP general test <1211> sterility assurance stated that		

	The preparation of sterile products encompass a wide range of materials including active pharmaceutical ingredients (small and large molecules), excipients, solvents (usually water), process gases and processing aids, all of which contribute to the microbiological quality attributes of the product. Depending upon the product being manufactured, this can require consideration of bacterial, endotoxin, and particulate contamination. Specific microbiological quality testing requirements for inactive and active ingredients testing is often specified in a relevant USP–NF monograph. Requirements for microbiological testing for total aerobic bacteria, yeast and mold counts, and specified organisms are given in Microbial Enumeration Tests and Tests for Specified Microorganisms, and the recommended but non-mandatory enumeration targets for microbiological testing are given in Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use. Some specific products may require other testing for specified organisms, including viruses, as a requirement of their regulatory approval. Requirements for bacterial endotoxin testing in injectable products are covered, which describes qualification of Limulus amebocyte lysate testing for acceptable levels of bacterial endotoxin. Raw material specifications must be appropriate to ensure that the manufacturing process consistently results, as demonstrated through process validation, in products conforming to the microbiological critical quality attributes.		
9.	3.2.P.1	Clarify the role of benzyl alcohol in the applied formulation.	Firm replied that "Benzyl alcohol is used as solvent (to enhance the solubility of drug substance) reference Handbook of pharmaceutical excipients 7th Edition by RayMond C Rowe a. It is also the part of innovator formulation. In literature of "Voltarol injection" which is MHRA approved, only the qualitative composition of injection is given and it does not mention quantities of excipients reference document is attached as annexure-IB.
10.	3.2.P.1	According to the literature of innovator brand the recommended quantity of Sodium metabisulphite is 2 mg per 3 ml and Benzyl alcohol is 120 mg per 3 ml, while the quantity of both excipients used in the applied formulation is different from the recommended quantity by the innovator, scientifically rationalize the quantity of both excipients used in the applied formulation.	Firm replied that in literature of "Voltarol injection" which is MHRA approved, only the qualitative composition of injection is given and it does not mention quantities of excipients. As per FDA document, limit of inactive ingredients for approved drug products, the maximum limit of benzyl alcohol in intramuscular injection is 144 mg and in our formulation it is 126mg. Limit of sodium metabisulphite is 40mg and in our formulation it is 9.98mg. *However, the USFDA Inactive ingredient database do not mentioned the maximum potency per unit dose of benzyl alcohol and sodium metabisulphite in the IM/IV liquid injection.*
11.	3.2.P.2.2.1	Justify for not performing the test of osmolality, particulate matter,sterility and Bacterial Endotoxin test while establishing the pharmaceutical equivalence against the reference product.	Firm replied that *All the tests including sterility, bacterial endotoxin, particulate matter were performed (mentioned in report under section 3.2.P.5.4 batch analysis) but were not added to pharmaceutical equivalence report. Pharmaceutical equivalence study report containing test results for particulate matter, Bacterial Endotoxin and sterility test* is submitted.
12.	3.2.P.3.3	Justify for prefering the aseptic filling procedure over terminal sterilization in the manufacturing procedure of drug product.	Firm replied that "*According to an article published in Journal of Pharmaceutical Sciences, Vol. 90, 541-544 (2001) Wiley-Liss, Inc. and the American*

			Pharmaceutical Association, "A known impurity "1-(2,6-diclorophenyl) indolin-2-one" is formed in the production of a parenteral dosage form of Diclofenac sodium if terminally sterilized by autoclave" research article is attached as annexure-III". Due to above reason we preferred aseptic filling over terminal sterilization.
13.	3.2.P.5.1	Submit reference of specification of pH test.	Firm replied that "At the time of product development we searched for reference of pH but did not found any authentic document, then we tested different brands of diclofenac sodium injection and found the pH around 8.3, so we set 8.3 as our target pH and adjusted the limits ± 0.5 of target pH (Limit: 7.8 – 8.8). Later on we got another reference "Handbook of Pharmaceutical Manufacturing Formulations Sterile Products" by Sarfaraz K. Niazi, Pharmaceutical Scientist, Inc. Deerfield, Illinois, USA, published in 2009 which gives the range of pH of diclofenac sodium injection from 8.0 – 9.0. Initial results of our stability batches and after 03 and 06-month stability studies are well within the limit which is given in above mentioned book.
14.	3.2.p.5.1	Justify for not including the test of osmolality in the finished product specification since it is the critical parameter in the injectable formulation.	Firm replied that "Osmolality test was performed on product development stage so it was not reported in finish product specification. Osmolality test results and revised finish product specifications after addition of osmolality test are submitted".
15.	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	Stability data for 03 and 06 month of drug product was submitted by the firm.
16.	3.2.P.8	Clarify the volume of glass ampoule use for primary packaging of drug product, since it is mentioned 1ml on stability data sheet while the applied formulation is of 3ml.	In stability sheets 1ml glass ampoule is written by typographic mistake, corrected stability sheets are attached
17.	2.3.R.1.1	Submit minimum handling capacity of the equipment used in the formulation of trail batches.	Firm submitted the data of Minimum handling capacity of the equipment used for trial batches

Decision: Deferred for the submission of following shortcomings:

- **Scientific rationale for not performing terminal sterilization, with reference to the innovator product.**
- **Justify the quantitative composition of Sodium metabisulphite and Benzyl alcohol with reference to the innovator product, sinec the submitted reply has not verified from *USFDA Inactive ingredient database.***

791.	Name, Address of Applicant / Marketing Authorization Holder	M/s Bio-Next Pharmaceuticals Plot No. 50, Street No. S-10, RCCI Industrial Estate, Rawat Islamabad- Pakistan
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial 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. 7851 dated 10/03/2021
	Details of fee submitted	PKR 50,000/-: dated 23/04/2020
	The proposed proprietary name / brand name	Nextcraft 1MIU Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium….1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white coloured Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics
	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)	Colistim Injection by Pharmasol (Pvt) Ltd
	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.	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.
	Module-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 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	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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. Colistim Injection by Pharmasol (Pvt) Ltd.		
	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		Mac-Chem Products (India) Pvt. Ltd. N-211/2/10, midc, Boisar District –Thane.		
API Lot No.		A1680997, A1681004, A1600290		
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.		L-159	L-182	L-199
Batch Size		18200 Vials	28000 Vials	30000vials
Manufacturing Date		05-2018	09-2018	12-2018
Date of Initiation		29-05-18	03-10-18	21-12-2018
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).		
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 (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018. The certificate is valid till 10-09-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5kg from Mac-Chem Products (India)Pvt. Ltd N-211/2/10, MIDC, Boisar District –Thane. The license was issued on 14-02-2020. • Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed 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 record of testing of all batches including COA and summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The product specifications of colistimethate sodium injection based on USP and there is no application of HPLC in testing method because the assay method based on microbial assay therefore compliance record of HPLC is not applicable here.		
6.	Record of Digital data logger for temperature and humidity monitoring	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability		

	of stability chambers (real time and accelerated)	chambers.

Remarks of Evaluator:

Observations	Firm's response
• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies. Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution. While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.
Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free Colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090vials, 11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:
Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.

Decision of 321st meeting of Registration Board:
Registration Board deferred the case for following points:

1. Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
2. Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
3. Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
4. Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.

Response of the Firm:
Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
Firm submitted the Batch manufacturing record of three commercial batches of colicraft 1MIU Injection from M/s. Bio Labs Pvt. Ltd., from which it is evident that sterile colistimethate sodium has been used in the formulation of colicraft and lyophilization has done in the premises of M/s. Bio-Labs Pvt. Ltd.
Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
Firm has submitted only the microbial assay procedure of drug product without any performance data.
Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
Firm has submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasol Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay).
Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.
Firm has submitted the revised stability data sheets of batches L-159, L-199 and L-182 in which results of loss on drying test were included.

Decision of 324th meeting of Registration Board:
Deferred for submission of following:

• Analytical data for the performance of microbial assay of drug substance and drug product for complete stability studies, in accordance with USP general chapter of microbial assay <81>. • Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation.		
Response of the Firm: Analytical data for the performance of microbial assay of drug substance and drug product for complete stability studies, in accordance with USP general chapter of microbial assay <81>. Firm has submitted the raw data sheets of stability batches L-159, L-199 and L-182 along with the performance report of microbial assay of drug product. Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation. Firm has again submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasol Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay) and according to the available record , M/s. Pharmasol Pvt. Ltd has not manufactured the colistim injection by way of lyophilisation.		
Decision: Approved. • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm will revise the label claim as per the decision taken by the Registration Board in 323rd meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**		
792.	Name, Address of Applicant / Marketing Authorization Holder	M/s. Benson Pharmaceuticals Plot #3 Mai Road National Industrial Zone RCCI Rawat Pakistan.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial 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. 9700 dated 02/04/2021
	Details of fee submitted	PKR 50,000/-: vide slip no. 1913592 dated 08/03/2021
	The proposed proprietary name / brand name	Coliben 1MIU Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium……..……1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white colored Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics
	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)	Colistim Injection by Pharmasol (Pvt) Ltd
	GMP status of the Finished product	GMP certificate issued based upon inspection conduct 23-

	manufacturer	4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.
	Module-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 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	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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. Colistim Injection by Pharmasol (Pvt) Ltd.
	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	Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane.		
API Lot No.	A1680997, A1681004, A1600290		
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.	L-159	L-182	L-199
Batch Size	18200 Vials	28000 Vials	30000vials
Manufacturing Date	05-2018	09-2018	12-2018

Date of Initiation	29-05-18	03-10-18	21-12-2018
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).
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 (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018.The certificate is valid till 10-09-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5Kg from Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc, Boisar District –Thane. The license was issued on 14-02-2020. • Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed 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 record of testing of all batches including 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.

Remarks of Evaluator:

• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies. Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution. While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.

Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090 vials, 11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:
Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.

Decision of 321st meeting of Registration Board:
Registration Board deferred the case for following points:

5. Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
6. Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
7. Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
8. Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.

Response of the Firm:

Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
Firm submitted the Batch manufacturing record of three commercial batches of colicraft 1MIU Injection from M/s. Bio Labs Pvt. Ltd., from which it is evident that sterile colistimethate sodium has been used in the formulation of colicraft and lyophilization has done in the premises of M/s. Bio-Labs Pvt. Ltd.
Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
Firm has submitted only the microbial assay procedure of drug product without any performance data.
Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
Firm has submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasole Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay).
Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.
Firm has submitted the revised stability data sheets of batches L-159, L-199 and L-182 in which results of loss on drying test were included.

Decision of 324th meeting of Registration Board:
Deferred for submission of following:

- Analytical data for the performance of microbial assay of drug substance and drug product for complete stability studies, in accordance with USP general chapter of microbial assay <81>.
- Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation.

Response of the Firm:
Analytical data for the performance of microbial assay of drug substance and drug product for complete stability studies, in accordance with USP general chapter of microbial assay <81>.
Firm has submitted the raw data sheets of stability batches L-159, L-199 and L-182 along with the performance report of microbial assay of drug product.

Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation.

Firm has again submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasol Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay) and according to the available record , M/s. Pharmasol Pvt. Ltd has not manufactured the colistim injection by way of lyophilisation.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Registration Board in 323rd meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**

793.	Name, address of Applicant / Marketing Authorization Holder	M/s Novartana Pharmaceuticals (Pvt). Ltd 87-B Plot of Sundar Industrial Area, Raiwind Road, Lahore Pakistan.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt). Ltd Plot No. 145industrial 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.10322 dated 02/04/2021
	Details of fee submitted	PKR 50,000/-: vide slip no. 1913592 dated 08/03/2021
	The proposed proprietary name / brand name	ColiNova 1MIU Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium…….1MIU
	Pharmaceutical form of applied drug	Glass vial filled with almost white to off-white colored Lyophilized Powder.
	Pharmacotherapeutic Group of (API)	Antibiotics
	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)	Colistim Injection 80mg by Pharmasol (Pvt) Ltd. Reg.no. 089922
	GMP status of the Finished product manufacturer	GMP certificate no. F.3-19/2019-Addl.Dir. (QA&LT-I) issued based upon inspection conducted on 23-04-2019, valid up to 22-04-2022.
	Section Approval Status	Firm has Lyophilized vial section as per the GMP certificate issued based upon inspection conducted on 23-04-2019, valid up to 22-04-2022.
	Name and address of API manufacturer.	DMF Holder Address: Mac Chem Products (India) Pvt. Ltd. 304, Town Centre, Andheri-Kurla Road, Andheri East Mumbai Manufacturing and Testing Facilities: Mac-Chem Products (India)Pvt.Ltd N-211/2/10, MIDC, Boisar District –Thane. 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, 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	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(CLS0219006, CLS0219008, CLS0219009)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation

		protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Biological Assay for their product against the comparator i.e. Colistim Injection 80mg by Pharmasol (Pvt) Ltd.		
	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		Mac-Chem Products (India)Pvt.LtdN-211/2/10, MIDC, Boisar District –Thane.		
API Lot No.		A1680997, A1681004, A1600290		
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.		L-159	L-182	L-199
Batch Size		18200 Vials	28000 Vials	30000vials
Manufacturing Date		05-2018	09-2018	12-2018
Date of Initiation		29-05-18	03-10-18	21-12-2018
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empaglif 10mg & 25mg tablet in 296th meeting (Bio-Labs (Pvt). Ltd, Islamabad).		
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 (NEW-WHO GMP/CERT/KD/74238/2018/11/24897) issued by Maharashtra food and drug administration dated 11-09-2018. The certificate is valid till 10-09-2021.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Colistimethate sodium 5Kg from Mac-Chem Products (India)Pvt.Ltd N-211/2/10, midc,Boisar District –Thane. The license was issued on 14-02-2020. • Firm has submitted copy of commercial invoice dated 14-02-2020 specifying import of Colistimethate sodium 5Kg. The invoice is signed 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 record of testing of all batches including 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.

Remarks of Evaluator:

Shortcomings	Response of the Firm
• Provide detailed analytical procedures for the testing of drug substance by the drug product manufacturer. • Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Firm submitted the analytical method verification studies. Verification has been done on assay procedure which is also not as per the USP.
Justify 90.1mg filled weight of colistimethate sodium per vial against the labelled claim of colistin activity as per the USP monograph of "colistimethate for injection".	Nominal potency of colistimethate sodium used for calculation of filled weight is not correct, according to the innovator product of Colistimethate sodium 1MIU the nominal potency of the drug substance =12,500 IU/mg. So, using of 90.1 filled weight is still not scientifically rationale.
All quality test as per USP monograph has not been performed while establishing the pharmaceutical equivalence against the reference product. Provide results of all quality test of applied and reference product as per USP to establish pharmaceutical equivalence.	Test for uniformity of dosage unit, loss on drying, and free colistin under Colistimethate Sodium are not performed while establishing pharmaceutical equivalence with the reference product, while these tests are included in the USP monograph of colistimethate sodium injection.
Details of type and quantity of diluents used for reconstitution for of applied product is required.	According to the submitted information, to reconstitute the injection, use 3ml 0.9% sodium chloride solution. While the international reference product including the innovator, use the range of 7ml-10ml of water for injection or 0.9% sodium chloride for reconstitution of colistimethate injection.
Provide detailed analytical procedures used to evaluate the quality of drug product by the Manufacturer M/s. Bio-Lab Pvt. Ltd.	Firm submitted the analytical procedure for the testing of drug substance but the microbial assay method is not in accordance with USP in terms of composition of media, volume of media, method of analysis, incubation temperature and potency calculation. Further, the test for uniformity of dosage unit, loss on drying, heavy metals, and free colistin under Colistimethate Sodium are not included in finished product specification, since these tests are included in the USP monograph.
According to the filled BMR batch size of Batch L-159, L-199 and L-182 is 11090 vials, 11,000 vials and 11050 vials respectively. While according to the stability data sheet batch size of all three batches are L-159 18,200 vials, L-199 30,000 vials and L-182 28,000 vials. Justification is required regarding the disparity observed in the batch sizes of the same batch.	Firm submitted the reply that "Batch sizes mentioned on stability was written mistakenly. Please consider BMR batch sizes (11,111 packs) as valid batch size. Correct stability data has been submitted.

Decision of 316th meeting of Registration Board:

Deferred for the submission of following:

- Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
- Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.

- Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
- For further deliberation regarding the label claim of Colistimethate sodium in line with the product approved in reference regulatory agencies and pharmacopeia.

Response of the Firm:
Scientific justification for using microbial assay procedure of drug substance and drug product different from that specified in relevant USP monograph.
Firm has submitted the revised microbial assay method which is again not in accordance with USP general chapter microbial assay <81> in terms of analysis and calculations.
Scientific justification using fill weight of 90.1 mg with respect to nominal potency of 1MIU Colistimethate sodium i.e.12,500IU/mg.
Firm has submitted the calculation, according to which quantity of 87.144mg of colistimethate injection has been filled per vial after adjustment of water content and sodium factor. Further, firm set the internal fill weight ±4% i.e. 83.65mg to 90.62 mg and fill weight set at 90mg/vial.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the pharmaceutical equivalence studies.
Firm has submitted revised pharmaceutical equivalence report in which only test for uniformity of dosage unit has been added but test for loss on drying and free colistin still not been included.
Scientific justification for not performing critical tests like "test for uniformity of dosage unit", "loss on drying" and "free colistin" during the stability studies.
Firm has submitted the revised stability data and COA of relevant stability batches, in which test for loss on drying and free colistin was still not included neither any scientific justification has been submitted.

Decision of 321st meeting of Registration Board:
Registration Board deferred the case for following points:

1. Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
2. Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
3. Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
4. Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.

Response of the Firm:
Submission of batch manufacturing details of most recent commercial batch from M/s Bio Labs Pvt Ltd., for applied formulation to confirm the fact whether Colistimethate injection is formulated from pre-lyophilised drug substance or otherwise.
Firm submitted the Batch manufacturing record of three commercial batches of colicraft 1MIU Injection from M/s. Bio Labs Pvt. Ltd., from which it is evident that sterile colistimethate sodium has been used in the formulation of colicraft and lyophilization has done in the premises of M/s. Bio-Labs Pvt. Ltd.
Performance of microbial assay of drug substance and drug product in accordance with USP general chapter of microbial assay <81>.
Firm has submitted only the microbial assay procedure of drug product without any performance data.
Submission of Pharmaceutical equivalence report in which all the quality test should be included in accordance with USP monograph of colistimethate injection.
Firm has submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasole Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay).
Performance of loss on drying test for drug product as per USP monograph of colistimethate injection.
Firm has submitted the revised stability data sheets of batches L-159, L-199 and L-182 in which results of loss on drying test were included.

Decision of 324th meeting of Registration Board:
Deferred for submission of following:

- Analytical data for the performance of microbial assay of drug substance and drug product for complete stability studies, in accordance with USP general chapter of microbial assay <81>.
- Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation.

Response of the Firm:
Analytical data for the performance of microbial assay of drug substance and drug product for complete stability

studies, in accordance with USP general chapter of microbial assay <81>.
Firm has submitted the raw data sheets of stability batches L-159, L-199 and L-182 along with the performance report of microbial assay of drug product.

Pharmaceutical Equivalence studies against the innovator/reference product manufactured by way of lyophilisation.
Firm has again submitted the Pharmaceutical equivalence report performed against the comparator product Colistim Injection of M/s. Pharmasol Pvt. Ltd. Batch.no. KC032, which includes (Identification, LOD, pH, Uniformity of dose, Particulate matter, Free colistin, Sterility, bacterial endotoxin test & assay) and according to the available record , M/s. Pharmasol Pvt. Ltd has not manufactured the colistim injection by way of lyophilisation .

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Registration Board in 323rd meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**

794.	Name, address of Applicant / Marketing Authorization Holder	Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, Pakistan.
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, 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.6974 dated 14-03-2022
	Details of fee submitted	PKR 75,000/- dated 08/12/2021
	The proposed proprietary name / brand name	Iguramod 25mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Iguratimod …… 25mg
	Pharmaceutical form of applied drug	White colored, Round shaped, Film coated oral tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Disease Modifying Anti-Rheumatic Drug (DMARD)
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	1x10's, 2x10's, 3x10's (as per SRO)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Careram Tablets 25mg by Eisai Co., Ltd., PMDA Approved.
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New GMP Inspection granted on 09/09/2021 Tablet (General) section approved.

	Name and address of API manufacturer.	Simcere Pharmaceutical Co., Ltd (Simcere Pharm) Hongsha, Town, Sanya City, Hainan, China Valid till 03-08-2021
	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 has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (A17-100701, A17-100702, A17-100703)
	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 Careram Tablets 25mg by Eisai Co., Ltd by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is Careram Tablets 25mg by Eisai Co., Ltd in Acid media (0.1N HCl), Buffer (pH 4.5) & Buffer (pH 8.0). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Hainan Simcere Pharmaceutical Co., Ltd (Simcere Pharm) Hongsha, Town, Sanya City, Hainan, China		
API Lot No.	A17-180608		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (1×10's, 2×10's, 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: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 (Months)		
Batch No.	TF-09	TF-10	TF-11

Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	04-01-2020	04-01-2020	04-01-2020
No. of Batches	03		

Administrative Portion

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 "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.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HI20160011 issued by HAINAN PROVINCIAL FOOD AND DRUG ADMINISTRATION valid till 03/08/2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Courier slip tracking number: 452563080508 delivery date: Aug 08, 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 Evaluator:
Clinical Indication:
Rheumatoid Arthritis
Approved with the warning box:
Warning
In an overseas clinical trial, pancytopenia leading to a fatal outcome was observed in patients administered 125 mg/day. This drug should be used by physicians with sufficient knowledge of this drug and experience in treating rheumatoid arthritis at medical facilities where adequate measures can be taken in an emergency.

S.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 as per the guidance document approved by Registration Board.	Firm submit specification of drug substance and analytical procedure used for routine testing of drug substance by drug product manufacturer.
2.	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) of drug substance performed by the Drug Product manufacturer under section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board. Further justify how the analysis of	Firm submit analytical method validation report of drug substance by drug product manufacturer.

	drug substance was conducted without performing verification studies of the analytical method of drug substance.	
3.	Justify for not performing the comparative dissolution testing at pH 6.8, since it is the recommended medium in which the dissolution studies should be conducted. Further, you have to performed the comparative dissolution testing using test and innovator /reference products under a variety of test conditions as recommended in 293rd meeting of Registration Board. The test conditions may include different dissolution media (pH 1 to 6.8), addition of surfactant, and use of apparatus 1 and 2 with varying agitation. In all cases, dissolution profiles in comparison with the innovator / reference product should be generated. Submit the data in accordance with the said guidance of Registration Board.	Firm replied that Comparative dissolution studies were performed on multiple dissolution buffers including the phosphate buffer pH 6.8 as per USFDA guidelines (mentioned in 293rd meeting of Registration Board), no results were obtained in buffer pH 6.8 as tablet remained intact in this buffer. That's why calculation was not done. Tablet showed more than 90% dissolution in another buffer pH 8.0 as shown in the CDP.For reference we can enclose calculation sheet of CDP in phosphate buffer pH 6.8.
4.	Composition of applied product submitted in respective section is not qualitatively similar to the composition of innovator product, so, in this case please submit the compatibility study of active with the excipients.	Firm submitted the compatibility study of drug substance with excipient.
5.	Justify for selecting the pH 8.0 for the dissolution medium in the light of international literature, review literature of innovator drug, Pharmacopeial recommendations and BCS classification of drug substance.	Iguratimod belong to BCS class-II drug, dissolution of these drugs are obtained in intestinal pH range. Comparative drug profile performed with the dissolution medium pH 6.8 in which tablet remain intact. That's why its result were not included in CDP.
6.	Justify for adapting the broader acceptance criteria i.e. NLT 75% within 60 minutes, since the drug shows more than 90% drug dissolution within 60 minutes as evident from the stability data. Further, justify the adapted dissolution acceptance criteria in the light of guidance "for setting dissolution release specification" approved in 293rd meeting of Registration Board.	Firm replied that the dissolution studies were performed in phosphate buffer pH 8.0 according to the Chinese Journal of Pharmaceutical Analysis that is a Professional Journal administrated by China Association for Science & Technology sponsored by China Association held by National Institute for Food and Drug control. For BCS-II drugs the time points can be taken 30,45 and 60minutes for NLT 75%. But our product attains dissolution more than 85% at 45 minutes so we can take dissolution limit 75% Q at 45 minutes. We have changed the limits in Finished product specification. According to USFDA guidance document for dissolution "For slowly dissolving or poorly water soluble drugs (BCS class 2), a two-point dissolution specification, one at 15 minutes to include a dissolution range (a dissolution window) and the other at a later point (30, 45, or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product".
7.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the invoice receipt, which is not attested from DRAP.
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 of 324th meeting of Registration Board: Deferred for following: • Documents for the procurement of API with approval from DRAP. • Scientific justifications for the adopted parameters and specifications for dissolution test, while referring to the guidelines from reference regulatory authorities.
Response of the Firm: Documents for the procurement of API with approval from DRAP. Firm in their reply stated that "Previously the invoice was not attested by DRAP, therefore we procured the API again along with attestation of invoice. We made new batches with the new procured API and all the documents along stability data of new batches are being submitted now." Firm has submitted complete new dossier on form-5F without submission of fee with the request to consider this new product formulation data along with stability data for the registration of their applied product.
Decision: Deferred for evaluation of newly submitted data as per the CTD guidance document approved by Registration Board. Further, Firm shall submit full fee for pre-registration changes as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

Agenda of Evaluator PEC-XX

Deferred case of 326th meeting:

Registration applications of newly granted DML or New section (Human)

795.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33964 dated 24/11/2022
	Details of fee submitted	PKR 30,000/- dated 21/11/2022
	The proposed proprietary name / brand name	Caremont 10 mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium……10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Accord Healthcare Limited United Kingdom MHRA Approved

	For generic drugs (me-too status)	M/s Sami Pharma Brand Name & Strength: Montika 10mg Film coated Tablet Registration Number: 035561.
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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)	Official monograph of is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances (specified & unspecified), 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 Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against Montika 10 mg Tablet by SAMI Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA				
Manufacturer of API		M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.		MKS/2107023		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-01	T-02	T-03
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		09-2021	09-2021	09-2021
Date of Initiation		09-2021	09-2021	09-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.DIS.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		

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

Remarks of Assessor (DD PEC-XX):
2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.
3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.
3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

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.

Remarks of Assessor:
Now the firm has submitted reply against above mentioned shortcomings as follows:

Sr.#	Observations	Reply	Remarks
1.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
4.	Batch no of comparator product and test product has not been mentioned under CDP.	Not provided	Not complied
5.	Documents for the procurement of API (approval from DRAP) to be submitted.	Provided Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023.	Complied

		Acknowledgment/approval from I&E DRAP, Islamabad dated 31.08.2021	
6.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

Remarks of Assessor:
The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

1. **Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer**
2. **Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)**
3. **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date)**

796.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.33969 dated 24/11/2022
	Details of fee submitted	PKR 30,000/- dated 21/11/2022
	The proposed proprietary name / brand name	**Caremont 4 mg chewable tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet contains: Montelukast as sodium……4 mg
	Pharmaceutical form of applied drug	Chewable tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Accord Healthcare Limited United Kingdom MHRA approved
	For generic drugs (me-too status)	M/s Sami Pharma Montika 4mg chewable Tablet Registration Number: 035560

	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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)	Official monograph of is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances (specified & unspecified), 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 Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against Montika 4 mg Tablet by SAMI Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.	MKS/2107023		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.DIS.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 Date 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX):
2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.
3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted.

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.

Remarks of Assessor:
Now the firm has submitted reply against above mentioned shortcomings as follows:

Sr.#	Observations	Reply	Remarks
1.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
4.	Batch no of comparator product and test product has not been mentioned under CDP.	Not provided	Not complied
5.	Documents for the procurement of API (approval from DRAP) to be submitted.	Provided Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Acknowledgment/approval from I&E DRAP, Islamabad dated 31.08.2021	Complied
6.	Compliance Record of HPLC software 21CFR &	Not provided	Not complied

	audit trail reports is not submitted		

Remarks of Assessor:
The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer.**
b) **Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)**
c) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date)**

797.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.37335 dated 21/12/2022
	Details of fee submitted	PKR 30,000/- dated 07/12/2022
	The proposed proprietary name / brand name	Caremont 4 mg sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast as sodium……..4 mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merck Sharp & Dohme Limited Singulair® Paediatric 4 mg Granules MHRA Approved
	For generic drugs (me-too status)	M/s Getz Pharma Montget 4mg powder sachet Registration Number: 044046
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Sachet (General) section was approved.

	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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)	Official monograph of is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances (specified & unspecified), 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 Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against Montiget 4mg Sachet by M/s Getz Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 linearity, range, accuracy, precision,

		specificity.	
STABILITY STUDY DATA			
Manufacturer of API		M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)	
API Lot No.		MKS/2107023	
Description of Pack (Container closure system)		Aluminium foil sheet (14's)	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		T-01	T-02	T-03
Batch Size		100 sachet	100 sachet	100 sachet
Manufacturing Date		09-2021	09-2021	09-2021
Date of Initiation		09-2021	09-2021	09-2021
No. of Batches		03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.Dis.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 Date 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Assessor (DD PEC-XX): 2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided. 3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided 3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer. 3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.			

3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

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.

Remarks of Assessor:
Now the firm has submitted reply against above mentioned shortcomings as follows:

Sr.#	Observations	Reply	Remarks
1.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
4.	Batch no of comparator product and test product has not been mentioned under CDP.	Not provided	Not complied
5.	Documents for the procurement of API (approval from DRAP) to be submitted.	Provided Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Acknowledgment/approval from I&E DRAP, Islamabad dated 31.08.2021	Complied
6.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

Remarks of Assessor:
The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer**
b) **Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)**
c) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date)**

798.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 36503 dated 15/12/2022
	Details of fee submitted	PKR 30,000/-: dated 07/12/2022
	The proposed proprietary name / brand name	**Rosucare 10 mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Rosuvastatin calcium…10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist (wrongly mentioned)
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CRESTOR Tablets 10 mg By M/s AstraZeneca Pharmaceutical USA. USFDA Approved
	For generic drugs (me-too status)	Rovista tablets 10mg by M/s Getz Pharma Reg No 044044
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC- Sachin, Dist: -Surat (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, 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 Rosuvastatin Calcium is available in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for organic impurities, unspecified impurities and 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	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: SCT/ST/001/2015 SCT/ST/002/2015 SCT/ST/003/2015
	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 and comparative dissolution profile was performed against Rovista 10 mg Tablet by Getz Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 were in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC- Sachin, Dist: -Surat (Gujrat) India
API Lot No.	21RU000026
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	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).	Firm has submitted Invoice No E1/3012100205 Dated 21.06.2021 confirming import of Rosuvastatin calcium 0.25gm Batch No 21RU000026. Approval from DRAP is required.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX):

1.5.5 Provide correct Pharmacotherapeutic group of Drug Substance.

1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 Potency adjustment (salt factor) of Drug substance to be justified in Batch formula i.e 10.4mg of Rosuvastatin calcium eq to 10mg Rosuvastatin, since reference product (MHRA approved) is provided as:

46.36 mg Rosuvastatin calcium eq to 10mg Rosuvastatin.

3.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Calcium phosphate) is not provided.

3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.

3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

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.

Remarks of assessor:

Sr.#	Observation	Reply	Remarks
1.	Provide correct pharmacotherapeutic group of Drug Substance.	Pharmacotherapeutic group of Drug Substance has been corrected as HMG CoA reductase	Fee of Rs 7500/- is required as per SRO
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Copy of Retention of license No G/25/1723 is submitted valid till 23.01.2026 issued by Food and Drug Control Administration Gujrat state	Complied
3.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
4.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
5.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
6.	Potency adjustment (salt factor) of Drug substance to be justified in Batch formula i.e 10.4mg of Rosuvastatin calcium eq to 10mg Rosuvastatin, since reference product (MHRA approved) is provided as: 46.36 mg Rosuvastatin calcium eq to 10mg Rosuvastatin.	Firm has provided reference of RRA (Netherland) approved formulation wherein potency of rosuvastatin is mentioned as 10.40mg of Rosuvastatin calcium eq to 10mg Rosuvastatin	Complied Same has been verified from this link. https://www.geneesmiddeleninformatiebank.nl/smpc/h126585_smpc_en.pdf
7.	Compatibility of the Drug Substance(s) with excipient	Firm has provided reference of product monograph/SmPC of	Complied Compatibility study of the Drug Substance(s)

	(Calcium phosphate) is not provided.	MHRA/EMA approved product i.e Crestor Tablet wherein Calcium phosphate was mentioned as excipient	with excipient is not required	
8.	Batch no of innovator product and test product has not been mentioned under CDP.	Not provided	Not complied	
9.	Documents for the procurement of API (approval from DRAP) to be submitted.	Firm has submitted Invoice No E1/3012100205 Dated 21.06.2021 confirming import of Rosuvastatin calcium 0.25gm Batch No 21RU000026.	Approval from DRAP is required	
10.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied	
Remarks of Assessor: The reply submitted against above mentioned shortcomings was found unsatisfactory				
Decision: Registration Board deferred the case for following shortcomings: **a) Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer** **b) Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)** **c) Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).** **d) Documents for the procurement of API (approval from DRAP) to be submitted.** **e) Fee of Rs 7500/- is required as per SRO for correction of pharmacotherapeutic group**				

799	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27912 Date: 03/10/2022
	Details of fee submitted	PKR 30000 dated: 28-07-2022 . SLIP No. 9108432875
	The proposed proprietary name / brand name	Actogen 100ml Vial

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Paracetamol 10mg/ml solution for infusion
	Pharmaceutical form of applied drug	Solution for Infusion
	Pharmacotherapeutic Group of (API)	Anti-Pyretic
	Reference to Finished product specifications	Innovator Specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Brand Name: Provas (10mg/ml) Registration holder: M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi. Registration Number: 050650
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt) Ltd, 3 km, Head Balloki Road, Phool Nagar, Kasur. GMP Certificate No. 10444/2016-DRAP/2016
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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, physical form, manufacturers, description of manufacturing process and controls, 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 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 not been established/submitted with innovator Product, but with Provas Infusion of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi

	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of validation of analytical method (In-House) for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Citi Pharma (Pvt) Ltd, 3 km, Head Balloki Road, Phool Nagar, Kasur. GMP Certificate No. 10444/2016-DRAP/2016		
API Lot No.	Not Provided		
Description of Pack (Container closure system)	1's		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 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	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)	Not Submitted. Firm has stated that Biogen is a new license section and no such data is submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not required.
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	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 :
Provide updated GMP certificate of API manufacturer M/s Citi Pharma Kasur as the submitted GMP certificated is dated 2016.
API manufacturer (M/s citi Pharma Kasur) has performed melting point test for identification of API but has set specifications different from those as mentioned in BP.
API manufacturer (M/s citi Pharma Kasur) has performed impurities testing as mentioned in BP but the acceptance criteria is kept at Not more than 1 % while the one mentioned in BP is max .2%
Provide the detailed analytical method with complete detail (method verification) along with test reports of API as performed by the Drug Product manufacturer.
The Manufacturing Protocol/Procedure for manufacture/Product Development (including sterility testing)

are not submitted.
Batch detail along with BMR (including sterility testing) is not provided for manufacturing of Drug Product.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.
Submit microbial reports for the sterility testing of drug product along during stability studies.
Pharmaceutical Equivalence studies along with test reports 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 with innovator Product of Drug Product are not submitted.
Submit microbial reports for the sterility testing of drug product during stability studies.
Provide compatibility study protocol along with reports as the excipients being used are different from the ones mentioned/used in innovator Product (USFDA)
In chromatogram of stability studies, study on blank and respective chromatogram of blank is not submitted.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing needs to be submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.

Decision 322nd meeting : Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Updated reply

Sr. No	Observations	Reply	Remarks
1.	Provide updated GMP certificate of API manufacturer M/s Citi Pharma Kasur as the submitted GMP certificate is dated 2016.	Not provided	Later on GMP certificate based on inspection dated 17.12.2020 was provided.
2.	API manufacturer (M/s citi Pharma Kasur) has performed melting point test for identification of API but has set specifications different from those as mentioned in BP	The mentioned melting point specification range is as per BP.	Justified
3.	API manufacturer (M/s citi Pharma Kasur) has performed impurities testing as mentioned in BP but the acceptance criteria is kept at Not more than 1 % while the one mentioned in BP is max .2%	The mentioned impurities specification/ acceptance criteria is as per BP.	Justified
4.	Provide the detailed analytical method with complete detail (method verification) along with test reports of API as performed by the Drug Product manufacturer.	Detailed analytical method with method verification studies/ test reports of API are provided.	Complied
5.	The Manufacturing Protocol/Procedure for manufacture/Product Development (including sterility testing) are not submitted.	Not provided	Manufacturing Protocol/Procedure for manufacture/Product Development to be provided with details of sterilization mechanism (whether aseptic filling/membrane filtration/terminal sterilization)
6.	Batch detail along with BMR (including sterility testing) is	Provided	Complied

	not provided for manufacturing of Drug Product		
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
8.	Submit microbial reports for the sterility testing of drug product along during stability studies.	Provided	Complied
9.	Pharmaceutical Equivalence studies along with test reports 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 with innovator Product of Drug Product are not submitted.	Pharmaceutical Equivalence have been established against established brand Provas Infusion by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi Batch No 148 G	Complied
10.	Provide compatibility study protocol along with reports as the excipients being used are different from the ones mentioned/used in innovator Product (USFDA)	Excipients being used are same as used in innovator Product (USFDA)	Verified.
11.	In chromatogram of stability studies, study on blank and respective chromatogram of blank is not submitted.	Not provided	Later on firm submitted analytical study report of blank and respective chromatogram
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.	Provided	Complied

Decision 326th meeting of RB: Deferred for submission of manufacturing procedure for applied product along with details of sterilization procedure applied.

Remarks of Assessor:
Now the firm has submitted following:
Detailed manufacturing process along with process control
Sterilization process (Terminal sterilization at 121ºC for 15 minutes)

Firm has provided required documents, which are found satisfactory.

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.**

800	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 is provided along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28776 Date: 11/10/2022
	Details of fee submitted	PKR 30000 dated: 14-07-2022 . SLIP No. 9829497909
	The proposed proprietary name / brand name	Cilagen 250mg Injection IV (Powder for injection/infusion)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem (as Monohydrate)---------250mg Cilastatin (as Sodium)---------250mg
	Pharmaceutical form of applied drug	Powder for solution for injection/infusion
	Pharmacotherapeutic Group of (API)	Anti-Biotics (Anti Bacterial)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO Innovator Product (MHRA) : Pack sizes: 1 x 250 mg vial 10 x 250 mg vial Not all pack sizes may be marketed.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Brand Name: Cilapen 250mg Injection Registration holder: Bosh pharmaceuticals Registration Number: 048490
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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, physical form, manufacturers, description of manufacturing process and controls, 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 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 not been established/submitted.		
	Analytical method validation/verification of product	Not Submitted.		
	STABILITY STUDY DATA			
	Manufacturer of API	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019 valid till 02-10-2022		
	API Lot No.	Imipenem Monohydrate & Cilastatin Sodium: API Lot No is AB06493		
	Description of Pack (Container closure system)	As per SRO		
	Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
	Time Period	Real time: 06 months Accelerated: 06 months		
	Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	001	002	003
	Batch Size	700 vials	700 vials	700 vials
	Manufacturing Date	11-2021	11-2021	11-2021
	Date of Initiation	04-12-2021	04-12-2021	04-12-2021
	No. of Batches	03		
	DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted. Firm has stated that Biogen is a new license		

	facility and no such data is submitted
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28
Documents for the procurement of API with approval from DRAP (in case of import).	The invoice of relevant batch AB06493 used in Product Development is not provided.
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.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Evaluation by PEC:
Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.
Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer.
The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.
Batch detail along with BMR is not provided for manufacturing of Drug Product.
Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.
Submit microbial reports for the sterility testing of drug product during stability studies.
Pharmaceutical Equivalence studies along with test reports are not submitted.
Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.

Decision 322nd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr No	Observation	Reply	Remarks
1.	Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Substance manufacturer.
2.	Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Product manufacturer.
3.	The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.	Not provided	Not complied
4.	Batch detail along with BMR is not provided for	Provided	Complied

	manufacturing of Drug Product.		
5.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 provided Invoice No 7000041892 dated 12.10.2021	Complied
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
7.	Submit microbial reports for the sterility testing of drug product during stability studies	Provided	Complied
8.	Pharmaceutical Equivalence studies along with test reports are not submitted	Pharmaceutical Equivalence studies along with test reports are provided against Tienam 500mg injection by M/s OBS pharma Batch No 154 C Quality parameters compared were identification, LOD, Ph, constituted solution, uniformity of dosage unit, particulate matter, Assay, BET, Sterility	Complied
9.	Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.	Supportive data i.e. chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc. are provided	Complied

Decision 326th meeting: Deferred for following reasons:
The Manufacturing Protocol/Procedure for manufacture/Product Development to be submitted.
Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.

Remarks:
Firm has submitted manufacturing protocol, manufacturing process /flow diagram for the product.
Stability data of API as performed by the API manufacturer has been submitted as follows:

Batches	2854000	2854022	2854406
Condition /duration	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH

	6months	6months	6months

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.**

801	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 is provided along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28777 Date: 11/10/2022
	Details of fee submitted	PKR 30000 dated: 14-07-2022 . SLIP No. 63961987615
	The proposed proprietary name / brand name	Cilagen 500mg Injection IV (Powder for injection/infusion)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem (as Monohydrate)---------500mg Cilastatin (as Sodium)---------500mg
	Pharmaceutical form of applied drug	Powder for solution for injection/infusion
	Pharmacotherapeutic Group of (API)	Anti-Biotics (Anti Bacterial)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO Innovator Product (MHRA) : Pack sizes: 1 x 250 mg vial 10 x 250 mg vial Not all pack sizes may be marketed.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Primaxin Injection 500mg), Merck Inc USA.
	For generic drugs (me-too status)	Brand Name: Cilapen 500mg Injection Registration holder: Bosh pharmaceuticals Registration Number: 048491
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India

		GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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, physical form, manufacturers, description of manufacturing process and controls, 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 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 not been established/submitted.
	Analytical method validation/verification of product	Not Submitted.
	STABILITY STUDY DATA	
	Manufacturer of API	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019 valid till 02-10-2022
	API Lot No.	Imipenem Monohydrate & Cilastatin Sodium: API Lot No is AB06493
	Description of Pack (Container closure system)	As per SRO
	Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

	Time Period	Real time: 06 months Accelerated: 06 months		
	Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	004	005	006
	Batch Size	700 vials	700 vials	700 vials
	Manufacturing Date	11-2021	11-2021	11-2021
	Date of Initiation	04-12-2021	04-12-2021	04-12-2021
	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)	Not Submitted. Firm has stated that Biogen is a new license facility and no such data is submitted		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The invoice of relevant batch AB06493 used in Product Development is 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 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	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: Pack size of Drug Product is not submitted. Provide the analytical method with complete detail as the submitted documents contain, missing/cutting along with test reports of API as performed by the Drug Substance manufacturer. Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer. The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted. Batch detail along with BMR is not provided for manufacturing of Drug Product. Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted. Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided. Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided. Submit microbial reports for the sterility testing of drug product along during stability studies. Pharmaceutical Equivalence studies along with test reports of Drug Product with innovator Product are not submitted. Provide supportive data i.e. attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. Detail of equipment/machinery needs to be submitted. The chromatograms of HPLC submitted along with stability data sheets do not specify the analyte (whether standard , sample etc).			
	Decision 322nd meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.			

Sr No	Observation	Reply	Remarks
1.	Pack size of Drug Product is not submitted.	Not provided	Later on firm provided proposed Pack size of Drug Product as 1's As per SRO.
2.	Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Substance manufacturer.
3.	Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Product manufacturer.
4.	The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.	Not provided	Not complied
5.	Batch detail along with BMR is not provided for manufacturing of Drug Product.	Provided	Complied
6.	Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.	Not provided	Not complied
7.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 provided Invoice No 7000041892 dated 12.10.2021	Complied
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
9.	Submit microbial reports for the sterility testing of drug product during stability studies	Provided	Complied
10.	Pharmaceutical Equivalence studies along with test reports are not submitted	Pharmaceutical Equivalence studies along with test reports are provided against Tienam 500mg injection by M/s OBS pharma Batch No 154 C Quality parameters compared were	Complied

		identification, LOD, Ph, constituted solution, uniformity of dosage unit, particulate matter, Assay, BET, Sterility	
11.	Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.	Supportive data i.e. chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc. are provided	Complied
12.	Detail of equipment/machinery needs to be submitted.	Complied	Complied
13.	The chromatograms of HPLC submitted along with stability data sheets do not specify the analyte (whether standard , sample etc).	Provided	Complied

Decision 326th meeting: Deferred for following reasons:
The Manufacturing Protocol/Procedure for manufacture/Product Development to be submitted.
Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.

Remarks:
Firm has submitted manufacturing protocol, manufacturing process /flow diagram for the product.
Stability data of API as performed by the API manufacturer has been submitted as follows:

Batches	2854000	2854022	2854406
Condition /duration	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6months	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6months	Real time : 30°C ± 2°C / 65% ± 5%RH 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6months

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 of 327th meeting:

802	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4615 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Deslor 5mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Desloratadine …….5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antihistamines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarinex 5mg tablet by M/s Schering-Plough USFDA approved
	For generic drugs (me-too status)	Larinex 5mg Tablet by M/s Getz Pharma Pakistan, Reg. No. 039175
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API manufacturer.	M/s Smaart Pharmaceuticals Limited. B-22/23, MIDC, Ajanta Road, Jalgaon Maharashtra (India) - 425 003.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD 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 has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (DH-1501, DH-1502, DH-1503)

	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 Clarinex 5mg tablet by M/s Schering-Plough Corporation (Batch No CL9562) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form, Disintegration time and microbial limit test). CDP has been performed against the same brand that is Clarinex 5mg tablet by M/s Schering-Plough Corporation in Acid media (pH 1.0-1.2), Acetate buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Smaart Pharmaceuticals Limited. B-22/23, MIDC, Ajanta Road, Jalgaon Maharashtra (India) - 425 003.		
API Lot No.	SMAART/DSL/2021/003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10'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.	DS-01	DS-02	DS-03
Batch Size	2,000 tab	2,000 tab	2,000 tab
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	10-05-2022	10-05-2022	10-05-2022
No. of Batches	03		

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.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted document (invoice No E-086/2020-2021) for import of 5Kg of Desloratadine (Batch No SMAART/DSL/2021/003) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP

		Islamabad dated 08-03-2021.
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	Not Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PECXX):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
3.2.S.4 Acceptance criteria/specifications for impurities (both single and total impurities) as mentioned in CoA from Drug Substance re different from those mentioned in USP. Justify it
3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study
3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study
3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Magnesium stearate) is not Provided since said ingredient is not found in innovator's formulation.
3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No 6093820 dated 29.04.2020 issued by Food and Drug Administration Maharashtra state valid up to 28.04.2021	GMP certificate submitted is invalid
2.	Acceptance criteria/specifications for impurities (both single and total impurities) as mentioned in CoA from Drug Substance are different from those mentioned in USP. Justify it	Drug substance specifications submitted from Drug Product manufacturer were as per USP	Performance of impurity testing of Drug substance as per USP criteria is required either from Drug substance manufacturer or Drug product manufacturer
3.	Parameters like Linearity and Range are not performed under product Analytical method	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and	Justified

	verification study	repeatability) were performed rather than validation studies	
4.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study.	Provided	Complied
5.	Compatibility of the Drug Substance(s) with excipient (Magnesium stearate) is not Provided since said ingredient is not found in innovator's formulation.	Not provided	Magnesium stearate found available in MHRA approved formulation i.e Desloratadine Mylan tablet 5mg https://www.medicines.org.uk/emc/product/2600/smpc#gref
6.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
7.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	
Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory.			
Decision: Registration Board deferred the case for following shortcomings: **a) Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin** **b) Performance of impurity testing of Drug substance as per USP criteria is required either from Drug substance manufacturer or Drug product manufacturer** **c) Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate to be provided**			

803	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4616 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	**Diflupine 150mg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Fluconazole…….150mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use, triazole derivatives.
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Diflucan 150mg Capsule By Pfizer Pakistan.
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Raj Pioneer Lab India, Pvt Ltd. 94-A,95-B & 96-A, Industrial area No. 01, A.B. Road Dewas, Madhya Pradesh, 455001,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)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability 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: RD/FCZ/001, RD/FCZ/002, RD/FCZ/003

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Diflucan capsule 150mg (Batch No 1890017) by M/s Pfizer Pakistan by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Diflupine capsule (Batch No F001). CDP has been performed against the same brand that Diflucan capsule 150mg (Batch No 1890017) in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity and system suitability.		
STABILITY STUDY DATA				
Manufacturer of API (pellets)		M/s Raj Pioneer Lab India, Pvt Ltd. 94-A,95-B & 96-A, Industrial area No. 01, A.B. Road Dewas, Madhya Pradesh, 455001,India.		
API Lot No.		FLC/FD/19/11/20-21		
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.		F001	F002	F003
Batch Size		1500 tablet	1500 tablet	1500 tablet
Manufacturing Date		05-2022	05-2022	05-2022
Date of Initiation		05-06-2022	05-10-2022	05-11-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 25Kg of Fluconazole (Batch No FLC/FD/19/11/20-21) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021.		

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

Remarks of Assessor (DD PEC XX):

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

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks:
Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No DWXGMP201912408 dated 01.01.2020 issued by Food and Drug Administration Madhya Pradesh valid up to 5 years.	Complied
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided
3.	Parameters like Linearity and Range are not performed	Being pharmacopoeial Drug Product analytical method	Justified

	under product Analytical method verification study	verification studies (specificity, accuracy and repeatability) were performed rather than validation studies	
4.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study.	Provided	Complied
5.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 22-02-2021. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
6.	Analysis date mentioned for batches F002 and F003 at 0 month as 05/10/2022 (F002) and 05/11/2022 (F003) while date mentioned at 3rd month and 6th month as 08/08/2022 and 11/08/2022 respectively. Clarify it	Date format followed was Month/Day/Year Analysis date mentioned for batches F002 and F003 at 0 month as 05/10/2022 (F002) and 05/11/2022 (F003) Was actually 10/05/2022 and 11/05/2022 while date mentioned at 6th month 11/08/2022 was 08/11/2022.	Clarified
7.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	
Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory.			
Decision: Deferred for submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided			

804	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot#40, Street#S-6,National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 4614 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Moxopine 400mg tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCl …….400mg
	Pharmaceutical form of applied drug	Light yellow color, oblong, biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox 400mg tablets by M/s Bayer Corporation, Approved in USFDA
	For generic drugs (me-too status)	Moxiget 400mg tablets by M/s Getz Pharma Pakistan, Reg. No. 047117
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API manufacturer.	M/s Rini Life Sciences Pvt. Limited. RR Industrial Estate, Khasra No 115/2/3, Bhawrasla, Sanwer road, 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)	Official monograph of Moxifloxacin HCl is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (MOX2000, MOX2001, MOX2002)
	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 Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). against Test product i.e Moxopine tablet 400mg (Batch No MP-01) CDP has been performed against the same brand that is Avelox 400mg tablets (Batch No AT9562) by M/s Bayer Corporation in Acid media (pH 1.0-1.2), Acetate buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including, accuracy, precision, specificity and system suitability.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Rini Life Sciences Pvt. Limited. RR Industrial Estate, Khasra No 115/2/3, Bhawrasla, Sanwer road, India.		
API Lot No.		MH/002/09/2021		
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.		MP-01	MP-02	MP-03
Batch Size		2000 tablets	2000 tablets	2000 tablets
Manufacturing Date		05-2022	05-2022	05-2022
Date of Initiation		13-05-2022	13-05-2022	13-05-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 50Kg of Moxifloxacin HCl (Batch No MH/002/09/2021) invoice no. GESAC2/3 dated 04.04.2022 wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned		

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

Remarks of Assessor (DD PEC XX):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study.

3.2.P.2 Quantity of Lactose monohydrate used in innovator product as 68mg while firm used 87.8mg Lactose monohydrate in instant formulation. Justify it.

3.2.P.8 Documents for import of API (invoice no. GESAC2/3 dated 04.04.2022) was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, Clarify it. Moreover, approval from DRAP has not been provided.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided.

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks:

Now firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No INDBGMP202105552 dated 23.06.2021 issued by Food and Drug Administration Madhya Pradesh valid up to 5 years.	Complied
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided
3.	Parameters like Linearity and Range are not performed under product Analytical method verification study	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and repeatability) were performed rather than validation studies	Justified

4.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study	Provided	Complied
5.	Quantity of Lactose monohydrate used in innovator product as 68mg while firm used 87.8mg Lactose monohydrate in instant formulation. Justify it.	Lactose monohydrate is used as filler/diluent in tablet. It doesn't have any impact on formulation	Justified
6.	Documents for import of API (invoice no. GESAC2/3 dated 04.04.2022) was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, Clarify it. Moreover, approval from DRAP has not been provided.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided.
7.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	

Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory.

Decsion: Deferred for submission of analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided.

805	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4379 dated 15/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 25mg tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...25mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 039621
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD 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 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 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Seroquel tablet 25mg Batch No 4983763 by ICI Pakistan Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Q-Pine 25mg tablet Batch No Q001. CDP has been performed against the same brand that Seroquel tablet 25mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API Lot No.	LF-QUEF/112020/013		
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.	Q001	Q002	Q003
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	07-05-2022	09-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.

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

Remarks of Assessor (DD PEC XX):

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

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No S-GMP/20082155 issued by Food and Drug Control Administration Gandhinagar Gujrat state valid up to 09.07.2022	GMP certificate submitted is invalid
2.	Analytical Method Verification studies including specificity, accuracy and repeatability	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided
3.	Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided	Not provided	Drug-excipient compatibility study to be provided
4.	Parameters like Linearity and Range are not performed under product Analytical method verification study	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and repeatability) were performed rather than validation studies	Justified

5.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study	Provided	Complied
6.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
7.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	

Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Drug-excipient compatibility study (Talc and IPA).**
c) **Results of Analytical verification study of Drug Substance preferably HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc)**
d) **Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate to be provided**

806	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4378 dated 15/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 100mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...100mg
	Pharmaceutical form of applied drug	Tablet

	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 042222
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD 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 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 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Seroquel tablet 100mg by ICI Pakistan Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Q-Pine 100mg tablet

		CDP has been performed against the same brand that Seroquel tablet 100mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity and system suitability.		
STABILITY STUDY DATA				
Manufacturer of API (pellets)		M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API Lot No.		LF-QUEF/112020/013		
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.		Q004	Q005	Q006
Batch Size		1500 tablet	1500 tablet	1500 tablet
Manufacturing Date		05-2022	05-2022	05-2022
Date of Initiation		07-05-2022	09-05-2022	10-05-2022
No. of Batches		03		
Administrative Portion				
1	Reference of previous approval of applications with stability study data of the firm (if any)	Nil		
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .		
3	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.		
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms for Batch No Q005 and Q006 were not 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	Submitted		

	stability chambers (real time and accelerated)	

Remarks of Assessor (DD PEC XX):

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

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No S-GMP/20082155 issued by Food and Drug Control Administration Gandhinagar Gujrat state valid up to 09.07.2022	GMP certificate submitted is invalid
2.	Analytical Method Verification studies including specificity, accuracy and repeatability	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided
3.	Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided	Not provided	Drug-excipient compatibility study to be provided
4.	Parameters like Linearity and Range are not performed under product Analytical method verification study	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and repeatability) were performed rather than validation studies	Justified
5.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study	Provided	Complied

6.	Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided	Innovator product: Seroquel tablet 100mg by ICI Pakistan Ltd Test Product: Q-Pine 100mg tablet	Batch No of innovator and Test product yet to be provided
7.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
8.	Chromatograms for Batch No Q005 and Q006 to be submitted against each time point.	Provided	Complied
9.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	

Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Drug-excipient compatibility study (Talc and IPA).**
c) **Results of Analytical verification study of Drug Substance preferably HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc)**
d) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
e) **Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate to be provided**

807	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4617 dated 17/02/2023

	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 200mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Evokalm Tablet by M/s Pharmevo, Karachi Reg. No. 053199
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD 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 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 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical

		procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Evokalm tablet 200mg by M/s Pharmevo, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Q-Pine 200mg tablet CDP has been performed against the same brand that Evokalm tablet 200mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA				
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India			
API Lot No.	LF-QUEF/112020/013			
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.	Q007	Q008	Q009	
Batch Size	1500 tablet	1500 tablet	1500 tablet	
Manufacturing Date	05-2022	05-2022	05-2022	
Date of Initiation	07-05-2022	09-05-2022	10-05-2022	
No. of Batches	03			

Administrative Portion		
1	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
3	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.

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

Remarks of Assessor (DD PEC XX):

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

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks:
Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No S-GMP/20082155 issued by Food and Drug Control Administration Gandhinagar Gujrat state valid up to 09.07.2022	GMP certificate submitted is invalid
2.	Analytical Method Verification studies including specificity, accuracy and repeatability	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided
3.	Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided	Not provided	Drug-excipient compatibility study to be provided
4.	Parameters like Linearity and Range are not performed under product Analytical method verification study	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and repeatability) were performed	Justified

		rather than validation studies	
5.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study	Provided	Complied
6.	Brand names of Comparator and Test product used in Pharmaceutical equivalence study/CDP, to be provided	Comparator product: Evokalm tablet 200mg by M/s Pharmevo, Karachi Test Product: Q-Pine 200mg tablet	Batch No of comparator and Test product yet to be provided
7.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
8.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	

Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Drug-excipient compatibility study (Talc and IPA).**
c) **Results of Analytical verification study of Drug Substance preferably HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc)**
d) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
e) **Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate to be provided**

808	Name, address of Applicant / Marketing Authorization Holder	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Name, address of Manufacturing site.	M/s Pine Pharmaceuticals Plot No. 40. Street No. S-4,,RCCI, Industrial estate. Rawat.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4618 dated 17/02/2023
	Details of fee submitted	PKR 30,000/- dated 06/02/2023
	The proposed proprietary name / brand name	Q-Pine 300mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Quetiapine (as fumarate)...300mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Psycholeptic, Diazepines, oxazepines, thiazepines and oxepines
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Rekyt Tablet by M/s High Q, Karachi Reg. No. 112752
	GMP status of the Finished product manufacturer	New DML granted on 29.04.2022, approved in 285th meeting of CLB. The sections approved as under: Tablet (General) section Capsule (General) section Cream/ointment (General) section
	Name and address of API (pellets) manufacturer.	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD 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 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 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: QTP/II/V/026/14-15, QTP/II/V/027/14-15, QTP/II/V/028/14-15,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers,

		description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Evokalm tablet 300mg by M/s Pharmevo, Karachi by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation and DT) against Test Product Q-Pine 300mg tablet CDP has been performed against the same brand that Evokalm tablet 300mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity and system suitability.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Laksh Finechem (Pvt) Ltd Plot No. 1801/02, Phase –IV G.I.D.C Vitthal Udyognagar, Anand, Gujrat India		
API Lot No.	LF-QUEF/112020/013		
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.	Q010	Q011	Q012
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	07-05-2022	09-05-2022	10-05-2022
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. G/25/2046 dated 16.05.2014 valid till 15.05.2019 issued by Food and Drug Administration ,Gujrat state, India .
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZHI-CI/5073/1220 dated 04-12-2020 for import of 55Kg of Quetiapine fumarate (Batch No LF-QUEF/112020/013) wherein name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020.

	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC XX):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not Provided. Since said ingredients are not found in innovator's formulation.

3.2.P.2 Parameters like Linearity and Range are not performed under product Analytical method verification study

3.2.P.2 Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study

3.2.P.2 Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided. Moreover, registration status of Evokalm tablet 300mg to be provided.

3.2.P.8 Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.

3.2.P.8 CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted against each time point.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product testing to be provided

Decision 327th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided GMP certificate No S-GMP/20082155 issued by Food and Drug Control Administration Gandhinagar Gujrat state valid up to 09.07.2022	GMP certificate submitted is invalid
2.	Analytical Method Verification studies including specificity, accuracy and repeatability	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided

3.	Compatibility of the Drug Substance(s) with excipients (Talc and IPA) is not provided	Not provided	Drug-excipient compatibility study to be provided
4.	Parameters like Linearity and Range are not performed under product Analytical method verification study	Being pharmacopoeial Drug Product analytical method verification studies (specificity, accuracy and repeatability) were performed rather than validation studies	Justified
5.	Results of specificity parameter along with HPLC chromatograms (sample, standard, placebo and blank) has not been provided under product Analytical method verification study	Provided	Complied
6.	Brand names of innovator and Test product used in Pharmaceutical equivalence study/CDP, to be provided Moreover, registration status of Evokalm tablet 300mg to be provided.	Comparator product: Cequal tablet 300mg by M/s seraph pharmaceutical Test Product: Q-Pine 300mg tablet	Batch No of comparator and Test product yet to be provided
7.	Documents for import of API was submitted wherein the name of M/s Panacea pharmaceuticals Islamabad, Pakistan was mentioned, attested by AD (I&E) DRAP Islamabad dated 31-12-2020. Clarify it.	We have borrowed API from M/s Panacea pharmaceuticals Islamabad as per decision of DRAP Authority 134th meeting.	Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate yet to be provided
8.	CoA Raw data sheet and Chromatograms for Batch No Q012 were not submitted against each time point	Provided	Complied
9.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Our HPLC is not 21CFR compliant however record of Digital data logger for temperature and humidity monitoring is submitted	

Remarks: The reply submitted against above mentioned shortcoming was found unsatisfactory

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Drug-excipient compatibility study (Talc and IPA).**
c) **Results of Analytical verification study of Drug Substance preferably HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc)**
d) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
e) **Loan agreement to be provided between M/s Panacea pharmaceuticals Islamabad and applicant. Moreover, approval from DRAP/clearance certificate to be provided**

Registration applications of newly granted DML (Human)
M/s Akhsah Pharmaceuticals (Pvt) Ltd, Plot No. 47, Street No S-10,RCCI, Industrial estate, Rawat

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)

809	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section..
	Status of application	☒ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 31016 dated 01-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31/10/2022
	The proposed proprietary name / brand name	ANVIL TAB 10 MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine……..10mg
	Pharmacotherapeutic Group of (API)	antihistamine
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1 x10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EBASTINE ARROW 10 mg film-coated tablets ANSM (France) Approved
	For generic drugs (me-too status)	Beceptor 10mg tablet by M/s Sami pharmaceutical Reg No 094929
	Name and address of API manufacturer.	M/s Bal Pharma Limited 5 th Floor, Laxmi Narayan Complex 10/1, Palace Road Bangalore – 560 052, Karnataka, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 (EBS5100107, EBS5100207 and EBS5100307) 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 was determined against Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi Quality parameters such as Description, identification, dissolution and assay against Test product (Batch No TB-01-A10) Firm has submitted CDP results of their product against the same comparator product Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	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	Bal Pharma Limited 5 th Floor, Laxmi Narayan Complex 10/1, Palace Road Bangalore – 560 052, Karnataka, INDIA
API Lot No..Batch number	5001012201003
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TB-03-A10	TB-02-A10	TB-03-A10
Batch Size	5300 Tablet	5300 Tablet	5300 Tablet
Manufacturing Date	04/22	04/22	04/22
Date of Initiation	27/4/22	27/4/22	27/4/22
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. DCD/CR 2096/SPL.CL-I/2017-2018) dated 05-04-2018 issued by Drugs Control Department, Government of Karnataka, India. The certificate is valid till 1 year from date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# M02/2122/EXP/AEX/00362 dated 31st January 2022, with received quantity i.e. 0.5Kg) for the purchase of Ebastine (Batch No 5001012201003) from Bal Pharma Limited Bangalore – 560 052, Karnataka, India with attestation of DRAP dated 03/03/2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted CoA for each time point to be provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Again firm has submitted invalid GMP certificate (valid till 05.04.2019)	Not complied
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 The DS manufacturer adopted BP specification (2020) of Ebastine while Drug product manufacturer did not perform quality test (sulphate, residual solvent) as per BP monograph moreover assay limit mentioned was not as per BP and silver suphadiazine was mentioned	Firm has submitted corrected CoA of Ebastine as per BP wherein quality parameters and assay limit was mentioned as per BP.	Complied

	instead of Ebastin with assay parameter (CoA)		
4.	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 has been provided	Results of specificity parameter to be provided preferably HPLC chromatograms of sample, blank and standard
5.	3.2.P.2.2.1 CDP has been performed against comparator product Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi instead of innovator product in Pakistan i.e Kestine tablet by M/s Highnoon Laboratories, Lahore.	Not submitted	Yet to be justified
6.	3.2.P.2.2.1 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	Not provided	Not complied
7.	3.2.P.4 Applied specification (as mentioned in Form5F) is BP while applied formulation is available in JP only. Rectify it along with prescribed fee.	Finished product specification has been corrected as JP in Form5F	Fee of Rs 7500/- to be provided as per SRO.
8.	3.2.P.4 Analytical Method Verification studies of Drug Product including results of specificity parameter be provided (against blank, placebo, standard and sample) preferably HPLC chromatograms.	Not provided	Results of specificity parameter be provided (against blank, placebo, standard and sample) preferably HPLC chromatograms.
9.	3.2.P.8 Stability data supported by documents like chromatograms, raw data sheets and summary sheets has been provided except CoA against each time point. Provide it.	Provided	Complied
10.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Fee of Rs 7500/- to be provided for correction of finished product specification.**
c) **Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance**
d) **Justify selection of comparator product Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi instead of innovator product i.e Kestine tablet by M/s Highnoon Laboratories, Lahore for performing pharmaceutical equivalence/CDP.**
e) **Results of specificity parameter preferably HPLC chromatograms (against blank, placebo, standard and sample) under analytical method verification of Drug Product.**
f) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
g) **Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.**

810	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section..
	Status of application	☒ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 31015 dated 01-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31/10/2022
	The proposed proprietary name / brand name	ANVIL TAB 20 MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ebastine……..20mg
	Pharmacotherapeutic Group of (API)	antihistamine
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ebastine 20mg tablet (Netherland approved)
	For generic drugs (me-too status)	Beceptor 20mg tablet by M/s Sami pharmaceutical Reg No 094930
	Name and address of API manufacturer.	M/s Bal Pharma Limited 5th Floor, Laxmi Narayan Complex 10/1, Palace Road Bangalore – 560 052, Karnataka, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 (EBS5100107, EBS5100207 and EBS5100307) 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 was determined against Ebaget D 20mg tablet (Batch No 006T76) by Getz pharma Pvt Ltd, Karachi Quality parameters such as Description, identification, dissolution and assay against Test product (Batch No TB-01-A20) Firm has submitted CDP results of their product against the same comparator product Ebaget D 20mg tablet (Batch No 006T76) by Getz pharma Pvt Ltd, Karachi in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	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	Bal Pharma Limited 5 th Floor, Laxmi Narayan Complex 10/1, Palace Road Bangalore – 560 052, Karnataka, INDIA		
API Lot No..Batch number	5001012201003		
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TB-01-A20	TB-02-A20	TB-03-A20

Batch Size	5300 Tablet	5300 Tablet	5300 Tablet
Manufacturing Date	04/22	04/22	04/22
Date of Initiation	27/4/22	27/4/22	27/4/22
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. DCD/CR 2096/SPL.CL-I/2017-2018) dated 05-04-2018 issued by Drugs Control Department, Government of Karnataka, India. The certificate is valid till 1 year from date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# M02/2122/EXP/AEX/00362 dated 31st January 2022, with received quantity i.e. 0.5Kg) for the purchase of Ebastine (Batch No 5001012201003) from Bal Pharma Limited Bangalore – 560 052, Karnataka, India with attestation of DRAP dated 03/03/2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted CoA for each time point to be provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor:

Sr.#	Observations	Reply	Remarks
1.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Again firm has submitted invalid GMP certificate (valid till 05.04.2019)	Not complied
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 The DS manufacturer adopted BP specification (2020) of Ebastine while Drug product manufacturer did not perform quality test (sulphate, residual solvent) as per BP monograph moreover assay limit mentioned was not as per BP and silver suphadiazine was mentioned instead of Ebastin with assay parameter (CoA)	Firm has submitted corrected CoA of Ebastine as per BP wherein quality parameters and assay limit was mentioned as per BP.	Complied
4.	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 has been provided	Results of specificity parameter to be provided preferably HPLC chromatograms of sample, blank and standard

5.	3.2.P.2.2.1 CDP has been performed against comparator product Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi instead of innovator product in Pakistan i.e Kestine tablet by M/s Highnoon Laboratories, Lahore.	Not submitted	Yet to be justified
6.	3.2.P.2.2.1 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	Not provided	Not complied
7.	3.2.P.4 Applied specification (as mentioned in Form5F) is BP while applied formulation is available in JP only. Rectify it along with prescribed fee.	Finished product specification has been corrected as JP in Form5F	Fee of Rs 7500/- to be provided as per SRO.
8.	3.2.P.4 Analytical Method Verification studies of Drug Product including results of specificity parameter be provided (against blank, placebo, standard and sample) preferably HPLC chromatograms.	Not provided	Results of specificity parameter be provided (against blank, placebo, standard and sample) preferably HPLC chromatograms.
9.	3.2.P.8 Stability data supported by documents like chromatograms, raw data sheets and summary sheets has been provided except CoA against each time point. Provide it.	Provided	Complied
10.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.

Decision: Registration Board deferred the case for following shortcomings:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**
b) **Fee of Rs 7500/- to be provided for correction of finished product specification.**
c) **Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance**
d) **Justify selection of comparator product Beceptor 10mg tablet (Batch No 008G) by Sami pharmaceutical, Karachi instead of innovator product i.e Kestine tablet by M/s Highnoon Laboratories, Lahore for performing pharmaceutical equivalence/CDP.**
e) **Results of specificity parameter preferably HPLC chromatograms (against blank, placebo, standard and sample) under analytical method verification of Drug Product.**
f) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
g) **Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.**

811	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 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 31013 dated 01-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31/10/2022
	The proposed proprietary name / brand name	Ibex 100mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Celecoxib……..100mg
	Pharmacotherapeutic Group of (API)	Non-steroidal Anti-inflammatory Drug
	Pharmaceutical form of applied drug	Oral capsule
	Reference to Finished product specifications	BP specification
	Proposed Pack size	2 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Celecoxib 100mg capsule by Lupin Ltd
	For generic drugs (me-too status)	Celbexx 100mg capsule by M/s Getz pharmaceutical Reg No 028694
	Name and address of API manufacturer.	M/S AARTI DRUGS LIMITED PLOT NO.W-60(B)W-61(B)W-62(B)W-71(B)W-72(B)W-73(B),MIDC,TARAPUR,DIST THANE 401506 MAHARASHTRA 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 (CEL/13040001, CEL/13040002 and CEL/13040003) 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 was determined against Celbex 100mg capsule (Batch No 173C01) by Getz pharmaceutical, (Pvt) Ltd Karachi. Quality parameters such as Description, identification, dissolution and assay against Test product (Batch No CP-01-1100 RT) Firm has submitted CDP results of their product against the same comparator product Celbex 100mg capsule (Batch No 173C01) by Getz pharmaceutical, (Pvt) Ltd Karachi 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	M/S AARTI DRUGS LIMITED PLOT NO.W-60(B)W-61(B)W-62(B)W-71(B)W- 72(B)W-73(B),MIDC,TARAPUR,DIST THANE 401506 MAHARASHTRA STATE,INDIA.		
API Lot No..Batch number	CEL/11060021		
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CP-01-I100	CP-02-I100	CP-03-I100
Batch Size	5300 Cap	5300 Cap	5300 Cap

Manufacturing Date	03/22	03/22	03/22
Date of Initiation	08/4/22	08/4/22	08/4/22
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. New-WHO-GMP/CERT/KD/103280/2021/11/37083) dated 16-08-2021 issued by Food and Drug Administration, MS Bandra (E) Mumbai, Maharashtra State, India. The certificate is valid till 15 August 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# EXP/3299/21-22 dated 29th January 2022, with received quantity i.e. 5Kg) for the purchase of Celecoxib (Batch No CEL/11060021) from Aarti Drugs Limited, India with attestation of DRAP (I&E Islamabad) dated 03/03/2022
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	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.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies from product manufacturer.	Provided	Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance
2.	3.2.P.2.2.1 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	Not provided	Not complied
3.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point

Decision: Registration Board deferred the case for following shortcomings:

a) **Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance**
b) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
c) **Stability data (both accelerated and real time) to be provided for 6th month time point.**

812	Name, address of Applicant / Marketing	M/s Akhsah Pharmaceuticals (Pvt) Ltd, Plot No.

	Authorization Holder	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 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 31012 dated 01-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31/10/2022
	The proposed proprietary name / brand name	Ibex 200mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Celecoxib……..200mg
	Pharmacotherapeutic Group of (API)	Non-steroidal Anti-inflammatory Drug
	Pharmaceutical form of applied drug	Oral capsule
	Reference to Finished product specifications	BP specification
	Proposed Pack size	2 x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Celecoxib 200mg capsule by Lupin Ltd
	For generic drugs (me-too status)	Celbexx 200mg capsule by M/s Getz pharmaceutical Reg No 028693
	Name and address of API manufacturer.	M/S AARTI DRUGS LIMITED PLOT NO.W-60(B)W-61(B)W-62(B)W-71(B)W-72(B)W-73(B),MIDC,TARAPUR,DIST THANE 401506 MAHARASHTRA 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 (CEL/13040001, CEL/13040002 and CEL/13040003) 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 was determined against Celbex 200mg capsule (Batch No 347C02) by Getz pharmaceutical, (Pvt) Ltd Karachi. Quality parameters such as Description, identification, dissolution and assay against Test product (Batch No CP-01-1200) Firm has submitted CDP results of their product against the same comparator product Celbex 200mg capsule (Batch No 347C02) by Getz pharmaceutical, (Pvt) Ltd Karachi 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	M/S AARTI DRUGS LIMITED PLOT NO. W-60(B)W-61(B)W-62(B)W-71(B)W- 72(B)W-73(B),MIDC,TARAPUR,DIST THANE 401506 MAHARASHTRA STATE,INDIA.
API Lot No..Batch number	CEL/11060021
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: 3months

	Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CP-01-I200	CP-02-I200	CP-03- I200
Batch Size	5550 cap	5550 cap	5550 cap
Manufacturing Date	04/22	04/22	04/22
Date of Initiation	08/4/22	08/4/22	08/4/22
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. New-WHO-GMP/CERT/KD/103280/2021/11/37083) dated 16-08-2021 issued by Food and Drug Administration, MS Bandra (E) Mumbai, Maharashtra State, India. The certificate is valid till 15 August 2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# EXP/3299/21-22 dated 29th January 2022, with received quantity i.e. 5Kg) for the purchase of Celecoxib (Batch No CEL/11060021) from Aarti Drugs Limited, India with attestation of DRAP (I&E Islamabad) dated 03/03/2022
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	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.	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies from product manufacturer.	Provided	Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance
2.	3.2.P.2.2.1 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	Not provided	Not complied
3.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point

Decision: Registration Board deferred the case for following shortcomings:

a) Results of specificity parameter preferably HPLC chromatograms (against blank, standard and sample) under analytical method verification of Drug Substance **b) Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).** **c) Stability data (both accelerated and real time) to be provided for 6th month time point.**

813	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28384 dated 06-10-2022
	Details of fee submitted	PKR 30,000/- Dated 29/09/2022
	The proposed proprietary name / brand name	Canadiene 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Clotrimazole……...100mg
	Pharmacotherapeutic Group of (API)	Azole antifungal group of API Clotrimazole
	Pharmaceutical form of applied drug	Vaginal tablet
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1 x6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Canesten 100mg Pessary by M/s Bayer plc 400 South Oak Way Reading RG2 6AD
	For generic drugs (me-too status)	Canesten 6 100mg vaginal Tablet by M/s Bayer pharmaceuticals Pakistan Reg No 107225
	Name and address of API manufacturer.	M/s Halycon labs Pvt. Ltd. Plot No 409, Phase-IV G.I.D.C Industrial estate, Naroda, Ahmadabad, 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 (HCZ05216, HCZ05316 and HCZ05416) 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 was determined against Canesten 100mg Tablet (Batch No BAA753) by M/s Bayer pharmaceuticals Pakistan. Quality parameters such as Description, identification, DT and assay against Test product (Batch No TB-03-C100 RT) CDP not applicable (dissolution test is not required in USP)
	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 Halycon labs Pvt. Ltd. Plot No 409, Phase-IV G.I.D.C Industrial estate, Naroda, Ahmadabad, India
API Lot No..Batch number	HCZ13921
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: 3months Accelerated: 3 months
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)

Batch No.	TB-01-C100	TB-02-C100	TB-03-C100
Batch Size	5500 tab	5500 tab	5500 tab
Manufacturing Date	05/22	05/22	05/22
Date of Initiation	28/5/22	28/5/22	28/5/22
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. 21113028) issued by Food and Drug Control Administration, Gandhinagar, Gujrat State, India. The certificate is valid till 16 November 2024.
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.	3.2.P.2.2.1 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	Complied
2.	3.2.P.8 Documents for the procurement of API to be submitted.	Documents for the procurement of API Batch No HCZ13921 has been provided dated 12.02.2022	Complied
3.	3.2.P.8 Uniformity of dose has not been performed during stability studies.	Test Uniformity of dose has been incorporated in stability studies from 6th month to onward	Complied
4.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point

Decision: Registration Board deferred the case for submission of stability data (both accelerated and real time) for 6th month time point.

814	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section..
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28385 dated 06-10-2022
	Details of fee submitted	PKR 30,000/- Dated 29/09/2022
	The proposed proprietary name / brand name	Canadiene 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Clotrimazole……...500mg
	Pharmacotherapeutic Group of (API)	Azole antifungal group of API Clotrimazole
	Pharmaceutical form of applied drug	Vaginal tablet
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1 x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Canesten 500mg Pessary by M/s Bayer plc 400 South Oak Way Reading RG2 6AD
	For generic drugs (me-too status)	Canesten 1 500mg vaginal Tablet by M/s Bayer pharmaceuticals Pakistan Reg No 107224
	Name and address of API manufacturer.	M/s Halycon labs Pvt. Ltd. Plot No 409, Phase-IV G.I.D.C Industrial estate, Naroda, Ahmadabad, 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 (HCZ05216, HCZ05316 and

		HCZ05416) 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 was determined against Canesten –I Tablet (Batch No BAA710) by M/s Bayer pharmaceuticals Pakistan. Quality parameters such as Description, identification, DT and assay against Test product (Batch No TB-01-C500 RT) CDP not applicable (dissolution test is not required in USP)
	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 Halycon labs Pvt. Ltd. Plot No 409, Phase-IV G.I.D.C Industrial estate, Naroda, Ahmadabad, India		
API Lot No..Batch number	HCZ13921		
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	TB-01-C500	TB-02-C500	TB-03-C500
Batch Size	5300 tab	5300 tab	5300 tab
Manufacturing Date	05/22	05/22	05/22
Date of Initiation	21/5/22	21/5/22	21/5/22
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. 21113028) issued by Food and Drug Control Administration, Gandhinagar, Gujrat State, India. The certificate is valid till 16 November 2024.

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.	3.2.P.2.2.1 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	Complied
2.	3.2.P.8 Documents for the procurement of API to be submitted.	Documents for the procurement of API Batch No HCZ13921 has been provided dated 12.02.2022	Complied
3.	3.2.P.8 Uniformity of dose has not been performed during stability studies.	Test Uniformity of dose has been incorporated in stability studies from 6th month to onward	Complied
4.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point

Decision: Registration Board deferred the case for submission of stability data (both accelerated and real time) for 6th month time point.

815	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 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 31011 dated 01-11-2022
	Details of fee submitted	PKR 30,000/- Dated 31/10/2022
	The proposed proprietary name / brand name	Amicus 150mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Fluconazole……...150mg
	Pharmacotherapeutic Group of (API)	Trizole antifungal group
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1 x6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved Azocan 150mg capsule by FDC International Ltd
	For generic drugs (me-too status)	Fungone 150mg capsule by M/s Sami pharmaceuticals Pvt Ltd Pakistan Reg No 044273
	Name and address of API manufacturer.	M/s Hema Pharmaceuticals Pvt Ltd Plot No 6201/A &B, G.I.D.C opp EWAC Alloys Ankleshwar -393 202, Dist Bharuch, 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 (12PDFC001, 12PDFC002 and 12PDFC003) 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 was determined against Fungone Tablet (Batch No 008F) by M/s Sami pharmaceutical Karachi. Quality parameters such as Description, identification, Dissolution and assay against Test product (Batch No CP-01-A150) CDP was performed against same comparator product Fungone Tablet (Batch No 008F) 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	M/s Hema Pharmaceuticals Pvt Ltd Plot No 6201/A &B, G.I.D.C opp EWAC Alloys Ankleshwar -393 202, Dist Bharuch, India		
API Lot No..Batch number	21FC0015		
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CP-01-A150	CP-02-A150	CP-03-A150
Batch Size	5508 cap	5508 cap	5508 cap
Manufacturing Date	04/22	04/22	04/22
Date of Initiation	30/4/22	30/4/22	30/4/22
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. S-GMP/2062028) issued by Food and Drug Control Administration, Gandhinagar, Gujrat State, India. The certificate is valid till 11-06- 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Provided copy of commercial invoice (Invoice# EXP/135/21-22 dated 13th January 2022, with received quantity i.e. 2.5Kg) for the purchase of Fluconazole (Batch No 21FC0015) from M/s Hema Pharmaceuticals Pvt Ltd with attestation of DRAP (I&E Islamabad) dated 02/03/2022
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	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.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	Valid Approval of API/ DML/GMP certificate of API manufacturer to be provided
2.	3.2.S.4 Analytical Method Verification studies of Drug Substance including specificity (against sample, standard, and blank) performed by the Drug Product manufacturer to be provided	Provided	Complied
3.	3.2.S.4 Provide certificate of analysis of relevant batch(es) of Drug Substance(s) (21FC0015) used in product development by both Drug Substance and Drug Product manufacturer.	Provided	Complied
4.	3.2.P.2.2.1 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	Not provided	Not complied
5.	3.2.P.2.2.1 Justify selection of comparator product i.e Fungone capsule by Sami Pharmaceutical (Pvt) Ltd for conducting pharmaceutical equivalence study/CDP instead of innovator brand i.e Diflucan capsule	Not provided	Not complied
6.	3.2.P.4 Analytical Method Verification studies of Drug Product including specificity (against sample, standard, placebo and blank) performed by the Drug Product manufacturer to be provided	Not provided	Results of specificity parameter preferably HPLC chromatograms (against blank, placebo, standard and sample) under analytical method verification of Drug Product to be provided
7.	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.	Provided	Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.

Decision: Registration Board deferred the case for following shortcoming:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned**
b) **Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).**
c) **Results of specificity parameter preferably HPLC chromatograms (against blank, placebo, standard and sample) under analytical method verification of Drug Product to be provided**
d) **Stability data (both accelerated and real time) to be provided for 6th month time point. Moreover, data against each time point for all 3 batches to be provided.**

816.	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	Inspection report for grant of DML has been provided (dated 24.08.2021)
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 14-09-2021 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28383 (R&I) DRAP, dated 06/10/2022
	Details of fee submitted	PKR 30,000/- Dated 29-09-2022
	The proposed proprietary name / brand name	Elox 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
	Pharmaceutical form of applied drug	Film coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Leflox 500mg tablet by M/s Getz pharma, Pakistan.
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co 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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(DC-0401-1203001, DC-0401-1203002, DC-0401-1203003)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Leflox 500mg tablet by M/s Getz pharma, Pakistan. (Batch No 700F09) Quality parameters such as identification, dissolution and assay were compared against Elox 500mg Tablet (Batch No TB-01-E500) CDP has been performed against the same brand that is Leflox 500mg tablet by M/s Getz pharma, Pakistan (Batch No 700F09) 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	Zhejiang East-Asia Pharmaceutical Co Ltd		
API Lot No.	DC-004-2110012		
Description of Pack (Container closure system)	Alu-Alu Blister (1x10'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.	TB-01/E500	TB-02/E500	TB-03/E500
Batch Size	5100 Tablet	5100 Tablet	5100 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	14-04-2022	14-04-2022	14-04-2022
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)	Not applicable
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).	Provided copy of commercial invoice (Invoice# LEV220113-L dated 13th January 2022, with received quantity i.e. 12Kg) for the purchase of Levofloxacin hemihydrate from Zhejiang East-Asia Pharmaceutical Co Ltd. China with attestation of DRAP dated 02/03/2022
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	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Assessor:

Sr.#	Observation	Reply	Remarks
1	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided	Not provided	Not complied
2	Uniformity of dose is not provided in finished product specification and stability studies.	Test Uniformity of dose has been incorporated in stability studies from 6th month to onward	Complied
3	Provide 6th month and onward stability data for all three batches	Not provided	Only summary data sheet has been provided. Detailed stability data (CoA, raw data sheets and chromatograms etc) to be provided against each time point from 6th month onward.
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	Complied.

Decision: Registration Board deferred the case for following shortcoming:

a) **Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned**
b) **Detailed stability data (CoA, raw data sheets and chromatograms etc) to be provided against each time point from 6th month onward.**

M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
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:
Injectable ampoule Section (General)
Capsule Section (General)
Dry powder suspension section (General)
Sachet section (General)
Dry powder vial section (General)

817	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker Private Limited, 45 KM Dina Nath Multan road, Lahore.
	Name, address of Manufacturing site.	M/s May & Baker Private Limited, 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	Inspection report for grant of DML to be provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Dry powder suspension (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	04-05-2023 Dy No 11136
	Details of fee submitted	PKR 30,000/- Dated 04-05-2023
	The proposed proprietary name / brand name	Mayzithro 200mg/5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml constituted Suspension contains: Azithromycin Dihydrate eq. to Azithromycin…..200mg
	Pharmacotherapeutic Group of (API)	Antibacterial, macrolides
	Pharmaceutical form of applied drug	Dry powder suspension
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	15ml, 25ml, 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax powder for Oral suspension MHRA approved
	For generic drugs (me-too status)	Azomax 200mg/5ml Suspension of M/s Novartis Pharma (Reg.No. 022201)
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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 i.e AZI 112, AZI 111 and AZI 115 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	Pharmaceutical equivalence was determined against Azomax 200mg/5ml product by M/s AGP Pvt Limited. (Batch No A8553) Quality parameters such as Description, identification, Ph,, average weight, LOD, volume of reconstitution, color of reconstitution, Bulk density, and assay were compared against Test product (Batch No T 01)
	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 No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	AZI160		
Description of Pack (Container closure system)	Amber color plastic 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.	T01	T02	T03
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	16-05-2022	16-05-2022	16-05-2022
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)	N/A
2.	Approval of API/ DML/GMP certificate of API	Firm has submitted GMP certificate No F.3-

	manufacturer issued by concerned regulatory authority of country of origin.	26/2019-Addl.Dir (QA&LT-I)-56 dated 22.08.2022 based on inspection dated 14.06.2022 valid till 13.06.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable However, firm has submitted invoice No 60009 dated 09.05.2022 wherein 15Kg clarithromycin taste Masked micro pellets 35% (Batch No AZ160) was purchased
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 recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor:

Sr.#	Observations	Updated status	Remarks
1	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 provided chromatograms only for in use stability study	In use stability data (reconstituted form) to be provided wherein all pharmacopoeial quality parameters will be tested and results should be shown in summary data sheet for each batch.
2	3.2.P.2 CDP has not been performed while dissolution testing is mentioned in USP monograph.	Not provided	Not complied
3	3.2.P.2 Applied formulation contains taste masked micro pellets of Azithromycin while same has not been found in innovator formulation or any reference product. Justify it.	Not provided	Not complied
4	3.2.P.2 Provide Drug excipients compatibility study report for following excipients used in micro pellets (Microcrystalline cellulose, Mannitol, pre-gelatinized starch and coating material such as Methacrylic copolymer dispersion, Glyceryl monostearate, Di ethyl phthalate and titanium dioxide being qualitatively different from innovator product.	Not provided	Not complied
5	3.2.P.2.2.1 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	Complied

6	3.2.P.5 & 3.2.P.8 Deliverable volume testing, uniformity of dosage and dissolution testing has not been performed under finished product specification and stability study	Deliverable volume testing has been incorporated in stability testing however uniformity of dosage and dissolution testing not performed	Not complied
7	3.2.P.4 Results of specificity and accuracy has not been provided under analytical method verification study of Drug Product	Results of specificity (against standard, blank and placebo) and accuracy yet to be provided.	Not complied
8	3.2.P.7 Provide details about container closure system (description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume)	Material of construction of plastic bottle yet to be provided	Not complied
9	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Analytical Method used for analysis of API yet to be provided	Not complied
10	3.2.S.4 Neither Drug substance (micro pellets) manufacturer nor finished product manufacturer has performed Dissolution testing while micro pellets (tasked masked) are coated with Methacrylic copolymer dispersion which is used in enteric coating.	Dissolution testing of micro pellets not performed by both Drug substance (micro pellets) manufacturer and finished product manufacturer.	Not complied
11	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	BMR of stability batches has not provided (T01, T02 and T03)	Not complied
12	Provide Inspection report of product manufacturer for grant of DML	Not provided	Not complied

Decision: Registration Board deferred the case for following shortcomings:

a) **In use stability data (reconstituted form) of all pharmacopoeial quality parameters summarized in data sheet for each batch.**
b) **CDP to be performed**
c) **Justification for using taste masked micro pellets of Azithromycin in light of innovator formulation or any reference product.**
d) **Provide Drug excipients compatibility study report for following excipients used in micro pellets (Microcrystalline cellulose, Mannitol, pre-gelatinized starch and coating material such as Methacrylic copolymer dispersion, Glyceryl monostearate, Di ethyl phthalate and titanium dioxide being qualitatively different from innovator product.**
e) **Performance of uniformity of dosage and dissolution testing and incorporating under finished product specification and stability study**
f) **Results of specificity (against standard, blank and placebo) and accuracy to be provided under analytical method verification study of Drug Product**
g) **Provide details about container closure system (Material of construction of plastic bottle)**
h) **Analytical Method used for analysis of API from Drug Product manufacturer to be provided**
i) **Dissolution testing of micro pellets to be performed by either Drug substance (micro pellets) manufacturer or finished product manufacturer.**
j) **Provide Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided**

818	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker Private Limited, 45 KM Dina Nath Multan road, Lahore.
	Name, address of Manufacturing site.	M/s May & Baker Private Limited, 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	Inspection report for grant of DML to be provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 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	18-05-2023 Dy No 12209
	Details of fee submitted	PKR 30,000/- Dated 04-05-2023
	The proposed proprietary name / brand name	Maylax 100 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Itraconazole…… 100mg
	Pharmacotherapeutic Group of (API)	Antimycotic for systemic use, triazole derivative
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	4’s,6’s, 14’s, 28’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Itraconazole Capsule 100mg MHRA approved
	For generic drugs (me-too status)	Rolac of M/s Sami pharma, Karachi (Reg.No. 024491)
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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 (Batch No ICZ1464, ICZ1465, ICZ1466) 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 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	Firm has submitted pharmaceutical equivalence of their product against the comparator product Rolac 100mg Manufactured by Sami Pharmaceutical Karachi. Firm has submitted CDP results of their product against the comparator product Rolac capsule 100mg (Batch No 011H) in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	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 No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	Not provided		
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.	T01	T02	T03
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	01-03-2022	01-03-2022	01-03-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
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 GMP certificate No F.3-26/2019-Addl.Dir (QA&LT-I)-56 dated 22.08.2022 based on inspection dated 14.06.2022 valid till 13.06.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Purchase invoice wherein batch no of Itraconazole pellets (22%) was mentioned, to be 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	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor:

Sr.#	Observations	Updated status	Remarks
1	3.2.P.2 Provide Drug excipients compatibility study report for Microcrystalline cellulose and Titanium dioxide being qualitatively different from innovator product.	It is evidence from the stability studies that product is compatible with the excipients and Drug Product is stable throughout the stability studies.	Not Complied Drug excipients compatibility study report for Microcrystalline cellulose and Titanium dioxide yet to be provided
2	3.2.P.2 CDP has been performed against generic product (locally manufactured) instead of innovator product Sporanox capsule by M/s Janssen-Cilag limited. Uk (also registered in Pakistan Reg No 012647)	CDP report has been submitted against innovator brand Sporanox capsule by M/s Janssen-Cilag limited. Uk MA holder M/s Aspin pharma Pvt Ltd. Batch No BV0012	Complied
3	3.2.P.2 Provide CDP report with detailed result (% result of drug in different time interval in each medium from both Test and comparator product, along with values for f1 and f2).	CDP report with detailed result (% result of drug in different time interval in each medium) has been provided but f1 and f2 values are not calculated.	Not complied f1 and f2 values are to be calculated.
4	3.2.P.4 Results of specificity and accuracy has not been provided under analytical method verification study of Drug Product	Results of specificity (against standard, blank and placebo) yet to be provided.	Not complied
5	3.2.P.8 Purchase invoice wherein batch no of Itraconazole pellets (22%) was mentioned, to be provided	Firm has provided loan letter from M/s vision Islamabad that	

		Iitraconazole IR pellets have been provided as loan.	
6	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 Finished Product Manufacturer yet to be provided	Not complied
7	3.2.S.4 Drug substance (IR pellets) manufacturer performed Dissolution testing as mentioned in analytical method/CoA while same has not been provided under CoA of Itraconazole pellets IR from Drug product manufacturer.	Dissolution testing has been performed as provided in CoA of Itraconazole pellets IR from Drug product manufacturer.	complied
8	3.2.S.7 Submit real time stability data of Drug Substance up to shelf life. Already submitted data was for 6-month period.	Not provided	Not complied

Decision: Deferred for following:

a) **Drug excipients compatibility study report for Microcrystalline cellulose and Titanium dioxide being qualitatively different from innovator product.**
b) **Calculate f1 and f2 values under CDP**
c) **Results of specificity (against standard, blank and placebo) to be provided under analytical method verification study of Drug Product**
d) **Purchase invoice/document wherein batch no of Itraconazole pellets (22%) was mentioned, to be provided**
e) **Method used for analysis of API from Finished Product Manufacturer to be provided**
f) **Submit real time stability data of Drug Substance up to shelf life.**

819	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 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	Inspection report for grant of DML to be provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 29-04-2022 specifying Dry Powder suspension section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11134 (R&I) DRAP, dated 04/05/2023
	Details of fee submitted	PKR 30,000/- Dated 04-05-2023
	The proposed proprietary name / brand name	Maycil 125mg/5ml oral suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml constituted suspension contains: Clarithromycin……..….125mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, macrolide
	Pharmaceutical form of applied drug	Solution for injection (wrongly mentioned)

	Reference to Finished product specifications	USP
	Proposed Pack size	15ml, 30ml, 60ml and 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Klaricid 125mg/5ml oral suspension by M/s Abbott pharma
	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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: CTM0511, CTM0510, CTM0513
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Klaricid 125mg/5ml product by M/s Abbott Laboratories, Pakistan. (Batch No (10) 452640XV) Quality parameters such as Description, identification, Ph,, average weight, LOD, volume of reconstitution, color of reconstitution and assay were compared against Test product (Batch No T 01)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.
STABILITY STUDY DATA		
Manufacturer of API (taste	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial triangle ,	

masked micro pellets)	Kahuta road, Islamabad		
API Lot No.	CTM0644		
Description of Pack (Container closure system)	Amber color plastic 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.	T1	T2	T3
Batch Size	1000 Bottles	1000 Bottles	1000 Bottles
Manufacturing Date	26-05-2022	26-05-2022	26-05-2022
Date of Initiation	27-05-2022	28-05-2022	29-05-2022
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 applicable
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 F.3-26/2019-Addl.Dir (QA&LT-I)-56 dated 22.08.2022 based on inspection dated 14.06.2022 valid till 13.06.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable However, firm has submitted invoice No 60007 dated 18.05.2022 wherein 30Kg clarithromycin taste Masked micro pellets 27.5% (Batch No CTM0644) was purchased
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 recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Assessor (PEC-XX):

Sr.#	Observations	Reply/ Updated status	Remarks
1	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 provided chromatograms only for in use stability study	In use stability data (reconstituted form) to be provided wherein all pharmacopoeial quality parameters will be tested and results should be shown in summary data sheet for each batch.

2	3.2.P.2 Provide Drug excipients compatibility study report for sodium citrate dehydrate, being qualitatively different from innovator product.	It is evidence from the stability studies that product is compatible with the excipients and Drug Product is stable throughout the stability studies.	Not Complied Drug excipients compatibility study report for sodium citrate dehydrate yet to be provided
3	3.2.P.2.2.1 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	Complied
4	3.2.P.5 Deliverable volume testing has not been mentioned under finished product specification and stability study	Deliverable volume testing has been incorporated in stability testing	Complied
5	3.2.P.5 Results of specificity and accuracy has not been provided under analytical method verification study of Drug Product	Results of specificity (against standard, blank and placebo) and accuracy yet to be provided.	Not Complied
6	3.2.P.7 Provide details about container closure system (description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume)	Material of construction of plastic bottle yet to be provided	Not Complied
7	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Analytical Method used for analysis of API/pellets yet to be provided	Not Complied
8	3.2.S.4 Drug substance (micro pellets) manufacturer performed Dissolution testing as mentioned in analytical method/CoA while same has not been provided under CoA of clarithromycin granules from Drug product manufacturer.	Dissolution testing has been performed as provided in CoA of clarithromycin granules from Drug product manufacturer.	Complied
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	Provided	Complied

Decision: Deferred for following:

a) **Drug excipients compatibility study report for sodium citrate being qualitatively different from innovator product.**
b) **Results of specificity (against standard, blank and placebo) and accuracy to be provided under analytical method verification study of Drug Product**
c) **Method used for analysis of API from Finished Product Manufacturer to be provided**
d) **Provide details about container closure system (Material of construction of plastic bottle)**
e) **In use stability data (reconstituted form) of all pharmacopoeial quality parameters summarized in data sheet for each batch.**

820	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 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	Inspection report for grant of DML to be provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 29-04-2022 specifying Dry Powder suspension section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11135 (R&I) DRAP, dated 04/05/2023
	Details of fee submitted	PKR 30,000/- Dated 02-05-2023
	The proposed proprietary name / brand name	Maycil 250mg/5ml DS oral suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml constituted suspension contains: Clarithromycin……..….250mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, macrolide
	Pharmaceutical form of applied drug	Solution for injection (wrongly mentioned)
	Reference to Finished product specifications	USP
	Proposed Pack size	15ml, 30ml, 60ml and 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Klaricid 250mg/5ml oral suspension by M/s Abbott pharma Reg No 076148
	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, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: CTM0511, CTM0510, CTM0513
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation studies, specifications, analytical procedure and validation studies batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was determined against Klaricid 250mg/5ml DS product by M/s Abbott Laboratories, Pakistan. (Batch No (17) 462786XV) Quality parameters such as Description, identification, Ph,, average weight, LOD, volume of reconstitution, color of reconstitution and assay were compared against Test product (Batch No T 01)
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug product.

STABILITY STUDY DATA			
Manufacturer of API (taste masked micro pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial triangle , Kahuta road, Islamabad		
API Lot No.	CTM0644		
Description of Pack (Container closure system)	Amber color plastic 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.	T1	T2	T3
Batch Size	1000 Bottles	1000 Bottles	1000 Bottles
Manufacturing Date	22-05-2022	22-05-2022	22-05-2022
Date of Initiation	23-05-2022	24-05-2022	25-05-2022
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 applicable
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 F.3-26/2019-Addl.Dir (QA&LT-I)-56 dated 22.08.2022 based on inspection dated 14.06.2022 valid till 13.06.2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable However, firm has submitted invoice No 60007 dated 18.05.2022 wherein 30Kg clarithromycin taste Masked micro pellets 27.5% (Batch No CTM0644) was purchased
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 recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Assessor (PEC-XX):

Sr.#	Observations	Reply/ Updated status	Remarks
1	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 provided chromatograms only for in use stability study	In use stability data (reconstituted form) to be provided wherein all pharmacopoeial quality parameters will be tested and results should be shown in summary data sheet for each batch.
2	3.2.P.2 Provide Drug excipients compatibility study report for sodium citrate dehydrate, being qualitatively different from innovator product.	It is evidence from the stability studies that product is compatible with the excipients and Drug Product is stable throughout the stability studies.	Not Complied Drug excipients compatibility study report for sodium citrate dehydrate yet to be provided
3	3.2.P.2.2.1 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	Complied
4	3.2.P.4 Deliverable volume testing has not been mentioned under finished product specification and stability study	Deliverable volume testing has been incorporated in stability testing	Complied
5	3.2.P.4 Results of specificity and accuracy has not been provided under analytical method verification study of Drug Product	Results of specificity (against standard, blank and placebo) and accuracy yet to be provided.	Not Complied
6	3.2.P.7 Provide details about container closure system (description of the primary container closure systems, including materials of construction, unit	Material of construction of plastic bottle yet	Not Complied

	count or fill size, container size or volume)	to be provided	
7	3.2.S.4 Method used for analysis of API from Finished Product Manufacturer to be provided along with analytical method validation studies.	Analytical Method used for analysis of API/pellets yet to be provided	Not Complied
8	3.2.S.4 Drug substance (micro pellets) manufacturer performed Dissolution testing as mentioned in analytical method/CoA while same has not been provided under CoA of clarithromycin granules from Drug product manufacturer.	Dissolution testing has been performed as provided in CoA of clarithromycin granules from Drug product manufacturer.	Complied
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	Provided	Complied

Decision: Deferred for following::

a) **Drug excipients compatibility study report for sodium citrate being qualitatively different from innovator product.**
b) **Results of specificity (against standard, blank and placebo) and accuracy to be provided under analytical method verification study of Drug Product**
c) **Method used for analysis of API from Finished Product Manufacturer to be provided**
d) **Provide details about container closure system (Material of construction of plastic bottle)**
e) **In use stability data (reconstituted form) of all pharmacopoeial quality parameters summarized in data sheet for each batch.**

Deferred cases:

821	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.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the firm	The firm is granted GMP certificate based on inspection conducted on 28-08-2019.
	Dy. No. and date of submission	Dy. No. 20437 dated 27-07-2021
	Details of fee submitted	PKR 50,000/-: dated 08-04-2021
	The proposed proprietary name / brand name	BALOXA 20MG TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baloxavir Marboxil……..20mg
	Pharmaceutical form of applied drug	White to off-white colored, oval shaped film coated tablets, plain on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Antiviral (WHO ATC code: J05AX25)
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XOFLUZA ™ (Baloxavir marboxil) Tablets 20mg of M/s Genetech USA, Inc (USFDA approved)
	For generic drugs (me-too status)	Not applicable
	Name and address of API manufacturer.	M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd, Address: Jintang Industry Zone, Shaowu City, Fujian 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, 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 and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A, B, individual impurity and total impurity, 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	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: (180801, 180802, 180803)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence and CDP studies could not be performed due to the unavailability of innovator products, justification regarding the comparative studies and innovator pack procurement have been submitted.
	Analytical method validation/verification of product	Method validation studies have been submitted including precision, accuracy and specificity studies.

STABILITY STUDY DATA	
Manufacturer of API	M/s Fujian Jinshan Zhundian Pharmaceutical Co. Ltd., Address: Jintang Industry Zone, Shaowu City, Fujian Province, China
API Lot No.	200101
Description of Pack (Container closure system)	Alu-Alu 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)		
BALOXA 20MG TABLET				
Batch No.		Lab-01	Lab-02	Lab-03
Batch Size		1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date		07-2020	07-2020	07-2020
Date of Initiation		21-08-2020	21-08-2020	21-08-2020
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1 2	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.		
3 4	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. FJ20160009 issued by Food and Drug Administration of china valid till 22/02/2021. As per Chinese Government website no more GMP certificates are being issued after December 2019.		
5 6	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice (Invoice# WIS200028 MAR 18, 2020 with received quantity i.e. 300 g) for the purchase of Baloxavir Marboxil by M/s Fujian Jinsahn Zhundian Pharmaceutical Co., Ltd attested by DRAP dated 25-03-2020.		
	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.		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The Firm has submitted audit trail record of product testing of HPLC for all test intervals.		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).		

Remarks of Evaluator:

Sr.#	Observations communicated	Response by the firm
1.	Submit differential fee for the registration of applied product since the applied product since the application was received in R&I section of DRAP after 7th May 2021.	Differential fee deposit slip # 772863043 of Rs. 25000/- has been submitted.

2.	The reference product literature showed that the structure and absolute stereochemistry of Baloxavir marboxil is verified by single crystal x-ray determination. The submitted COA from drug substance manufacturer does not contain this test.	The structure and absolute stereochemistry of Baloxavir Marboxil is verified by single crystal x-ray determination is mentioned on COA as polymorphic form, i.e: form I. Revised COA and XPRD Spectra is attached for your reference.
3.	Give a detailed account on polymorphic form of drug substance used in drug product development since several polymorphic forms of drug substance are possible as per reference literature.	Description of polymorphic form of material is defined in DMF (3.2.S.3.1.9 summary) as material is polymorphic form I.
4.	Elaborate the test of "Microbial limit Test" mentioned in certificate of analysis of Baloxavir Marboxil.	Microbial examination of non-sterile products is performed as per following USP method given in the texts on Microbial Enumeration Test <61>, Tests for Specified Microorganisms <62> and Microbiological examination of non-sterile products (acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use) <1111>. As per pharmacopeia the acceptance criteria for non-sterile pharmaceutical products based on the total aerobic microbial count (TAMC), total yeast and molds count (TYMC) and objectionable microorganisms which must be absent and these are called as Microbial Limit Tests. We followed the same practice and set restricted microbiological limits as per SAMI's Specs, that is TAMC: NMT 100 cfu/g, TYMC: NMT 10 cfu/g as well as absence of pathogenic organisms including E. Coli, Salmonella, S. Aureus in our raw material.
5.	The submitted acceptance criteria for release and shelf life specifications are same. Scientific justification is required for adopting such acceptance criteria.	We develop the product specifications according to the general monograph of USP and from the chemistry reviews of USFDA, EMA. In addition, ICH Q6A states that the acceptance criteria are the same from release throughout shelf life of product. Therefore, we have also set the same specification limits for release and shelf life.
6.	The submitted process validation protocol does not describe the critical process steps and controls in defined ranges.	Existing protocol captures the required information and describes critical process parameters along with process controls. However, to make this more elaborative, we have revised these sections and version 2 of protocol is attached.
7.	Since the strategy for product development is planned according to identified QTPP which is based on evaluation of the innovator/reference product therefore, justify the authenticity of product development studies for applied formulation without comparison with innovator/reference product.	The innovator of Baloxavir Marboxil Tablet i.e. XOFLUZA 40mg & 20mg Tablets, already published a detailed characterization of API (Baloxavir Marboxil) in FDA chemistry review as well product assessment report of European Medicine Agency (EMA). This part of QTPP was derived from FDA chemistry review & EMA assessment report. Appearance of API, its solubility, pKa, partition coefficient, stereoisomerism and polymorphic form etc. were mentioned in detail by the innovator, therefore, all these required details are gathered from literature data. As the reference finished product is presented as immediate-release film-coated tablets for oral administration containing 20mg or 40mg of Baloxavir Marboxil as the active substance, therefore, we have designed our product same as reference product to ensure pharmaceutical equivalency.

		Product dissolution parameters and other related specification are already disclosed by the manufacturer of the reference product. Due to poor solubility of API, to ensure reproducible dissolution results, we have selected micronized grade of API for development of our product as suggested by the reference brand in FDA chemistry review. Due to unavailability of innovator samples, the dissolution profile in different pH mediums i.e., pH 1.2, 4.5 and 6.8 buffers as recommended in WHO for CDP is checked and the release profile found similar to that of innovator product "Xofluza Tablet" in FDA chemistry review publically available. Information related to product packaging, storage and labeling were also gathered from the above mentioned product assessment reports i.e. FDA chemistry review as well product assessment report of European Medicine Agency.

Decision 316th meeting of RB: Registration Board decided to defer the case for submission of pharmaceutical equivalence and CDP studies with innovator / reference product.

Remarks of Assessor:
Firm has provided pharmaceutical equivalence and CDP studies against reference product as follows:
Product name: Xofluza (Baloxavir marboxil) Tablets 20mg
Manufactured by: M/s Shionogi, Incorporated (USFDA approved)
Batch No: 0137
Exp date: 09-2025
Quality parameters compared were appearance, Disintegration time, Assay, identification, impurity dissolution, uniformity of dosage unit, and microbial enumeration test.
CDP was performed against same reference product in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was not required since more than 85% drug release within 15 min.

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.**

822.	Name and address of manufacturer/ Applicant	M/s Pharma Lord (Pvt.) Ltd., 12 KM, Lahore Road, Layyah, Punjab (Tablet general).
	Brand Name + Dosage Form + Strength	Allor 10mg Chewable Tablet.
	Composition	Each Chewable Tablet Contains: Loratadine ……..…10mg
	Diary No. Date of R & I & fee	Dy. No 10371 dated 05-03-2019; Rs.20,000 dated 05-03-2019.
	Pharmacological Group	Antihistamine for systemic use.
	Type of Form.	Form-5
	Finished product Specification.	USP specifications.
	Pack size & Demanded Price	1 x 10's; 10 x 10's.
	Approval status of product in Reference Regulatory Authorities.	Alavert 10mg orally disintegrating tablet, USFDA approved.
	Me-too status.	Lorefect tablets, Bosch pharmaceuticals, Reg. No. 023018.
	GMP status.	Same as above.
	Remarks of the	Evidence of applied formulation already approved by DRAP in

	Evaluator.	chewable formulation. Firm has also provided Allord, Allordin, Allfix & Allerdin as alternative brand names.
	Decision 312th meeting of RB:	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in chewable formulation along with registration number, brand name and name of firm.
	Remarks of Assessor	Firm has revised formulation as follows: Each Tablet Contains: Loratadine ……..…10mg Fee of Rs 30,000/- has been deposited in this regard (Deposit slip no. 51398823) dated 12.06.2023 Reference for Generic version of applied formulation was provided as: Antial tablet (Reg No 019675) by M/s Sami pharmaceuticals (Pvt) Ltd.
	Decision: Approved as per following label claim: **Each Tablet Contains:** **Loratadine ……..…10mg**	

823	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, LT 26 A/1 Landhi Industrial Area, Karachi-22
	Brand Name +Dosage Form + Strength	Reoflox-C oral solution.
	Composition	Each 100ml solution contains: Enrofloxacin …….25% w/v Colistin Sulphate……50 M.I.U.
	Diary No. Date of R& I & fee	Dy. No. 512, R&I Dated 20-06-2016, (Rs.20,000/-) (20-6-2016)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form -5
	Finished product Specifications	Not provided
	Pack size & Demanded Price	100ml, 500 ml, 1000ml, 2.5-liter, 5-liter bottle & Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Vitaflox-C 25% liquid of M/s Vetz Pharma
	GMP status	Last inspection was conducted on 24-12-2013 and the report concludes renewal of DML by way of formulation.
	Remarks of the Evaluator PEC	Latest inspection report. Species: Poultry & Ruminants Section needs to be verified. Provide specs. Firm has not submitted the reply even after being issued letter and reminder dated 13th Nov, 2017 & 4th Jan, 2018 respectively.
	Decision of 278th meeting of Registration Board.	Deferred for submission of latest GMP inspection report conducted within a period of last 1 year by DRAP.
	Submission by the firm.	Firm has submitted GMP inspection report conducted on 22-06-2021 wherein it is concluded that the firm is operating at an acceptable level of GMP compliance at the time of inspection.
	Remarks of the Evaluator PEC XIII	Inspection report has also mentioned that firm holds DML No. 000033 (by way of formulation) last renewed w.e.f. 09-01-2011. The last inspection was carried out by the panel for renewal of DML on 24-12-13.

	Decision 313th meeting of RB: Deferred for updated GMP and renewal status of the firm.
	Remarks: Firm has submitted latest panel inspection report (for DML renewal) dated 26.10.2022 wherein renewal of DML was recommended. Moreover, copy of updated DML (w.e.f 09.01.2021) has also been submitted.
	Decision: Approved.

Following application of M/s FYNK Pharmaceuticals, Lahore was considered and approved in 324th meeting of Registration Board:

824.	Name, address of Applicant / Marketing Authorization Holder	M/s FYNK Pharmaceuticals, 19 km, GT Road, Kalashah Kaku, Lahore
	Name, address of Manufacturing site.	M/s FYNK Pharmaceuticals, 19 km, GT Road, Kalashah Kaku, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 08-08-2019 is provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of covering letter for renewal of DML and approval letters of licensed 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. 11090 Date: 07/5/2022
	Details of fee submitted	PKR 30000 Slip No. 1530874057
	The proposed proprietary name / brand name	**TENDOL TABLET 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each immediate release Film Coated tablet contains: Tepentadol as Hydrochloride… 50mg
	Pharmaceutical form of applied drug	Tablet (General)
	Pharmacotherapeutic Group of (API)	Opioid Analgesic (ATC code : N02AX06)
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10’s,20’s & 30’s (Alu-Alu Blister)
	Proposed unit price	Rs.500 for 10’s Rs.1000 for 10’s Rs.1500 for 30’s
	The status in reference regulatory authorities	USFDA Approved NUCYNTA 50mg (Tepentadol HCL) Tablet manufactured by Janssen Ortho, LLC, gurabo,
	For generic drugs (me-too status)	Tapento Tablet 50 mg (M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi)
	Name and address of API manufacturer.	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India.

		Certificate No. 19041306 dated 25-04-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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, physical form, manufacturers, description of manufacturing process and controls, 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 is conducted at 40oC ± 2oC / 75% ± 5% RH for 6 months and data is provided for (batch no. TPT50040513, TPT50050513, TPT50050513). The real time stability data is conducted at 30oC ± 2oC / 65% ± 5% RH for 24 months. (TPT50111119, TPT50121119, TPT50131119)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 study is not performed against the innovator / Reference Product CDP has been performed against the same brand that is Plaxodol Tablet 50mg (M/s Jenner Pharma, Skeikhupura) instead of Innovator / Reference Product of same strength.in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India.
API Lot No.	Not Provided
Description of Pack (Container closure system)	The proposed pack size is 10's,20's & 30's Alu-Alu Blister.
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	Not Provided	Not Provided	Not Provided
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		

DOCUMENTS / DATA 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.	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India. Certificate No. 19041306 dated 25-04-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The document regarding import of Tramadol HCL is 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	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Evaluation by PEC:

Following Documents are found deficient:
Provide copy of valid DML.
Provide analytical method verification Protocol and test reports for API Tepentadol Hydrochloride as performed by Drug Product manufacturer.
Pharmaceutical equivalence study and test results are not submitted against Innovator / Reference Product of same strength For Tendol Tablets 100mg.
Comparative Dissolution Profile studies are performed for Tendol Tablets 75mg against Tapento Tablet 75mg manufactured by (M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi instead of Innovator / Reference Product of same strength.
RSD is not calculated for Robustness test as performed during analytical method validation of Drug Product.
Precision and accuracy test and test report in analytical method validation of Drug Product are not submitted.
Provide stability studies summary sheets on Prescribed format as recommended by the DRB in its 293rd meeting including batch No, batch size, manufacturing date, date of initiation, API lot No etc.
Documents for the procurement of API with approval from DRAP (in case of import) along with COA of relevant batch needs to be submitted.
Batch manufacturing record for all batches prepared for stability testing needs to be provided for all strengths.

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

Firm has submitted following reply/documents : Firm has submitted copy of valid DML No. 000494 valid till 10-10-2023. Firm has Provided analytical method verification Protocol and test reports for API Tepentadol Hydrochloride as performed by Drug Product manufacturer. Firm has stated that the innovator Product is Nucynta film coated tablet which is a controlled drug and is only available on prescription , therefore, locally manufactured Topentadol tablet manufactured by Jenner Pharma, Sheikhupura is used for CDP studies. Test reports for Robustness , Precision and accuracy in method validation are submitted. Documents for the procurement of API with approval from DRAP (in case of import) along with COA of relevant batch is submitted. Stability studies summary sheets on Prescribed format as recommended by the DRB in its 293rd meeting including batch No, batch size, manufacturing date, date of initiation, API lot No and storage conditions etc are submitted.
Decision of 324th meeting: 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.

Now the firm has submitted that strength mentioned in agenda was Tepentadol HCl 50mg while applied strength was 75mg. Firm has submitted copies of online challan as well, wherein Tepentadol HCl 75mg was applied against Challan no. 1530874057. Moreover, application of Tepentadol HCl 50mg was already considered and approved in same meeting (Case No 1332) hence instant case is resubmitted as follows:

	Name, address of Applicant / Marketing Authorization Holder	M/s FYNK Pharmaceuticals, 19 km, GT Road, Kalashah Kaku, Lahore
	Name, address of Manufacturing site.	M/s FYNK Pharmaceuticals, 19 km, GT Road, Kalashah Kaku, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 08-08-2019 is provided.
	Evidence of approval of manufacturing facility	Firm has submitted copy of covering letter for renewal of DML and approval letters of licensed 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. 11090 Date: 07/5/2022
	Details of fee submitted	PKR 30000 Slip No. 1530874057
	The proposed proprietary name / brand name	TENDOL TABLET 75mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each immediate release Film Coated tablet contains: Tepentadol as Hydrochloride… 75mg
	Pharmaceutical form of applied drug	Tablet (General)
	Pharmacotherapeutic Group of (API)	Opioid Analgesic (ATC code : N02AX06)
	Reference to Finished product specifications	Innovator Specifications

	Proposed Pack size	10's,20's & 30's (Alu-Alu Blister)
	Proposed unit price	Rs.500 for 10's Rs.1000 for 10's Rs.1500 for 30's
	The status in reference regulatory authorities	USFDA Approved NUCYNTA 75mg (Tepentadol HCL) Tablet manufactured by Janssen Ortho, LLC, gurabo,
	For generic drugs (me-too status)	Tapento Tablet 75 mg (M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi)
	Name and address of API manufacturer.	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India. Certificate No. 19041306 dated 25-04-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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, physical form, manufacturers, description of manufacturing process and controls, 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 is conducted at 40oC ± 2oC / 75% ± 5% RH for 6 months and data is provided for (batch no. TPT50040513, TPT50050513, TPT50050513). The real time stability data is conducted at 30oC ± 2oC / 65% ± 5% RH for 24 months. (TPT50111119, TPT50121119, TPT50131119)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 study is not performed against the innovator / Reference Product Comparative Dissolution Profile studies are performed for Tendol Tablets 75mg against Tapento Tablet 75mg manufactured by (M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi)

	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India.		
API Lot No.	Not Provided		
Description of Pack (Container closure system)	The proposed pack size is 10's,20's & 30's Alu-Alu Blister.		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	Not Provided	Not Provided	Not Provided
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		

DOCUMENTS / DATA 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.	Tapentadol Hydrochloride: M/s Ami Life Sciences Private Limited, Block No. 82/B, ECP Road, Taluka Padra, Gujrat, India. Certificate No. 19041306 dated 25-04-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The document regarding import of Tramadol HCL is 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	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Evaluation by PEC:

Following Documents are found deficient:
Provide copy of valid DML.
Provide analytical method verification Protocol and test reports for API Tepentadol Hydrochloride as performed by Drug Product manufacturer.
Pharmaceutical equivalence study and test results are not submitted against Innovator / Reference Product of same strength For Tendol Tablets 100mg.

Comparative Dissolution Profile studies are performed for Tendol Tablets 75mg against Tapento Tablet 75mg manufactured by (M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi instead of Innovator / Reference Product of same strength.
RSD is not calculated for Robustness test as performed during analytical method validation of Drug Product.
Precision and accuracy test and test report in analytical method validation of Drug Product are not submitted.
Provide stability studies summary sheets on Prescribed format as recommended by the DRB in its 293rd meeting including batch No, batch size, manufacturing date, date of initiation, API lot No etc.
Documents for the procurement of API with approval from DRAP (in case of import) along with COA of relevant batch needs to be submitted.
Batch manufacturing record for all batches prepared for stability testing needs to be provided for all strengths.

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

Firm has submitted following reply/documents :
Firm has submitted copy of valid DML No. 000494 valid till 10-10-2023.
Firm has Provided analytical method verification Protocol and test reports for API Tepentadol Hydrochloride as performed by Drug Product manufacturer.
Firm has stated that the innovator Product is Nucynta film coated tablet which is a controlled drug and is only available on prescription , therefore, locally manufactured Topentadol tablet manufactured by Jenner Pharma, Sheikhupura is used for CDP studies.
Test reports for Robustness , Precision and accuracy in method validation are submitted.
Documents for the procurement of API with approval from DRAP (in case of import) along with COA of relevant batch is submitted.
Stability studies summary sheets on Prescribed format as recommended by the DRB in its 293rd meeting including batch No, batch size, manufacturing date, date of initiation, API lot No and storage conditions etc are submitted.

Decision 234th meeting: 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.

Remarks: Correction in minutes (324th meeting of Registration Board) pertaining to above mentioned case solicited. Please.

Proceeing:
It was apprised to the Board that two product of Tendol 50mg Tablets and Tendol 75mg Tablets were presented and discussed, at S. No. 1332 and 1333, in 324th meeting of Registration Board but during the recording of minutes both product were recorded as tendol 50mg Tablets. Subsequesntly on the intimation of firm the correction in the minutes of 324th registration Board was presented in this meeting. Firm has submitted copies of online challan as well, wherein Tepentadol HCl 75mg was applied against Challan no. 1530874057.
Decision: Registration Board corrected the minutes of 324th meeting of Registration Board and approved TENDOL TABLET 75mg against Fee Challan No. against Challan no. 1530874057 which were indavetently mentioned as TENDOL TABLET 50 mg in 324th meeting of registration Board.

825.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter

		is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26862 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 003359682193
	The proposed proprietary name / brand name	BRIPROFEN 200 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofen …… 200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's, 20's,30's,100's,200's Blister (1000's Jar Pack)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Brand Name: Pando (200mg) Tablet Registration holder: M/s Efroze Pharma(Pvt) Ltd , Karachi. Registration Number: 012062
	Name and address of API manufacturer.	Ibuprofen (BP) : M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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 related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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 24 months. (Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)
	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 not been established/submitted with innovator Product, but with Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi. CDP has been performed against the same brand that is Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi instead of Innovator / Reference Product in Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method (BP) of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019		
API Lot No.	API batch No. Zibu21-029		
Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B-1	T-B-2	T-B-3
Batch Size	1086 Tablets	1086 Tablets	1086 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	03-05-2021	03-05-2021	03-05-2021
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 Submitted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not required.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	For march 2021 while the stability is initiated in May 2021.
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:
GMP certificate of API manufacturer is issued on 22-05-2019.
Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
Detail of equipment's/machinery as used in Product Development if not submitted.
Product Assay method as mentioned in Product Development is different from the one specified in (USP).
Specificity Method and test reports are not submitted for Drug Product.
%RSD is not calculated for tests performed for Drug Product analytical method verification.
In BMR check points include i.e. average tablet size to be 460mg, and target weight is also 460mg while the Tablet is of 200mg.
Chromatograms submitted along with stability data sheets in Briprofin 200mg tablets, date of data processing/acquiring is mentioned as 11-03-2021 while the stability is initiated in May 2021.

Decision of 323rd meeting of RB : Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Updated submission:

Sr No	Observation	Reply	Remarks
1.	GMP certificate of API manufacturer is issued on 22-05-2019.	API manufacturer has applied for renewal of GMP. Copy of valid DML is attached.	Submitted copy of DML is valid till 14.06.2021. updated GMP status is still required
2.	Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted	Analytical method verification of API from Drug product manufacturer is provided	Analytical method verification report/test results from Drug Substance manufacturer yet to be provided
3.	Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.	Detail of excipients along with specifications and compatibility studies is provided	Complied
4.	Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed	As weight of API is greater than 25mg so the weight variation is applied which is	Justified

	and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms	the parameter of uniformity of dosage unit as per USP. In stability report weight variation is performed and results are mentioned.	
5.	Detail of equipment's/machinery as used in Product Development if not submitted	Submitted	Complied
6.	Product Assay method as mentioned in Product Development is different from the one specified in USP.	Product Assay method is same as specified in USP. However for record purpose method is attached.	Verified.
7.	Specificity Method and test reports are not submitted for Drug Product.	Verification Method and test reports are provided wherein specificity parameter was not provided	Not Complied
8.	%RSD is not calculated for tests performed for Drug Product analytical method verification.	Analytical method verification study is provided wherein %RSD is mentioned.	Verified
9.	In BMR check points include i.e. average tablet size to be 460mg, and target weight is also 460mg while the Tablet is of 200mg.	Production weight of Briprofen 200mg tablet is 460mg and its average weight is also obtained in 460mg range. Selected check points/parameters are for Briprofen 200mg tablet.	Justified
10.	Chromatograms submitted along with stability data sheets in Briprofin 200mg tablets, date of data processing/acquiring is mentioned as 11-03-2021 while the stability is initiated in May 2021	Format of date on HPLC chromatograms was MM.DD.YY. Stability study was initiated in May 2021 and 6 months stability was completed on November 2021 and was tested on 3rd of Nov 2021. As the format of date on HPLC system is MM.DD.YY that's why date of data processing/acquiring shown as 11.03.2021.	Justified
Decision 326th meeting: Deferred for submission of Analytical Verification study/test reports of Drug Product including specificity parameter to be provided from Drug Product manufacturer.			
Remarks of Assessor: Firm has provided Analytical Verification study/test reports of Drug Product including specificity			

parameter from Drug Product manufacturer.		
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.**		
826	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26861 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 0137541252
	The proposed proprietary name / brand name	BRIPROFEN 400 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofen …… 400mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10’s, 20’s,30’s,100’s,200’s Blister (1000’s Jar Pack)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved, (Ibuprofin 400mg by The Boots Company PLC 1 Thane Road West Nottingham NG2 3AA)
	For generic drugs (me-too status)	Brand Name: Zafen (400mg) Tablet Registration holder: M/s Xenon Pharma , Lahore. Registration Number: 050650
	Name and address of API manufacturer.	Ibuprofen (BP) : M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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 related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, 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 24 months. (Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)
	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 not been established/submitted with innovator Product, but with Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi. CDP has been performed against the same brand that is Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi instead of Innovator / Reference Product in Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method (BP) of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019	

API Lot No.	API batch No. Zibu21-029		
Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B-1	T-B-2	T-B-3
Batch Size	1162 Tablets	1162 Tablets	1162 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	05-05-2021	05-05-2021	05-05-2021
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 Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : 22-05-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not required.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms, Raw data sheets, summary data sheets are submitted only at 0 months (May 2021)
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:
GMP certificate of API manufacturer is issued on 22-05-2019.
Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
Detail of equipment's/machinery as used in Product Development is not submitted.
Product Assay method as mentioned in Product Development is different from the one specified in (USP).
Specificity Method and test reports are not submitted for Drug Product.
%RSD is not calculated for tests performed for Drug Product analytical method verification.
Detail of excipients along with specifications is not submitted as the excipients used in Product development are different from the ones in innovator product.
Chromatograms, Raw data sheets, summary data sheets are submitted only at 0 months (May 2021).

Decision of 323rd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Sr No	Observation	Reply	Remarks
1.	GMP certificate of API manufacturer is issued on 22-05-	API manufacturer has applied for	Submitted copy of DML is valid till 14.06.2021.

	2019.	renewal of GMP. Copy of valid DML is attached.	updated GMP status is still required
2.	Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted	Analytical method verification of API from Drug product manufacturer is provided	Analytical method verification report/test results from Drug Substance manufacturer yet to be provided
3.	Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.	Detail of excipients along with specifications and compatibility studies is provided	Complied
4.	Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms	As weight of API is greater than 25mg so the weight variation is applied which is the parameter of uniformity of dosage unit as per USP. In stability report weight variation is performed and results are mentioned.	Justified
5.	Detail of equipment's/machinery as used in Product Development if not submitted	Submitted	Complied
6.	Product Assay method as mentioned in Product Development is different from the one specified in USP.	Product Assay method is same as specified in USP. However for record purpose method is attached.	Verified.
7.	Specificity Method and test reports are not submitted for Drug Product.	Verification Method and test reports are provided wherein specificity parameter was not mentioned	Not complied
8.	%RSD is not calculated for tests performed for Drug Product analytical method verification.	Analytical method verification study is provided wherein %RSD is mentioned.	Verified
9.	Chromatograms, Raw data sheets, summary data sheets are submitted only at 0 months (May 2021).	Chromatograms, Raw data sheets, summary data sheets are not provided against rest of the time points.	Not complied
Decision 326th meeting: Deferred for following reasons: Analytical Verification study/test reports of Drug Product including specificity parameter to be provided from Drug Product manufacturer. Chromatograms, Raw data sheets, summary data sheets of stability data to be provided against each time points.			
Remarks of Assessor: Firm has provided Analytical Verification study/test reports of Drug Product including specificity			

parameter from Drug Product manufacturer. Firm has submitted Chromatograms, Raw data sheets, summary data sheets of all three stability batches against each time point.
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.**

827.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Recibet Ointment 50mcg/0.5mg
	Composition	Each Gram Contains: Calcipotriol As Monohydrate…50mcg Betamethasone As Dipropionate…0.5mg
	Diary No. Date of R& I & fee	Dy. No.11757 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
	Pharmacological Group	Calcipotriol, Combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has submitted copy of BP specs. available in BP.
	Pack size & Demanded Price	15g; Leader price
	Approval status of product in Reference Regulatory Authorities.	Calcipotriol (as monohydrate) /Betamethasone (as dipropionate) Sandoz 50 micrograms per g / 500 micrograms per g ointment. MHRA approved
	Me-too status	Calbet Ointment. Reg. No. 84025
	GMP status	The firm was inspected on 15-16.01.2018, wherein GMP was rated Good.
	Remarks of the Evaluator.	The drug product specifications have not been evaluated.
		Revised the pharmacological group from antipsoriatics to Calcipotriol, Combinations. Mentioned eye ointment form in the manufacturing outlines. Later, revised it. Initially applied for Betamethasone As Dipropionate, then, revised Betamethasone As Dipropionate to Betamethasone in the label claim. Already adjusted the weights of API as per equivalency factors. Then, revised Calcipotriol As Monohydrate to Calcipotriol as Monohydrate 52.2mg eq. to calcipotirol..50mcg in master formula and 5.24mg in master formula (100kg). Already adjusted the weights of API as per equivalency factors the, revised Betamethasone As Dipropionate 0.643mg to Betamethasone as Dipropionate eq. to betamethasone… 0.5mg in the unit formula and 64g in master formula (100kg). Submitted Rs. 7500/- fee, challan- 6877773434
	Decision 317th meeting: Deferred for: Revision of label claim as per the innovator's product along with submission of Rs.22500/-. Submission of valid GMP inspection report conducted within a period of last three years.	
	Remarks: Firm has submitted fee of Rupees Rs.22500 (deposit slip no 46527293722) dated 22.06.2023 for revision of label claim as per innovator: Each gram contains: Calcipotriol (as monohydrate)……..50 micrograms Betamethasone (as dipropionate)……. 0.5 mg	

	Valid GMP inspection report conducted within a period of last three years (dated 30.09.2021) wherein firm was operating with Good level of GMP compliance.
	Decision: Approved

828.	Name, address of Applicant / Importer	M/s. Zam Zam Pharmaceutical, Karachi
	Details of Drug Sale License of importer	License No: 1205 Address: Suit no. 16 Beaumont Plaza, Beaumont Road, Karachi Validity: 15-FEB-2022. Status: License to sell drugs as distributor Renewal: Renewal application submitted on 14-Feb-2022.
	Name and address of marketing authorization holder (abroad)	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Ergene/TEKİRDAĞ/TURKEY
	Name, address of manufacturer(s)	POLİFARMA İLAÇ SAN. VE TİC. A.Ş. (Bulk Manufacturer) Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Ergene/TEKİRDAĞ/TURKEY AROMA İLAÇ SAN. LTD. ŞTİ (Primary and Secondary Packages) Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1, Kat: 2 Ergene/TEKİRDAĞ/TURKEY
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.2021/1411) dated 29-04-2021 Republic of Turkey Ministry of health Turkish Medicines and Medical Devices Agency for 200/mg 20ml Emulsion for I.V Injection/Infusion. 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. Furthermore, the CoPP is valid till 29-04-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from POLİFARMA İLAÇ SAN. VE TİC. A.Ş. The letter species that the manufacturer appoints M/s Zam Zam Pharmaceutical to register their products in Pakistan. The authorization letter is valid till 14-12-2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import

		☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 23850 Dated: 31-Aug-2021
	Details of fee submitted	PKR 150,000/-: 02-07-2021
	The proposed proprietary name / brand name	PROPOFOL-PF 1% 200mg/20ml emulsion for I.V. injection/infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of emulsion for injection/ infusion contains 10 mg of propofol as active ingredient.
	Pharmaceutical form of applied drug	Emulsion for injection or infusion. White coloured emulsion
	Pharmacotherapeutic Group of (API)	General Anaesthetic ATC-code: NOlAXlO
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	5x20ml ampoule in a box
	Proposed unit price	Rs 2400/-
	The status in reference regulatory authorities	Diprivan – Aspen Pharma – Ireland Fresenius Kabi – Austria
	For generic drugs (me-too status)	Propofol Abbot I.V. Injection, 10mg Each ml of emulsion for injection/ infusion contains 10 mg of propofol. Reg.no: 023142 20mlx5's – Rs 1367/=
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Bachem S.A Succursale De Vionnaz Route Du Simplon 22 CH-1895 Vionnaz Switzerland
	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 stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25oC ± 2oC 60% 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	Not 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	European Pharmacopoeia 20 mL, Type I, Clear, Glass Ampoule
	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 (40ºC ± 2ºC), %75 ± 5 Humidity for 6 months. The real time stability study data is conducted at (30ºC ± 2ºC), % 65 ± 5 Humidity for 24 months. (Batch # A06110007A, A06110009A, A06110010A)

Evaluation by PEC:

The formulation is different from RRA
Certificate of Analysis (COA) of both drug substance(s) manufacturer and drug product manufacturer:
Stability data of 3 batches at accelerated and real time conditions:

S.#	Section #	Deficiencies	Zam Zam Reply
1	1.6.5	Valid Latest DSL which should have been provided for application.	Copy of valid DSL licence is attached along with renewal dated 14 feb 2022
2	1.33	Importer shall provide Certificate of Pharmaceutical Product (CoPP) / Free Sale Certificate issued by the relevant regulatory authority in the country of origin and name of exporting country.	Original CoPP # 29/04/2021 already provided with dossier valid till 29-04-2023, facility is GMP certified
3	1.5	Original, Legalized, and valid GMP of drug product manufacturer is required.	Original legalized and valid GMP of POLIFARMA was provided dated 31Aug.2021.
4	2.3.P.4	The excipients are different from the reference product justification is needed	The declaration letter is provided. PROPOFOL-PF 1% 200 mg/20 mL Emulsion for I.V. Injection/Infusion product is qualitatively and quantitatively equivalent to Propofol 1% Fresenius Anaesthetic Agent for Intravenous Injection or Infusion. The excipients contained in PROPOFOL-PF 1% 200 mg/20 mL Emulsion for I.V. Injection/Infusion are the same as reference product PROPOFOL 1% Fresenius Anaesthetic Agent for Intravenous Injection or Infusion
5	3.2.S.44	Certificate of Analysis (COA) of both drug substances(s) manufacturer and drug product manufacturer Stability Data of 3 batches at accelerated and real time conditions	Certificate of analysis for 3 different batches conducted by the API manufacturer and the finished product manufacturer to the Propofol API used in production by Polifarma İlaç are provided. The API manufacturer does not have to proceed stability study each batches that manufactured. The stability data of the batches produced by the API manufacturer within the scope of process validation are provided.
6	3.2.S.4.3	Analytical method Verification studies	Related substances and assay analytical method

		including specificity, accuracy, and repeatability (method precision) performed by the Drug manufacturer drug substance (s) shall be submitted.	verification protocol and reports are provided
7	3.2.S.7	The name on stability data of drug substance is not clear not indicating clearly that who is conducting this stability.	The up-to-date signed and stamped stability data of drug substance is provided by BACHEM, Switzerland.
8	3.2.P.3.5	Process validation reports including the protocols and results for critical process steps shall be provided.	Latest PVP and PVR are provided

Decision 321st meeting : Deferred for submission of Pharmaceutical equivalence studies against the innovator drug product.

Remarks of Assessor:
Firm has submitted Pharmaceutical equivalence studies against reference product i.e Propofol 1% IV injection by FRESENIUS KABI DEUTSCHLAND GMBH (EMA approved) Batch No 10LK5235.
Following quality parameters were tested such as: Particles size, Globular size, Assay, free fatty acids, organic impurities. BET and sterility test.

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.**

Molecules/drugs reported short in the market:

M/s Ghani Brothers, Karachi vide letter dated 01-03-2023 has informed that they have applied for registration of Freefol-MCT 1% Injection 20ml Vial (Propofol 10mg/ml), manufactured by Daewon Pharm, Co Ltd, South Korea on 31-08-2022. The firm further informed that currently there is severe shortage of Propofol injection which is also an essential drug and also enclosed the minutes of 1st meeting of the Cabinet Committee on supplies of medicines and medical devices of Specialized Healthcare & Medical Education Department (SHC&ME), Govt. of Punjab held on 20-02-2023 in which it was discussed about shortage of medicines including Propofol Injection. The firm has requested to include the above subject mentioned product in the upcoming registration board meeting on priority basis, so that the product can be approved earliest possible to contribute in removing the shortage of Propofol injection from the market and serve the patients. In the light of above and on the directions of Chairman RB, following application(s) of Propofol are placed before the Board for its consideration:

829.	Name, address of Applicant / Importer	M/s Ghani Brothers, 1st Floor, Karimjee Building, Opp HBL Bank, North Napier Road, Karachi, Pakistan
	Details of Drug Sale License of importer	License No: 094 Address:. 1st Floor, Karimjee Building, Opp HBL Bank, North Napier Road, Karachi, Pakistan Address of Godown: NA Validity:.28-04-2023 Status: License to sell drugs as wholesale Renewal: NA
	Name and address of marketing authorization holder (abroad)	Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-gil Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-gil Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	South Korea

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate No 2021-A1-0028 and GMP certificate issued by Food and Drug Administration Republic of South Korea for Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml). 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 year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Sole Agency Agreement from Daewon Pharm Co. Ltd, South Korea. The letter species that the manufacturer appoints M/s Ghani Brothers. to register their products in Pakistan. The authorization letter is valid till 19-03-2026
	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. 24632 : 31-08-2022
	Details of fee submitted	PKR 150,000/-: on 11-10-2021, Challan No 623767235857
	The proposed proprietary name / brand name	Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Propofol…….200mg
	Pharmaceutical form of applied drug	White color Emulsion for injection Packed in vial.
	Pharmacotherapeutic Group of (API)	General Anesthetic properties (N01AX10)
	Reference to Finished product specifications	European pharmacopeia
	Proposed Pack size	20ml vial x10’s
	Proposed unit price	As per brand leader
	The status in reference regulatory authorities	Propofol Lipuro 1% (USFDA Approved).
	For generic drugs (me-too status)	Propofol 1% MCT Fresenius Injection of Fresenius (Reg #099485)
	Module-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	Bachem SA, Succursale de Vionnaz, 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, 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 as well as real time conditions. The real time stability data is conducted at 25 °C /60 % 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 performed against reference product i.e Fresofol MTC 1% Injection Lot No 16FC0249. All quality parameters as per official monograph were compared against Test product Lot No N001
	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 clear glass vial
	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. Batch No 19034. 19048, 19062 The real time stability study data is conducted at 30 °C / 75% RH. The real time stability study data of 3 batches is for 24months. Batch No R015, R016, R017.
Decision 326th meeting: Registration Board decided to refer the case to Authority for seeking guidance upon priority consideration of the applied formulation.		
Remarks: Since Authority in its 165th held on 20th July 2023, meeting has decided to consider "Propofol injection" as priority molecule hence case is resubmitted for consideration please.		
Decision: Approved. • **Manufacturer will place first three production batches on long-term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

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

Case 01: M/s Oncogen Pharma (Pvt.) Limited WH-26 & 27-A3, Korangi Creek Industrial Park, Karachi. was granted License w.e.f. 04-07-2022 with following sections: -

i. Tablet (Oncology)
ii. Capsule (Oncology)

831.	**Name, address of Applicant / Marketing Authorization Holder**	Oncogen Pharma (Pvt.) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	Oncogen Pharma (Pvt.) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm was granted DML by way of Formulation w.e.f. 04-07-2022 in 287th meeting of CLB held on 24th June, 2022, for following two (02) sections: - i. Tablet (Oncology) ii. Capsule (Oncology)
	Evidence of approval of manufacturing facility	The Firm was granted DML by way of Formulation w.e.f. 04-07-2022 in 287th meeting of CLB held on 24th June, 2022, for following two (02) sections: - i. Tablet (Oncology) iii. Capsule (Oncology)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5685 dated 28-02-2023.
	Details of fee submitted	Slip No. 67560067722 PKR 30,000/- dated 26-01-2023.
	The proposed proprietary name / brand name	**NILOGEN 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Nilotinib HCl Monohydrate (Ph. Eur.) equivalent to Nilotinib…… 150 mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	Hard gelatin capsule with blue color cap and off-white color body
	Pharmaceutical form of applied drug	L01EA03, Antineoplastic And Immuno-modulating Agents, BCR-ABL tyrosine kinase inhibitors.

	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	7 x 4's (28's) 10 x 4's (40's) 28 x 4's (112's) 30 x 4's (120's)
	Proposed unit price	The firm have proposed as follows in their application. 7 x 4's (28's) = 80,000/- 10 x 4's (40's) = 114,286/- 28 x 4's (112's) =320,000/- 30 x 4's (120's) =342,857/-
	The status in reference regulatory authorities	Tasigna (Nilotinib) 150mg Oral Capsules by M/s Novartis Pharmaceuticals Corporation (USFDA Approved).
	For generic drugs (me-too status)	Nitonib 150mg Capsule (Reg. No. 094596) by M/s Pharmasol (Pvt.) Ltd. Lahore.
	Name and address of API manufacturer.	M/s Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, 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:	Official monograph of Nilotinib HCl Monohydrate is available in European Pharmacopeia. Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and 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: (C39-202005002, C39-202005003 and C39-202005004)
	Module-III Drug Product:	Official monograph of Nilotinib Capsules is not present in any pharmacopeia. 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 Tasigna 150mg capsule, Batch No. LF7595 by Novartis Pharma Stein AG, Stein, Switzerland by performing quality tests (Appearance, Assay, Dissolution and Impurities). CDP has been performed against Tasigna 150mg capsule, Batch No. LF7595 by Novartis Pharma Stein AG, Stein, Switzerland in Acidic medium (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	Method validation studies have submitted including, system suitability, specificity, linearity, accuracy, precision, robustness and range.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, P.R. China.		
API Lot No.	C39-202208001 and C39-202208002		
Description of Pack (Container closure system)	Alu/ PVDC blisters packed in unit carton (28's, 40's, 112's and 120'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.	002NS03-150	002NS04-150	002NS05-150
Batch Size	1759 Capsules	1759 Capsules	1759 Capsules
Manufacturing Date	26-09-2022	07-10-2022	07-10-2022
Date of Initiation	20-10-2022	20-10-2022	20-10-2022
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)	None 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 Drug Manufacturing License (DML) License no. Lu20160171 issued by Shandong FDA China. (valid till 10-12-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm have submitted Form 6 (Drug Import License) bearing no. K-774556896948 dated

		30-07-2022 to import 4.5Kg Nilotinib HCl monohydrate from Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, P.R. China. The firm have submitted copy of Commercial Invoice, Packing List and AWB. **However Clearance Certificate (for Import against above mentioned Drug Import License) from Assistant Director, DRAP Karachi vide Commercial Invoice No. SDLX20228701M dated Aug 10th 2022 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 data of stability batches along with batch manufacturing record, analytical record and respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted compliance record and 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 & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 11125 dated 04 MAY 2023.

i. **Clearance Certificate (for Import against above mentioned Drug Import License) from Assistant Director, DRAP Karachi vide Commercial Invoice No. SDLX20228701M dated Aug 10th 2022 has not been 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.**

832.	**Name, address of Applicant / Marketing Authorization Holder**	Oncogen Pharma (Pvt.) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	Oncogen Pharma (Pvt.) Limited WH-26 & 27-A3 , Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The Firm was granted DML by way of Formulation w.e.f. 04-07-2022 in 287th

		meeting of CLB held on 24th June, 2022, for following two (02) sections: - ii. Tablet (Oncology) iii. Capsule (Oncology)
	Evidence of approval of manufacturing facility	The Firm was granted DML by way of Formulation w.e.f. 04-07-2022 in 287th meeting of CLB held on 24th June, 2022, for following two (02) sections: - ii. Tablet (Oncology) iv. Capsule (Oncology)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5684 dated 28-02-2023.
	Details of fee submitted	Slip No. 309651830 PKR 30,000/- dated 26-01-2023.
	The proposed proprietary name / brand name	**NILOGEN 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Nilotinib HCl Monohydrate (Ph. Eur.) equivalent to Nilotinib……. 200mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	Hard gelatin capsule with purple color cap and off-white color body.
	Pharmaceutical form of applied drug	L01EA03, Antineoplastic And Immuno-modulating Agents, BCR-ABL tyrosine kinase inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	7 x 4's (28's) 10 x 4's (40's) 28 x 4's (112's) 30 x 4's (120's)
	Proposed unit price	The firm have proposed as follows in their application. 7 x 4's (28's) = 100,000/- 10 x 4's (40's) = 142,857/- 28 x 4's (112's) =400,000/- 30 x 4's (120's) =428,571/-
	The status in reference regulatory authorities	Tasigna (Nilotinib) 200mg Oral Capsules by M/s Novartis Pharmaceuticals Corporation (USFDA Approved).
	For generic drugs (me-too status)	Nitonib 200mg Capsule (Reg. No. 094597) by M/s Pharmasol (Pvt.) Ltd. Lahore.
	Name and address of API manufacturer.	M/s Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, 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:	Official monograph of Nilotinib HCl Monohydrate is available in European Pharmacopeia. Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and 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: (C39-202005002, C39-202005003 and C39-202005004)
	Module-III Drug Product:	Official monograph of Nilotinib Capsules is not present in any pharmacopeia. 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 Tasigna 200mg capsule, Batch No. LF2154 by Novartis Pharma Stein AG, Stein, Switzerland by performing quality tests (Appearance, Assay, Dissolution and Impurities). CDP has been performed against Tasigna 200mg capsule, Batch No. LF2154 by Novartis Pharma Stein AG, Stein, Switzerland in Acidic medium (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	Method validation studies have submitted including, system suitability, specificity, linearity, accuracy, precision, robustness and range.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, P.R. China.		
API Lot No.	C39-202208001 and C39-202208002		
Description of Pack (Container closure system)	Alu/ PVDC blisters packed in unit carton (28's, 40's, 112's and 120'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.	002NS03-200	002NS04-200	002NS05-200
Batch Size	1866 Capsules	1866 Capsules	1866 Capsules
Manufacturing Date	26-09-2022	07-10-2022	07-10-2022
Date of Initiation	20-10-2022	20-10-2022	20-10-2022
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)	None 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 Drug Manufacturing License (DML) License no. Lu20160171 issued by Shandong FDA China. (valid till 10-12-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm have submitted Form 6 (Drug Import License) bearing no. K-774556896948 dated 30-07-2022 to import 4.5Kg Nilotinib HCl monohydrate from Shandong Lixin Pharmaceutical Co., Ltd. No. 9, Jinyang Road, Gaoqing Economic Development Zone, Zibo City, Shandong Province, P.R. China. The firm have submitted copy of Commercial Invoice, Packing List and AWB. **However Clearance Certificate (for Import against above mentioned Drug Import License) from Assistant Director, DRAP Karachi vide Commercial Invoice No. SDLX20228701M dated Aug 10th 2022 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 data of stability batches along with batch manufacturing record, analytical record and respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product	Firm has submitted compliance record and audit trail reports on product testing.

	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 & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:
Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 11126 dated 01-06-2023.

i. **Clearance Certificate (for Import against above mentioned Drug Import License) from Assistant Director, DRAP Karachi vide Commercial Invoice No. SDLX20228701M dated Aug 10th 2022 has not been submitted.**

Decision: Approved with Innovator's specifications.

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

Case 02: M/s. Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot was granted New DML w.e.f. 13-09-2021 with following sections: -

i. Tablet, capsule, and oral liquid (general)
ii. Liquid injectable - vial & ampoule (general)
iii. Capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections.

833.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 3130 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- Dated 14-12-2022

		(Challan / Receipt # 98850219)
	The proposed proprietary name / brand name	**Bezin 0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Sustained released pellets of Tamsulosin HCl equivalent to Tamsulosin … 0.4mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Drugs used in benign prostatic hypertrophy, Alpha-adrenoreceptor antagonists.
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2 x 10's, 1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omsula 0.4 mg prolonged-release capsule of M/s Gedeon Richter Plc. Gyömrői út 19-21. 1103 Budapest, Hungary (MHRA Approved).
	For generic drugs (me-too status)	Tamsolin 0.4mg Capsule (Reg. No. 50392) of M/s Getz Pharma Pvt. Ltd. Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 Tamsolin 0.4mg Capsule of M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product against Tamsolin 0.4mg Capsule of M/s Getz Pharma in pH 1.2 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability 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.	TMS363		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 1x10's and 2x10'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.	T001	T002	T003
Batch Size	840 Capsules	840 Capsules	840 Capsules
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	02/05/2022	02/05/2022	02/05/2022
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)	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. F.3-26/2019-Addl. Dir. (QA&LT-1)-56 dated 22nd August, 2022 issued based on inspection conducted on 14-06-2022 has been 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.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software	**Firm has not submitted certificate of 21**

	21CFR & audit trail reports on product testing	**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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Label claim has been mentioned as "Sustained released pellets of Tamsulosin HCl equivalent to Tamsulosin HCl 0.4mg". Please clarify/correct the same.	The firm submitted that the label claim for Bezin 0.4mg is as "sustained release pellets of Tamsulosin HCl equivalent to Tamsulosin 0.4mg" in dossier stating that there was a writing mistake.
ii.	Please confirm the Batch Size of Trial Batches as the same have been mentioned as 330 Capsules each & 840 Capsules each on separate instances.	The firm submitted that the batch size for trial is 840 capsules each, stating 330 was a typographic error.
iii.	Please provide documents for the procurement of API. Also confirm API Lot No. TMS363 or TM5363.	The firm submitted copy of Invoice for procurement of API Lot No. TMS363.
iv.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not provided.
v.	Please provide CDP Results for mentioned Time points.	Submitted.
vi.	1.3.7 Signatures of Authorized Persons are missing in provided document as required in this section of CTD application.	Submitted.
vii.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence and CDP.	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/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.**

834.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 10396 dated 19 APR 2023
	Details of fee submitted	PKR 30,000/- Dated 21-03-2023 (Challan / Receipt # 0678754635)
	The proposed proprietary name / brand name	**Moxi-Q 400mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin HCl equivalent to Moxifloxacin … 400mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Quinolone Anti-bacterial, Fluoroquinolones
	Pharmaceutical form of applied drug	Tablets
	Reference to Finished product specifications	USP
	Proposed Pack size	1×5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox 400 mg film-coated tablets of Bayer plc 400 South Oak Way Reading RG2 6AD, UK, (MHRA Approved).
	For generic drugs (me-too status)	Avelox Tablet (Reg. No. 024653) of M/s Bayer Pakistan (Pvt.) Limited.
	Name and address of API manufacturer.	M/s Pharmagen Limited 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 Avelox 400mg Tablet of M/s Bayer Pakistan (Pvt.) Limited Limited by performing quality tests (Identification, Assay, Dissolution and uniformity of dosage unit). Firm has submitted CDP results of their product against Avelox 400mg Tablet of M/s Bayer Pakistan (Pvt.) Ltd in pH 1.2, pH4.5 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited 34- Km, Ferozepur Road, Lahore.		
API Lot No.	00510711/007/2022		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 1x5'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.	TTR016	TTR017	TTR018

Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	20-10-2022	20-10-2022	20-10-2022
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.	**Copy of GMP Certificate No. 129/2020-DRAP(AD/1998630-530) dated 02-09-2020 based upon evaluation conducted on 22-06-2020 has been submitted. Valid for two years.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local Purchase. Copy of Invoice No. 645 dated 24/09/2022 for 01Kg of Moxifloxacin HCl above mentioned batch 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 were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please provide 06th Month Real Time Point Stability Study Testing Data.	Submitted.
ii.	Firm has not submitted certificate of 21 CFR compliance for the HPLC system.	Submitted.
iii.	GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin was valid for two years from 22-06-2020. Please provide a valid copy of the same	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.**

835.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 7391 dated 14 MAR 2023
	Details of fee submitted	PKR 30,000/- Dated 13-02-2023 (Challan / Receipt # 5908118217)
	The proposed proprietary name / brand name	**Quinn 250mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin … 250mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Quinolone Anti-bacterial, Fluoroquinolone
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO 250mg Tablets of M/s Bayer Hlthcare (USFDA Approved).
	For generic drugs (me-too status)	Ciproxin 250mg Tablets (Reg. No. 10118) of M/s Bayer Pakistan Pvt. Ltd.
	Name and address of API manufacturer.	M/s Pharmagen Limited 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Ciproxin 250mg Tablets of M/s Bayer Pakistan Pvt. Ltd by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product against Ciproxin 250mg Tablets of M/s Bayer Pakistan Pvt. Ltd in pH 1.2, pH4.5 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited 34- Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/026/2022		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 1x10'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.	QUINN TTR001	QUINN TTR002	QUINN TTR003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022

Date of Initiation	19-05-2022	19-05-2022	19-05-2022
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)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. 000325 w.e.f. 25-10-2015 and subsequent renewal application dated 11 AUG 2020 has been 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.	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 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 not submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers for applied product.**

Remarks of Evaluator:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
ii.	Please provide documents for the procurement of API.	**The firm has submitted copy of Invoice No. 646 dated 24/09/2022 from M/s Pharmagen Lahore for API Lot. 00510011-01/026/2022. However the Trial Batches have been manufactured and placed on Stability in 05/2022. Justification is required.**
iii.	Please provide record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers for applied product.	Submitted.
iv.	Please provide approval of API and GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
v.	Real Time Stability Study Data of API has been submitted for 12 Months only whereas applicant has mentioned that the same was conducted for 36 Months. Please clarify.	Submitted.

vi.	Submitted Undertakings / Commitments are without signatures? Please clarify.	Submitted.
vii.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence and CDP	Submitted.

Decision: Registration Board deferred the case for justification of following observation:
"The firm has submitted copy of Invoice No. 646 dated 24/09/2022 from M/s Pharmagen Lahore for API Lot. 00510011-01/026/2022. However the Trial Batches have been manufactured and placed on Stability in 05/2022."

836.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 7392 dated 14 MAR 2023
	Details of fee submitted	PKR 30,000/- Dated 13-02-2023 (Challan / Receipt # 5581284562)
	The proposed proprietary name / brand name	**Quinn 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin … 500mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Quinolone Anti-bacterial, Fluoroquinolone
	Pharmaceutical form of applied drug	Tablet
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO 500mg Tablets of M/s Bayer Hlthcare (USFDA Approved).
	For generic drugs (me-too status)	Ciproxin 500mg Tablets (Reg. No. 107222) of M/s Bayer Pakistan Pvt. Ltd.

	Name and address of API manufacturer.	M/s Pharmagen Limited 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Ciproxin 500mg Tablets of M/s Bayer Pakistan Pvt. Ltd by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product against Ciproxin 500mg Tablets of M/s Bayer Pakistan Pvt. Ltd in pH 1.2, pH4.5 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability for drug substance as well as

		drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited 34- Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/026/2022		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 1x10'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.	TTR001	TTR002	TTR003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	19-05-2022	19-05-2022	19-05-2022
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)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. 000325 w.e.f. 25-10-2015 and subsequent renewal application dated 11 AUG 2020 has been 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.	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 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 not submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers for applied product.**

Remarks of Evaluator:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
ii.	Please provide documents for the procurement of API.	**The firm has submitted copy of Invoice No. 646 dated 24/09/2022 from M/s Pharmagen Lahore for API Lot.**

		00510011-01/026/2022. However the Trial Batches have been manufactured and placed on Stability in 05/2022. Justification is required.
iii.	Please provide record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers for applied product.	Submitted.
iv.	Please provide approval of API and GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted.
v.	Real Time Stability Study Data of API has been submitted for 12 Months only whereas applicant has mentioned that the same was conducted for 36 Months. Please clarify.	Submitted.
vi.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence and CDP.	Submitted.

Decision: Registration Board deferred the case for justification of following observation: "The firm has submitted copy of Invoice No. 646 dated 24/09/2022 from M/s Pharmagen Lahore for API Lot. 00510011-01/026/2022. However the Trial Batches have been manufactured and placed on Stability in 05/2022."

837.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 5909 dated 02 MAR 2023
	Details of fee submitted	PKR 30,000/- Dated 20-12-2022 (Challan / Receipt # 8669126225)
	The proposed proprietary name / brand name	**QP-Zole 20mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatine capsule contains: Enteric coated pellets of Esomeprazole magnesium equivalent to Esomeprazole … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), Proton pump inhibitors.
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Esomeprazole 20mg Gastro-resistant Capsules of M/s Accord, Barnstaple, EX32 8NS, UK, (MHRA Approved).
	For generic drugs (me-too status)	Nexum 20mg Capsule (Reg. No. 33890) of M/s Getz Pharma Pvt. Ltd. Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 of M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product against Nexum 20mg Capsule of M/s Getz Pharma in pH 1.2 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability 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.	EMZ-002/2021		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 Capsules	658 Capsules	658 Capsules
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	14-10-2021	14-10-2021	14-10-2021
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)	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. F.3-26/2019-Addl. Dir. (QA&LT-1)-56 dated 22nd August, 2022 issued based on inspection conducted on 14-06-2022 has been 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.	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 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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
ii.	Please provide documents for the procurement of API. Also confirm API Lot No. as 002/2021 or 002/2022.	**The firm has submitted copy of Invoice No. 802550 dated 21-Apr-2022 from M/s Vision Pharma Islamabad for API Lot. EMZ-002/2021. However the Trial Batches have been manufactured and placed on Stability in 10/2021. Justification is required.**
iii.	Please provide CDP Results for mentioned Time points along with supporting documents.	Submitted.
iv.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence and CDP	Submitted.

Decision: Registration Board deferred the case for justification of following observation:
The firm has submitted copy of Invoice No. 646 dated 24/09/2022 from M/s Pharmagen Lahore for API Lot. 00510011-01/026/2022. However the Trial Batches have been manufactured and placed on Stability in 05/2022.

838.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 3132 dated 02 FEB 2023
	Details of fee submitted	PKR 30,000/- Dated 12-12-2022 (Challan / Receipt # 10591410096)
	The proposed proprietary name / brand name	**QP-Zole 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatine capsule contains: Enteric coated pellets of Esomeprazole magnesium equivalent to Esomeprazole… 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), Proton pump inhibitors.
	Pharmaceutical form of applied drug	Capsule
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Esomeprazole 40mg Gastro-resistant Capsules of M/s Accord, Barnstaple, EX32 8NS, UK, (MHRA Approved).
	For generic drugs (me-too status)	Nexum 40mg Capsule (Reg. No. 33891) of M/s Getz Pharma Pvt. Ltd. Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 of M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). Firm has submitted CDP results of their product against Nexum 40mg Capsule of M/s Getz Pharma in pH 1.2 and pH 6.8.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability 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.	EMZ-046463		
Description of Pack (Container closure system)	Alu-Alu Blister packed in unit carton 2x7'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.	T001	T002	T003
Batch Size	658 Capsules	658 Capsules	658 Capsules
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	27/04/2022	27/04/2022	27/04/2022
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)	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. F.3-26/2019-Addl. Dir. (QA&LT-1)-56 dated 22nd August, 2022 issued based on inspection conducted on 14-06-2022 has been 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	Firm has submitted analytical record for

	attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Firm has not 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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Stability Study Data T002 is of PRAQ 40mg Capsules (Please clarify / provide relevant data).	The firm have submitted that the submitted data is for Batch T002 of QP-Zole 40mg Capsules (a typographic mistake) and not of Praq 40mg.
ii.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
iii.	Please provide documents for the procurement of API. Also confirm API Lot No. as 002/2021 or 002/2022.	The firm has submitted copy of Invoice No. 802550 dated 21-Apr-2022 from M/s Vision Pharma Islamabad for API Lot. EMZ046463.
iv.	Please provide CDP Results for mentioned Time points along with supporting documents.	Submitted.
v.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence and CDP.	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.**
- **Registration Board further decided that registration letter will be issued after submission of applicable fee for correction / revision of data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

839.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing	Tablet, capsule, and oral liquid (general),

	facility	liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 10394 dated 19 APR 2023
	Details of fee submitted	PKR 30,000/- Dated 27-03-2023 (Challan / Receipt # 721847329)
	The proposed proprietary name / brand name	**Qadmol 120mg/5ml suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contains: Paracetamol … 120mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Analgesics and Antipyretics
	Pharmaceutical form of applied drug	Liquid Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml, 100 ml and 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CALPOL Infant Original 120mg/5ml Oral Suspension of McNeil Products Limited UK, (MHRA Approved).
	For generic drugs (me-too status)	Calpol Paed 120mg/5ml Suspension (Reg. No. 354) of M/s GlaxoSmithKline Pakistan Limited.
	Name and address of API manufacturer.	M/s Pharmagen Limited 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 Calpol Paed 120mg/5ml Suspension of M/s GlaxoSmithKline Pakistan Limited by performing quality tests (Identification, Assay, and filled volume).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited 34- Km, Ferozepur Road, Lahore.		
API Lot No.	00510921/335/2022		
Description of Pack (Container closure system)	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.	LS004	LS005	LS006
Batch Size	55 Bottles	55 Bottles	55 Bottles
Manufacturing Date	Dec-2022	Dec-2022	Dec-2022
Date of Initiation	23-12-2022	26-12-2022	26-12-2022
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.	Copy of DML No. 000325 w.e.f. 25-10-2015 and subsequent renewal application dated 11 AUG 2020 has been 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.	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 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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please provide 06th Month Real Time Point Stability Study Testing Data along with its supporting documents.	Submitted.
ii.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
iii.	Please provide documents for the procurement of API.	**The firm has submitted copy of Invoice No. CP22-11024 dated 08-Dec-2022 from M/s Citi Pharma Lahore for API Lot. PGS22-095.** **However, the Substance part in CTD dossier has been submitted of API Lot. 00510921/335/2022 of M/s Pharmagen Lahore. Justification is required.**
iv.	Please provide legible copy of approval of API and GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The firm has submitted copy of GMP Certificate of M/s Citi Pharma Lahore.** **However, the Substance part in CTD dossier has been submitted of M/s Pharmagen Lahore. Justification is required.**
v.	Submitted Undertakings / commitments are without signatures.	Submitted.
vi.	Please justify with supporting evidence whether the quantity of 55 Bottles is sufficient enough for complete testing of Accelerated as well Real Time Stability Study Testing throughout the proposed Shelf Life of product as committed.	**Justification is required along with quantities required for testing throughout the proposed shelf life.**
vii.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence	Submitted.

Decision: Registration Board deferred the case for justification of following observations:

	• **The firm has submitted copy of Invoice No. CP22-11024 dated 08-Dec-2022 from M/s Citi Pharma Lahore for API Lot. PGS22-095. However, the Substance part in CTD dossier has been submitted of API Lot. 00510921/335/2022 of M/s Pharmagen Lahore.** • **The firm has submitted copy of GMP Certificate of M/s Citi Pharma Lahore. However, the Substance part in CTD dossier has been submitted of M/s Pharmagen Lahore.** • **Batch size of stability batches shall be justified against the number of units required to complete stability studies.**	
840.	**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	New DML granted w.e.f. 13-09-2021.
	Evidence of approval of manufacturing facility	Tablet, capsule, and oral liquid (general), liquid injectable - vial & ampoule (general), capsules (cephalosporin), oral dry powder suspension (cephalosporin) and dry powder injectable (cephalosporin) sections approved vide letter No. F.1-5/2017-Lic dated 17th September, 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. 10395 dated 19 APR 2023
	Details of fee submitted	PKR 30,000/- Dated 21-03-2023 (Challan / Receipt # 31428572264)
	The proposed proprietary name / brand name	**Qadmol 250mg/5ml suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contains: Paracetamol … 250mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	Analgesics and Antipyretics
	Pharmaceutical form of applied drug	Liquid Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml, 100 ml and 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Calpol Six Plus Suspension 250mg/5ml Oral Suspension of McNeil Products Limited UK, (MHRA Approved).
	For generic drugs (me-too status)	Calpol 6 Plus 250mg/5ml Suspension (Reg. No. 12427) of M/s GlaxoSmithKline Pakistan Limited.
	Name and address of API manufacturer.	M/s Pharmagen Limited 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 Calpol 6 Plus 250mg/5ml Suspension of M/s GlaxoSmithKline Pakistan Limited by performing quality tests (Identification, Assay, and filled volume).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, precision and repeatability for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited 34- Km, Ferozepur Road, Lahore.
API Lot No.	00510921/335/2022
Description of Pack (Container closure system)	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.	LS004	LS005	LS006
Batch Size	55 Bottles	55 Bottles	55 Bottles
Manufacturing Date	Dec-2022	Dec-2022	Dec-2022
Date of Initiation	23-12-2022	26-12-2022	26-12-2022
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.	Copy of DML No. 000325 w.e.f. 25-10-2015 and subsequent renewal application dated 11 AUG 2020 has been 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.	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 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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please confirm the name of applied Product as "Qadmol 250mg/5ml Suspension or Qadmol Forte 250mg/5ml Suspension" as both names have been mentioned in your application on separate instances.	The firm have submitted that the brand name for their product is Qadmol Forte 250mg/5ml. Further stating that forte is missing in some places due to Typographic error.
ii.	Please provide 06th Month Real Time Point Stability Study Testing Data along with its supporting documents.	Submitted.
iii.	Please provide certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	Certificate of 21 CFR compliance for the HPLC system was submitted however audit trail report for product testing was not submitted.
iv.	Please provide documents for the procurement of API.	**The firm has submitted copy of Invoice No. CP22-11024 dated 08-Dec-2022 from M/s Citi Pharma Lahore for API Lot.**

		PGS22-095. **However, the Substance part in CTD dossier has been submitted of API Lot. 00510921/335/2022 of M/s Pharmagen Lahore. Justification is required.**
v.	Please provide legible copy of approval of API and GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**The firm has submitted copy of GMP Certificate of M/s Citi Pharma Lahore.** **However, the Substance part in CTD dossier has been submitted of M/s Pharmagen Lahore. Justification is required.**
vi.	Submitted Undertakings / commitments are without signatures.	Submitted.
vii.	Please justify with supporting evidence whether the quantity of 55 Bottles is sufficient enough for complete testing of Accelerated as well Real Time Stability Study Testing throughout the proposed Shelf Life of product as committed.	**Justification is required along with quantities required for testing throughout the proposed shelf life.**
viii.	Please provide evidence along with Batch details of Reference pack used for Pharmaceutical Equivalence	Submitted.

Decision: Registration Board deferred the case for justification of following observations:

- **The firm has submitted copy of Invoice No. CP22-11024 dated 08-Dec-2022 from M/s Citi Pharma Lahore for API Lot. PGS22-095. However, the Substance part in CTD dossier has been submitted of API Lot. 00510921/335/2022 of M/s Pharmagen Lahore.**
- **The firm has submitted copy of GMP Certificate of M/s Citi Pharma Lahore. However, the Substance part in CTD dossier has been submitted of M/s Pharmagen Lahore.**
- **Batch size of stability batches shall be justified against the number of units required to complete stability studies.**

Case 03: M/s Fortune Pharmaceuticals, Plot # K/201, SITE, Super Highway Phase-II, Karachi was granted New DML (No. 000924) w.e.f. 22-02-2021 with following sections: -

i. Capsule (General)
ii. Sachet Powder (General)
iii. Liquid Injection vials (General)
iv. Sterile Liquid Injection Ampoule SVP(General)
v. Tablet (General)
vi. Liquid Syrup (General)
vii. Cream / Ointment (General)

841.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot # K/201, SITE, Super Highway Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot # K/201, SITE, 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 DML (No. 000924) granted 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 14th June, 2021 for grant of DML 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. 15013 dated 14 JUN 2023
	Details of fee submitted	PKR 30,000/- dated 08-06-2023 (Fee Challan / Receipt # 89982021416).
	The proposed proprietary name / brand name	**MOXINE 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Moxifloxacin as Hydrochloride…… 400mg (BP Specifications)
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
	Pharmaceutical form of applied drug	Oral Film Coated Tablet
	Reference to Finished product specifications	BP
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox® 400mg Tablet by M/s Bayer Pharms, USA (USFDA approved).
	For generic drugs (me-too status)	Moxiget 400mg Tablet (Reg. No. 047117) by M/s Getz Pharma, Karachi.
	Name and address of API manufacturer.	M/s Shanku's Pharmaceuticals, Plot No. 9, 10, 11 Milan Industrial Estate, Vadsar Road, At Santej,Kajol- 382 721, District Gandhinagar Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	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 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 innovator's product Avelox 400mg Tablet by Bayer Corporation. Firm has submitted CDP results of their product against the innovator's product Avelox 400mg Tablet in 3 dissolution media.
	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 Shanku's Pharmaceuticals, Plot No. 9, 10, 11 Milan Industrial Estate, Vadsar Road, At Santej, Kajol- 382 721, District Gandhinagar Gujrat India.		
API Lot No.	MOX21085		
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.	MX-001	MX-002	N/A
Batch Size	5,000 Tablets	5,000 Tablets	N/A
Manufacturing Date	05-2022	05-2022	N/A
Date of Initiation	05/2022	05/2022	N/A
No. of Batches	02		

DOCUMENTS / DATA 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. 2072077) dated 01-07-2020 issued by Commissioner Foods & Drug Control Administration, 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 copy of Commercial Invoice No. EXP/151 (20-21) dated 22-08-2021 cleared on 18-11-2021 by AD (I&E) DRAP, Karachi, specifying 04Kgs of Moxifloxacin Hydrochloride.
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. The Firm have mentioned 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: -

i. Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as "M/s Fortune Pharmaceuticals" as well as "M/s Fortune Pharma (Pvt.) Ltd." in your application dossier on separate instances.
ii. Please provide Commitments / Undertakings as required vide Sections **1.5.15 – 1.5.20** of CTD application.
iii. Please 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, as required vide section '**2.3.R.1.1 Executed Production Documents'.**
iv. Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence and CDP.
v. Please provide calculations summary regarding utilization of 4Kgs of Moxifloxacin Hydrochloride (including but not limited to Production of Stability Batches / QC Testing / RND / Process loss etc.).
vi. None of the supporting respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. have been attested by the applicant. Please justify.

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

842.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals, Plot # K/201, SITE, Super Highway Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot # K/201, SITE, 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 DML (No. 000924) granted 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 14th June, 2021 for grant of DML specifying 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. 15014 dated 14 JUN 2023
	Details of fee submitted	PKR 30,000/- dated 08-06-2023 (Fee Challan / Receipt # 2865330684).
	The proposed proprietary name / brand name	**TRANXID 250mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Ampoule contains: Tranexamic Acid … 250mg (JP Specifications)
	Pharmacotherapeutic Group of (API)	Anti-fibrinolytic
	Pharmaceutical form of applied drug	IV/IM
	Reference to Finished product specifications	JP
	Proposed Pack size	5ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Transamin Injection 5% of M/s Daiichi Sankyo Co., Ltd., (PMDA Japan Approved).
	For generic drugs (me-too status)	Transamin Injection (Reg. No. 007534) by M/s Hilton Pharma. Karachi.
	Name and address of API manufacturer.	M/s Changzhou Yinsheng Pharmaceutical Co., LTD., Qiangtang Chemical Industry Zone, Xinbei District, Changzhou 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 validation, batch analysis and justification of specification, reference standard, container closure system 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 12 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH 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	Firm has submitted pharmaceutical equivalence of their product against the brand Transamin Injection by M/s Hilton 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	M/s Changzhou Yinsheng Pharmaceutical Co., LTD., Qiangtang Chemical Industry Zone, Xinbei District, Changzhou City, Jiangsu Province, China.		
API Lot No.	F0020311010		
Description of Pack (Container closure system)	USP Type I 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.	FTX-001	FTX-002	FTX-003
Batch Size	1500 Ampoules	1500 Ampoules	1500 Ampoules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12/2021	12/2021	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 not provided 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 not provided documents for the procurement of API with approval from DRAP.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA,	Firm has submitted analytical record for product testing. **None of the supporting respective**

	summary data sheets etc.	**documents like chromatograms, Raw data sheets, COA, summary data sheets etc. have been attested by the applicant.**
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted. The Firm have mentioned 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: -

i. Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as "M/s Fortune Pharmaceuticals" as well as "M/s Fortune Pharma (Pvt.) Ltd." in your application dossier on separate instances.
ii. Please provide Commitments / Undertakings as required vide Sections **1.5.15 – 1.5.20** of CTD application.
iii. Please 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, as required vide section '**2.3.R.1.1 Executed Production Documents'.** The submitted BMRs are not of relevant Batches (FTX-001, FTX-002 and FTX-003).
iv. Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence and CDP.
v. Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
vi. Please provide documents for the procurement of API with approval from DRAP.
vii. In Section 2.3.S.4.4 (a), it has been mentioned that *"COA of the relevant batch of both API Manufacturer and Biogen Pharmaceutical is provided in Module 3 under section 3.2.S.4.4"*. Please clarify.
viii. In Section 2.3.S.7.3 it has been mentioned that the drug substance is stable for 18 Months when stored in recommended conditions, however in Section 2.3.S.7.1 its Expiry Period has been mentioned as 1 Year. Please clarify.
ix. Please provide scientific justification / supporting evidence of adopting '100℃ for 30 minutes' conditions for autoclaving as mentioned in Section 2.3. P.3.3.
x. In submitted Batch Manufacturing Records, STEP –II suggests addition of Benzyl Alcohol. Please justify the rationale for using the same as no excipients other than WFI has been mentioned throughout the application.
xi. In Section 3.2.S.7, Long Term Stability Study Data submitted for Batch 100301 has been conducted on 25°C ± 2°C / 60% ± 5% RH, which is not as per Zone IV and also different from remaining other two batches. Please clarify.
xii. In Section 3.2 P.8.3, against point 5, it has been mentioned that *"Not applicable since no HPLC method is involved in this analysis".* Please clarify.
xiii. None of the supporting respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. have been attested by the applicant. Please justify.

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

Agenda Item No. 02: Priority applications on the basis of Export Facilitation of Locally Manufactured Drugs:

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-I (EFD) dated 12th January 2023 from Assistant Director (PR-I/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis

to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s Bio-Labs (Pvt.) Ltd.) have achieved the benchmark of export of more than 100,000 USD during the fiscal year 2021 - 2022 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

843.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Bio-Labs (Pvt.) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted copy of GMP Certificate No. F3-19/2019-Addl. Dir. (QA&LT-I) dated 28th Feb 2022 based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	The Firm have submitted copy of Grant of Additional Sections vide No. F.1-12/89-Lic (Vol-II) dated 23rd July 2012.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10399 dated 23 APR 2022.
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 302856939)
	The proposed proprietary name / brand name	**BIOFEN 200mg/50ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml vial contains: Ibuprofen … 200mg
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Pharmaceutical form of applied drug	Clear colourless sterile solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved of M/s B. Braun B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany.
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	Hubei Bio Cause Heilen Pharmaceuticals Co., Ltd. 122 Yangwan Road Jingmen City, Hubei Province 448000, 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 06 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 performed pharmaceutical equivalence against the product **Inbufin Infusion 400mg/100ml** of M/s Searle IV Solutions (Pvt.) Ltd. Lahore.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Hubei Biocause Heilen Pharmaceuticals Co., Ltd.		
API Lot No.	C100-2009056M		
Description of Pack (Container closure system)	50ml transparent 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.	IBF 21-057	IBF21-058	IBF 21-059
Batch Size	250 Vials	250 Vials	250 Vials
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	31-5-2021	31-5-2021	31-05-2021
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)	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. HB20170363 issued by China Food and Drug Administration valid till 28/8/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance Certificate No. 1201 dated 12 April 2021 issued by Assistant Director (I&E) DRAP Islamabad for import of 05Kgs of Ibuprofen (against Invoice No. **B21017106** dated **23-02-2021).**
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:

- The Firm have submitted that they have written mistakenly 200mg/100ml in deposit slip number 302856939 whereas the applied strength is 200mg/50ml.

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	It has been claimed in your application that the applied strength is not registered locally whereas the fee has been paid for Generic Drug Product application (i.e. PKR 30,000/-) instead of that of New Drug Product (i.e. PKR 75,000/-). Please clarify.	The firm has submitted that they'll submit the requisite differential fee.
ii.	Pharmaceutical equivalence has been performed against 400mg/100ml Infusion instead of 200mg/50ml Infusion. Please justify.	The firm has submitted that Pharmaceutical equivalence was performed with 400mg/100ml Infusion due to unavailability of Innovator/ Reference product. Furthermore, in Pharmaceutical equivalence, appearance, identification, pH, assay and particulate matter of Test and Reference products were compared having same specifications.

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.**

● **Furthermore, the firm shall submit requisite differential fee before issuance of Registration letter.**		
844.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted copy of GMP Certificate No. F3-19/2019-Addl. Dir. (QA&LT-I) dated 28th Feb 2022 based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	The Firm have submitted copy of Grant of Additional Sections vide No. F.1-12/89-Lic (Vol-II) dated 23rd July 2012.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10400 dated 23 APR 2022.
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 4478866626)
	The proposed proprietary name / brand name	**BIOFEN 400mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Ibuprofen … 400mg
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Pharmaceutical form of applied drug	Clear colourless sterile solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved of M/s B. Braun B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany.
	For generic drugs (me-too status)	Ubrof (Reg. No. 097180) of M/s Sami Pharma.
	Name and address of API manufacturer.	Hubei Bio Cause Heilen Pharmaceuticals Co., Ltd. 122 Yangwan Road Jingmen City, Hubei Province 448000, 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 06 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 performed pharmaceutical equivalence against the product **Inbufin Infusion 400mg/100ml** of M/s Searle IV Solutions (Pvt.) Ltd. Lahore.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Hubei Biocause Heilen Pharmaceuticals Co., Ltd.		
API Lot No.	C100-2009056M		
Description of Pack (Container closure system)	100ml transparent 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.	IBF 21-054	IBF21-055	IBF 21-056
Batch Size	250 Vials	250 Vials	250 Vials
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	29-5-2021	29-5-2021	29-05-2021
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)	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. HB20170363 issued by China Food and Drug Administration valid till 28/8/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance Certificate No. 1201 dated 12 April 2021 issued by Assistant Director (I&E) DRAP Islamabad for import of 05Kgs of Ibuprofen (against Invoice No. **B21017106** dated **23-02-2021).**
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:

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.**

845.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted copy of GMP Certificate No. F3-19/2019-Addl. Dir. (QA&LT-I) dated 28th Feb 2022 based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	The Firm have submitted copy of Grant of Additional Sections vide No. F.1-12/89-Lic (Vol-II) dated 23rd July 2012.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9106 dated 11 APR 2022.
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022

		(Challan / Receipt # 98836531)
	The proposed proprietary name / brand name	**BIOFEN 600mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Ibuprofen … 600mg
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Pharmaceutical form of applied drug	Clear colourless sterile solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved of M/s B. Braun B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany.
	For generic drugs (me-too status)	Ubrof (Reg. No. 105263) of M/s Sami Pharma.
	Name and address of API manufacturer.	Hubei Bio Cause Heilen Pharmaceuticals Co., Ltd. 122 Yangwan Road Jingmen City, Hubei Province 448000, 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 06 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 performed pharmaceutical equivalence against the product **Inbufin Infusion 400mg/100ml** of M/s Searle IV Solutions (Pvt.) Ltd. Lahore.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Hubei Biocause Heilen Pharmaceuticals Co., Ltd.		
API Lot No.	C100-2009056M		
Description of Pack (Container closure system)	100ml transparent 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.	IBF 21-051	IBF21-052	IBF 21-053
Batch Size	250 Vials	250 Vials	250 Vials
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	27-5-2021	27-5-2021	27-05-2021
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)	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. HB20170363 issued by China Food and Drug Administration valid till 28/8/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance Certificate No. 1201 dated 12 April 2021 issued by Assistant Director (I&E) DRAP Islamabad for import of 05Kgs of Ibuprofen (against Invoice No. **B21017106** dated **23-02-2021).**
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:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Pharmaceutical equivalence has been	The firm has submitted that Pharmaceutical

	performed against 400mg/100ml Infusion instead of 600mg/100ml Infusion. Please justify.	equivalence was performed with 400mg/100ml Infusion due to unavailability of Innovator/ Reference product. Furthermore, in Pharmaceutical equivalence, appearance, identification, pH, assay and particulate matter of Test and Reference products were compared having same specifications.

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.**

846.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted copy of GMP Certificate No. F3-19/2019-Addl. Dir. (QA&LT-I) dated 28th Feb 2022 based on inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	The Firm have submitted copy of Grant of Additional Sections vide No. F.1-12/89-Lic (Vol-II) dated 23rd July 2012.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22948 dated 15 AUG 2022.
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 7754985365)
	The proposed proprietary name / brand name	**BIOFEN 400mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ibuprofen … 400mg
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Pharmaceutical form of applied drug	Clear colourless sterile solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory	CALDOLOR by CUMBERLAND PHARMS,

	authorities	USFDA Approved.
	For generic drugs (me-too status)	Xaleve (Reg. No. 93088) of M/s Hudson Pharma.
	Name and address of API manufacturer.	Hubei Bio Cause Heilen Pharmaceuticals Co., Ltd. 122 Yangwan Road Jingmen City, Hubei Province 448000, 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 06 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 performed pharmaceutical equivalence against the product **Xaleve 400mg/4ml Injection** of M/s Hudson Pharma.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Hubei Biocause Heilen Pharmaceuticals Co., Ltd.
API Lot No.	C100-2009056M
Description of Pack (Container closure system)	4ml transparent 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.	IBF 21-064	IBF21-065	IBF 21-066
Batch Size	1000 Amp	1000 Amp	1000 Amp
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	09-6-2021	09-6-2021	09-06-2021
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. HB20170363 issued by China Food and Drug Administration valid till 28/8/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance Certificate No. 1201 dated 12 April 2021 issued by Assistant Director (I&E) DRAP Islamabad for import of 05Kgs of Ibuprofen (against Invoice No. **B21017106** dated **23-02-2021).**
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:

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.**

847.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145 Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm have submitted copy of GMP Certificate No. F3-19/2019-Addl. Dir. (QA&LT-I) dated 28th Feb 2022 based on

		inspection conducted on 03-08-2021.
	Evidence of approval of manufacturing facility	The Firm have submitted copy of Grant of Additional Sections vide No. F.1-12/89-Lic (Vol-II) dated 23rd July 2012.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20723 dated 22 JUL 2022.
	Details of fee submitted	PKR 30,000/- Dated 03-02-2022 (Challan / Receipt # 56572706)
	The proposed proprietary name / brand name	**BIOFEN 800mg/8ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 8ml ampoule contains: Ibuprofen … 800mg
	Pharmacotherapeutic Group of (API)	Non-steroidal anti-inflammatory drug (NSAID)
	Pharmaceutical form of applied drug	Clear colourless sterile solution
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CALDOLOR by CUMBERLAND PHARMS, USFDA Approved.
	For generic drugs (me-too status)	Ubrof (Reg. No. 105262) of M/s Sami Pharma.
	Name and address of API manufacturer.	Hubei Bio Cause Heilen Pharmaceuticals Co., Ltd. 122 Yangwan Road Jingmen City, Hubei Province 448000, 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 06 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 performed pharmaceutical equivalence against the product **Xaleve 400mg/4ml Injection** of M/s Hudson Pharma.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Hubei Biocause Heilen Pharmaceuticals Co., Ltd.		
API Lot No.	C100-2009056M		
Description of Pack (Container closure system)	8ml transparent 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.	IBF 21-061	IBF21-062	IBF 21-063
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	03-06-2021	06-06-2021	03-06-2021
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. HB20170363 issued by China Food and Drug Administration valid till 28/8/2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance Certificate No. 1201 dated 12 April 2021 issued by Assistant Director (I&E) DRAP Islamabad for import of 05Kgs of Ibuprofen (against Invoice No. **B21017106** dated **23-02-2021).**
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:
The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Pharmaceutical equivalence has been performed against 400mg/4ml Injection instead of 800mg/8ml Injection. Please justify.	The firm has submitted that Pharmaceutical equivalence was performed with 400mg/4ml Injection due to unavailability of Innovator/ Reference product. Furthermore, in Pharmaceutical equivalence, appearance, identification, pH, assay and particulate matter of Test and Reference products were compared having same specifications.

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.**

Agenda Item No. 03: Routine Applications of Human Drugs Locally Manufactured applied on Form - 5F.

848.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals, Plot No. 12, St. No. N-3, National Industrial Zone (RCCI) Rawat.**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals, Plot No. 12, St. No. N-3, National Industrial Zone (RCCI) Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 09th September 2021 based on inspection conducted on 09-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Renewal of DML dated 15-04-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5101 dated 23-02-2022
	Details of fee submitted	PKR 30,000/- Dated 14-02-2022 (Challan / Receipt # 60282654578)
	The proposed proprietary name / brand name	**DAXID 30mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole dual delayed release (DDR) pellets equivalent to Dexlansoprazole … 30mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	White to greyish white pellets enclosed in hard gelatin capsule shells.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 30mg Delayed Release Capsules (USFDA Approved)
	For generic drugs (me-too status)	DDR-30mg DR Capusle of M/s Genome Pharma (Reg. No. 088378)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated 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: DLP281, DLP283 and DLP284.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures,

		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 Dexilant 30mg Delayed Release Capsules (Batch. No. 11954694) manufactured by Takeda Pharms USA. Firm has submitted CDP results of their product against the innovator's product Dexilant 30mg Delayed Release Capsules in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad Pakistan.		
API Lot No.	DLP579		
Description of Pack (Container closure system)	Alu-Alu foil 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.	DEX-30T008	DEX-30T009	DEX-30T010
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	04 / 2021	04 / 2021	04 / 2021
Date of Initiation	21-04-2021	24-04-2021	27-04-2021
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 provided. Old GMP Inspection report enclosed instead.**
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&LT-I) dated 25th Feb, 2019 issued based on inspection conducted on 11th February, 2019 (valid till 10th February 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).	Local purchase. Firm has submitted copy of Invoice No. 701219 dated 10/9/2020 from M/s Vision Pharmaceuticals (Pvt.) Limited, Islamabad specifying 3.00Kg of Dexlansoprazole DDR 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 audit trail report for product testing. **Certificate of 21 CFR compliance for the HPLC system is 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:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows:

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	GMP Certificate was issued based on Inspection conducted on **09-03-2020** which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).	The firm have submitted copy of GMP certificate No. F.3-49/2020-Addl. Dir. (QA&LT-I)-24 dated 24th April 2022 based on inspection conducted on 22-02-2022.
ii.	The submitted GMP Certificate of API Manufacturer was issued based on Inspection conducted on 11th February 2019 and was valid until 10th February 2022. Please provide a valid GMP Certificate of API Manufacturer.	The firm have submitted copy of GMP Certificate of API Manufacturer No. F.3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22nd August 2022 based on inspection conducted on 14-06-2022.
iii.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	The firm have referred to their CTD (Form 5F) applications approved in 321st Meeting of Registration Board (20th – 22nd September, 2022).
iv.	Please provide Certificate of 21 CFR compliance for the HPLC system.	The Firm have claimed that they have used EZ Chrome Elite CDS Version 3.3.2 HPLC Software which is 21CFR11 Compliant.
v.	Please provide evidence of Innovator's pack i.e. Dexilant 30mg Delayed Release Capsules used for Pharmaceutical Equivalence and CDP.	The firm have submitted copy of packshot of Dexilant 30mg Capsules: Lot/ Batch # 119544694 SN 30329916841977 GTIN 00364764171308 Distributed by: Takeda Pharmaceuticals America Inc. Deerfield. IL 60015.

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.**

849.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals, Plot No. 12, St. No. N-3, National Industrial Zone (RCCI) Rawat.**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals, Plot No. 12, St. No. N-3, National Industrial Zone (RCCI) Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP Certificate dated 09th September 2021 based on inspection conducted on 09-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of Renewal of DML dated 15-04-2015 specifying Capsule General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5102 dated 23-02-2022
	Details of fee submitted	PKR 30,000/- Dated 14-02-2022 (Challan / Receipt # 869222341)
	The proposed proprietary name / brand name	**DAXID 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole dual delayed release (DDR) pellets equivalent to Dexlansoprazole … 60mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	White to greyish white pellets enclosed in hard gelatin capsule shells.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 60mg Delayed Release Capsules (USFDA Approved)
	For generic drugs (me-too status)	DDR-60mg DR Capusle of M/s Genome Pharma (Reg. No. 088379)
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated 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: DLP281, DLP283 and DLP284.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, 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 Dexilant 60mg Delayed Release Capsules (Batch. No. Not Provided) manufactured by Takeda Pharms USA. Firm has submitted CDP results of their product against the innovator's product Dexilant 60mg Delayed Release Capsules in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance and analytical method validation study reports for drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad Pakistan.
API Lot No.	DLP579
Description of Pack (Container closure system)	Alu-Alu foil 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.	DEX-60T011	DEX-60T012	DEX-60T013
Batch Size	2,000 Capsules	2,000 Capsules	2,000 Capsules
Manufacturing Date	05 / 2021	05 / 2021	05 / 2021
Date of Initiation	03-05-2021	04-05-2021	05-05-2021
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. Old GMP Inspection report enclosed instead.**
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&LT-I) dated 25th Feb, 2019 issued based on inspection conducted on 11th February, 2019 (valid till 10th February 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).	Local purchase. Firm has submitted copy of Invoice No. 701219 dated 10/9/2020 from M/s Vision Pharmaceuticals (Pvt.) Limited, Islamabad specifying 3.00Kg of Dexlansoprazole DDR 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 audit trail report for product testing. **Certificate of 21 CFR compliance for the HPLC system is 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:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows:

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	GMP Certificate was issued based on Inspection conducted on **09-03-2020** which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).	The firm have submitted copy of GMP certificate No. F.3-49/2020-Addl. Dir. (QA&LT-I)-24 dated 24th April 2022 based on inspection conducted on 22-02-2022.

ii.	The submitted GMP Certificate of API Manufacturer was issued based on Inspection conducted on 11th February 2019 and was valid until 10th February 2022. Please provide a valid GMP Certificate of API Manufacturer.	The firm have submitted copy of GMP Certificate of API Manufacturer No. F.3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22nd August 2022 based on inspection conducted on 14-06-2022.
iii.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	The firm have referred to their CTD (Form 5F) applications approved in 321st Meeting of Registration Board (20th – 22nd September, 2022).
iv.	Please provide Certificate of 21 CFR compliance for the HPLC system.	The Firm have claimed that they have used EZ Chrome Elite CDS Version 3.3.2 HPLC Software which is 21CFR11 Compliant.
v.	Please provide evidence of Innovator's pack i.e. Dexilant 60mg Delayed Release Capsules used for Pharmaceutical Equivalence and CDP along with details of Batch used.	The firm have submitted copy of packshot of Dexilant 60mg Capsules: Lot/ Batch # 11943099 SN 31580939740710 GTIN 00364764175306 Distributed by: Takeda Pharmaceuticals America Inc. Deerfield. IL 60015.

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.**

Agenda Item No. 04: Molecules / drugs reported short in the Market.

850	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt Ltd** **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi
	Details of Drug Sale License of importer	**License No:** 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi **Address of Godown:** NA **Validity:** 04/08/2024 **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	**M/s Unijules Life Sciences Limited** D-82, MIDC Area, Cross Road No. 4-A, Hingna, Nagpur 440028 Maharashtra State, India. www.unijules.com
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited** D-82, MIDC Area, Cross Road No. 4-A, Hingna, Nagpur 440028 Maharashtra State, India. www.unijules.com
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP Certificate No. COPP/CERT/ND/122573/2023/11/43804/212252 dated 23/01/2023 issued by Food and Drug Administration Mahrashtra Estate Mumbai for Iohexol Injection USP 350 mg I/ml, valid upto 28 Sep 2025. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year.
	Details of letter of authorization / sole agency agreement	**Firm has submitted original notarized letter of Distribution Certificate issued by M/s Vimage Parenteral LLP.** **The letter certifies that M/s Vimage Parenteral LLP authorizes M/s Lab Diagnostic Systems (SMC) Pvt Ltd. as their "Preferred" distributor for the territory of Pakistan to register / import / sell / promote their products in Pakistan.** The authorization letter is effective from March 2023 until March 2024 or Registration of the products and renewal by mutual consideration unless earlier terminated.
	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. 12603 dated 22 MAY 2023
	Details of fee submitted	PKR 150,000/- dated 03/03/2023 (Challan / Receipt # 65130510799)
	The proposed proprietary name / brand name	**Iohexid Injection 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Iohexol USP 755mg equivalent to Iodine Content 350mg. (USP Specifications)
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Radio contrast media
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

<table>
<tr><td></td><td>Proposed unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>OMNIPAQUE 350 (NDA: 018956) by M/s GE Healthcare, USA (USFDA Approved).</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>IOBRIX-350 INJECTION 100ml by M/s Hoffmann Human Health Pak Ltd (Reg#032138).</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>Firm has submitted QOS as per 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.</td></tr>
<tr><td></td><td>Name, address of drug substance manufacturer</td><td>Zhejiang Starry Pharmaceutical Company Limited, China.
No. 1, Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, 317300, China.</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>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.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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 36 Months.
<table>
<tr><th>Batch No.</th><th>Mfg. Date</th></tr>
<tr><td>C006-0802003</td><td>Feb 2008</td></tr>
<tr><td>C006-0802004</td><td>Feb 2008</td></tr>
<tr><td>C006-0802005</td><td>Mar 2008</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including 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.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>The firm has submitted Pharmaceutical equivalence / Comparative Analysis of their applied product against Reference product: Contrapaque 350 by Unique Pharma Labs Bharuch (B. No. I0D21007).</td></tr>
<tr><td></td><td>Analytical method validation / verification of product</td><td>Since the Finished Product Analytical Method is Pharmacopeial (USP), firm has submitted analytical method verification studies for their applied product by performing tests for specificity, precision, accuracy, linearity, ruggedness and stability of</td></tr>
</table>

		solution.
	Container closure system of the drug product	100 ml colorless USP Type I glass vials with 32 mm grey chlorobutyl rubber stopper and 33 mm aluminium flip off hook type light orange seals.
	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
2219K1801	10 - 2018
2219K1802	10 – 2018
2219K1803	10 - 2018

Remarks of Evaluator:

The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	The firm has submitted original notarized letter of Distribution Certificate issued by M/s Vimage Parenteral LLP, however the Product License Holder and Manufacturer, as evident from submitted CoPP, is M/s Unijules Life Sciences Limited. Please clarify with supporting evidence.	The firm, in their latest response, have submitted photocopy of notarized revised Distribution Certificate between M/s Unijules Life Sciences Limited and M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

- **The Board directed the PE&R division to process the case without waiting the formal approval of the minutes as the product is short in the market and Authority has approved for out of Que consideration.**
- **Registration Board further decided that registration letter will be issued after submission of Original Notarized Distribution Certificate between M/s Unijules Life Sciences Limited and M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.**

851	**Name, address of Applicant / Importer**	**M/s Lab Diagnostic Systems (SMC) Pvt Ltd** **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi
	Details of Drug Sale License of importer	**License No:** 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi **Address of Godown:** NA **Validity:** 04/08/2024 **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	**M/s Unijules Life Sciences Limited** D-82, MIDC Area, Cross Road No. 4-A, Hingna, Nagpur 440028 Maharashtra State, India. www.unijules.com
	Name, address of manufacturer(s)	**M/s Unijules Life Sciences Limited** D-82, MIDC Area, Cross Road No. 4-A, Hingna, Nagpur 440028 Maharashtra State, India. www.unijules.com
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **Photocopy of original**, legalized CoPP Certificate No. COPP/CERT/ND/122573/2023/11/43804/212252 dated 23/01/2023 issued by Food and Drug Administration Mahrashtra Estate Mumbai for Iohexol Injection USP 350 mg I/ml, valid upto 28 Sep 2025. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection once a year. (The firm have stated that the Original, legalized CoPP has been submitted with Iohexid Injection 100ml).
	Details of letter of authorization / sole agency agreement	**Firm has submitted Photocopy of original notarized letter of Distribution Certificate issued by M/s Vimage Parenteral LLP.** **The letter certifies that M/s Vimage Parenteral LLP authorizes M/s Lab Diagnostic Systems (SMC) Pvt Ltd. as their "Preferred" distributor for the territory of Pakistan to register / import / sell / promote their products in Pakistan.** The authorization letter is effective from March 2023 until March 2024 or Registration of the products and renewal by mutual consideration unless earlier terminated. (The firm have stated that the Original, legalized LOA has been submitted with Iohexid Injection 100ml).
	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. 11131 dated 04 MAY 2023
	Details of fee submitted	PKR 150,000/- dated 03/03/2023 (Challan / Receipt # 925772762459)
	The proposed proprietary name / brand name	**Iohexid Injection 50ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Iohexol USP 755mg equivalent to Iodine Content 350mg. (USP Specifications)
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Radio contrast media
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OMNIPAQUE 350 (NDA: 018956) by M/s GE Healthcare, USA (USFDA Approved).
	For generic drugs (me-too status)	IOBRIX-350 INJECTION 50ml by M/s Hoffmann Human Health Pak Ltd (Reg#032137).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Zhejiang Starry Pharmaceutical Company Limited, China. No. 1, Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, 317300, China.
	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 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.

Batch No.	**Mfg. Date**
C006-0802003	Feb 2008
C006-0802004	Feb 2008
C006-0802005	Mar 2008

	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Not submitted for applied filled volume (i.e. 50ml).**
	Analytical method validation / verification of product	Since the Finished Product Analytical Method is Pharmacopeial (USP), firm has submitted analytical method verification studies for their applied product by performing tests for specificity, precision, accuracy, linearity, ruggedness and stability of solution.
	Container closure system of the drug product	50 ml colorless USP Type I glass vials with 32 mm grey chlorobutyl rubber stopper and 33 mm aluminium flip off hook type light orange seals.
	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
0205A1701	01 - 2017
0765F1701	06 - 2017
2468A1901	01 - 2019

Remarks of Evaluator:
The following deficiencies / shortcomings were communicated to the firm and their response was received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	The firm has submitted original notarized letter of Distribution Certificate issued by M/s Vimage Parenteral LLP, however the Product License Holder and Manufacturer, as evident from submitted CoPP, is M/s Unijules Life Sciences Limited. Please clarify with supporting evidence.	The firm, in their latest response, have submitted photocopy of notarized revised Distribution Certificate between M/s Unijules Life Sciences Limited and M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.
ii.	Pharmaceutical equivalence / Comparative Analysis of applied product against Reference product (OMNIPAQUE 350, 50ml) has not been submitted. Please justify.	Submitted.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

- **The Board directed the PE&R division to process the case without waiting the formal approval of the minutes as the product is short in the market and Authority has approved for out of Que consideration.**
- **Registration Board further decided that registration letter will be issued after submission of Original Notarized Distribution Certificate between M/s Unijules Life Sciences Limited and M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.**

Agenda of Evaluator PEC-XXIII

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

a. Previously deferred cases

852.	Name and address of manufacturer	M/s Linta Pharmaceuticals Plot No. 3, St No. S-5, National

	/ Applicant	Industrial Zone, Rawat, Islamabad (DML No. 000810) Tablet section (General)
	Brand Name +Dosage Form + Strength	ZETI 10mg tablet
	Composition	Each film coated tablet contains: Ezetimibe ……..….10mg
	Diary No. Date of R& I & fee	Dy No. 14602 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792392 dated 06-03-2019
	Pharmacological Group	Other lipid modifying agents ATC Code C10AX09
	Type of Form	Form 5
	Finished Product Specification	Firm has not stated the product specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zetia 10mg tablet Company: Organon USFDA Approved
	Me-too status	Zitamibe 10mg Tablet Mass Pharma
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Change in specifications to Pharmacopoeial Specs (USP) along with PKR 7500/- fee is required • Evidence of product approved in reference regulatory authority is of uncoated tablets, applied product is film coated. Approval of film coated tablet in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation from film coated to uncoated tablet as available in reference regulatory authority is required, along with prescribed fee.
	Decision of 326th meeting of RB	Deferred for following: • Evidence of approval of applied formulation as film coated tablet dosage form, in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021. • Latest GMP inspection report conducted within last three years. • Submission of reference for pharmacopoeial specifications 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/DRAP-026/2023 dated 13-04-2023, 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) • Specification changed along with PKR7500 fee (Deposit Slip No. 65993271837 dated 14-04-23)

		• Formulation revised from film coated to uncoated tablet along with PKR30,000 fee (Deposit Slip No. 56812417 dated 14-04-23)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved as uncoated tablet with USP specification.	
853.	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	MCAM 15mg tablet
	Composition	Each tablet contains: Meloxicam…… 15mg
	Diary No. Date of R& I & fee	Dy No. 16736 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792367 dated 06-03-2019.
	Pharmacological Group	Oxicams ATC Code M01AC06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mobic 15mg tablet USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 326th meeting of RB	• Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
854.	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	MCAM 7.5mg tablet
	Composition	Each tablet contains: Meloxicam ……..….. 7.5mg
	Diary No. Date of R& I & fee	Dy No. 16735 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792368 dated 06-03-2019.
	Pharmacological Group	Oxicams ATC Code M01AC06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mobic 7.5mg tablet USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	Last GMP inspection conducted on 10-07-2019

	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
855.	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	TIZAN 2mg tablet
	Composition	Each tablet contains: Tizanidine Hydrochloride equivalent to Tizanidine ….....2mg
	Diary No. Date of R& I & fee	Dy No. 16737 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792365 dated 06-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC Code M03BX02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tizafed 2mg Tablet Fedro Pharmaceutical Labs Pvt Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
856.	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	TIZAN 4mg tablet
	Composition	Each tablet contains: Tizanidine Hydrochloride equivalent to Tizanidine….. 4mg

	Diary No. Date of R& I & fee	Dy No. 16738 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792363 dated 06-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC Code M03BX02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zanaflex 4mg tablet USFDA Approved
	Me-too status	Tizafed 4 mg Tablet Fedro Pharmaceutical Labs Pvt Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
857.	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	ATELOL 50mg tablet
	Composition	Each film coated tablet contains: Atenolol ……..…50mg
	Diary No. Date of R& I & fee	Dy No. 14604 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792394 dated 06-03-2019.
	Pharmacological Group	Selective Beta blocker
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Totamol 50mg tablet MHRA Approved
	Me-too status	Atokyt 100mg Tablet Hi-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
858.	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	ATELOL 100mg tablet
	Composition	Each film coated tablet contains: Atenolol ……..100mg
	Diary No. Date of R& I & fee	Dy No. 14603 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792393 dated 06-03-2019.
	Pharmacological Group	Selective Beta blocker
	Type of Form	Form 5
	Finished Product Specification	USP.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Atokyt 100mg Tablet Hi-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
859.	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	PIVASTA 2mg tablet
	Composition	Each film coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin ……..…….. 2mg
	Diary No. Date of R& I & fee	Dy No. 14578 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789181 dated 07-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code C10AA08
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Livalo 2mg tablet USFDA Approved
	Me-too status	Pinstatin 2mg Tablet Moringa Pharmaceuticals (Pvt) Ltd.
	GMP status	Last GMP inspection conducted on 10-07-2019

	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
860.	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	PIVASTA 1mg tablet
	Composition	Each film coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin…. 1mg
	Diary No. Date of R& I & fee	Dy No. 14577 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789180 dated 07-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code C10AA08
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Livalo 1mg tablet USFDA Approved
	Me-too status	Pinstatin 1mg Tablet Moringa Pharmaceuticals (Pvt) Ltd.
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
861.	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	ALGORIC tablet 100mg
	Composition	Each tablet contains: Allopurinol 100mg
	Diary No. Date of R& I & fee	Dy No. 16731 dated 07-03-2019 Fee paid PKR 20,000/- vide

		Deposit Slip No. 0792372 dated 06-03-2019.
	Pharmacological Group	Anti-gout preparations ATC Code M04AA01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyloric 100 mg Tablets MHRA Approved
	Me-too status	Zyloric 100mg Tablet GlaxoSmithKline Pakistan Limited
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	• Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
862.	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	ALGORIC tablet 300mg
	Composition	Each tablet contains: Allopurinol ……..…….300mg
	Diary No. Date of R& I & fee	Dy No. 16732 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792371 dated 06-03-2019.
	Pharmacological Group	Anti-gout preparations ATC Code M04AA01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyloric 300 mg Tablets MHRA Approved
	Me-too status	Zyloric 300mg Tablet GlaxoSmithKline Pakistan Limited
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	• Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
863.	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) Capsule section (General)
	Brand Name +Dosage Form + Strength	FINATE capsule 67mg
	Composition	Each hard gel capsule contains: Fenofibrate ……67 mg
	Diary No. Date of R& I & fee	Dy. No. 14570 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789173 dated 07-03-2019.
	Pharmacological Group	Lipid modifying agents ATC Code C10AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Lipantil Micro 67 mg, capsule MHRA Approved
	Me-too status	Valofibren 67mg Capsule Valor Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
864.	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) Capsule section (General)
	Brand Name +Dosage Form + Strength	FINATE capsule 200mg
	Composition	Each hard gel capsule contains: Fenofibrate …….…….200mg
	Diary No. Date of R& I & fee	Dy No. 14569 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789172 dated 07-03-2019.
	Pharmacological Group	Lipid modifying agents ATC Code C10AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipantil Micro 200 mg, capsule MHRA Approved
	Me-too status	Trifibe Capsules 200mg Pulse Pharmaceuticals (Pvt) Ltd., Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 326th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	• Same as above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
865.	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 20/10mg
	Composition	Each film coated tablet contains: Amlodipine ……..…….20mg Olmesartan Medoxomil ……..……5mg
	Diary No. Date of R& I & fee	Dy No. 14589 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789192 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.	Approved by US FDA
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Product monograph is available in USP. • Strength of applied product on cover letter, fee challan and other points in application form is 20/10mg. However, in the label claim strength mentioned is 20/5mg. Clarification is required along with correction of label claim and submission of prescribed 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 326th meeting of RB	Deferred for following: • Revision of label claim for the complete salt form of Amlodipine as per innovator product along with prescribed fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • Change in specifications to Pharmacopoeial Specs (USP). • Clarification regarding applied strength since covering letter and applied label claim mentions different strengths. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/DRAP-026/2023 dated 13-04-2023, 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 ……5mg Olmesartan Medoxomil…..……20mg along with PKR7500 fee (Deposit Slip No. 70175808721 dated 14-04-23) • Omsana AM Tablet 5/20mg (Me-too)

	Remarks of the Evaluator[xxiii].	• Change of Manufacturer's Specifications to USP Specifications AND Revision of label claim for the complete salt l
	Decision: Approved with USP Specification and following label claim: **"Each film coated tablet contains:** **Amlodipine (as besylate) ……5mg** **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.**	
866.	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	BISOCAR tablet 5mg
	Composition	Each film coated tablet contains: Bisoprolol fumarate…... 5mg
	Diary No. Date of R& I & fee	Dy No. 14594 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792384 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol fumarate 5 mg film-coated tablets Marketing Authorization Holder: Generics [UK] Limited t/a Mylan, UK. MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 327th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP specification.	
867.	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	BISOCAR tablet 2.5mg
	Composition	Each film coated tablet contains: Bisoprolol fumarate…….....2.5mg
	Diary No. Date of R& I & fee	Dy No. 16726 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792366 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code C07AB07
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol fumarate 2.5 mg film-coated tablets PL 04569/1255 Marketing Authorization Holder: Generics [UK] Limited t/a Mylan, UK. MHRA Approved
	Me-too status	Saibiso Tablet by Saibins Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 327th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) • Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP specification.	
868.	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	OFLO tablet 200mg
	Composition	Each film coated tablet contains: Ofloxacin…….....200mg
	Diary No. Date of R& I & fee	Dy No. 14575 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789178 dated 07-03-2019.
	Pharmacological Group	Fluoroquinolones ATC Code J01MA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ofloxacin 200mg film coated tablets Company: Teva UK Ltd MHRA Approved
	Me-too status	Ofloper 200mg Tablet Quaper Pvt Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 327th meeting of RB	Deferred for submission of latest GMP inspection report conducted within last three years.
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General)

		Cream/Ointment/Gel (General) Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with USP specification.	
869.	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) Capsule section (General)
	Brand Name +Dosage Form + Strength	VENFAX- SR Capsules 75mg
	Composition	Each extended release capsule contains: Extended release pellets of Venlafaxine Hydrochloride equivalent to Venlafaxine……75mg
	Diary No. Date of R& I & fee	Dy No. 14598 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792388 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX16
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alventa XL 75 mg prolonged-release capsules, hard MHRA Approved
	Me-too status	Venwell XR 75mg Capsule FYNK Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Source of pellets is not provided; source of pellets along with GMP certificate of that source, stability study of three batches of pellets and certificate of analysis of pellets are required. In case of imported pellets, requisite fee is also required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New) • Source of pellets is M/s Vision Pharmaceuticals (Local)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP specification.	
870.	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	VENFAX- SR Capsules 37.5mg
	Composition	Each extended release capsule contains: Extended release pellets of Venlafaxine Hydrochloride

		equivalent to Venlafaxine……37.5mg
	Diary No. Date of R& I & fee	Dy No. 14597 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792387 dated 06-03-2019.
	Pharmacological Group	Other antidepressants ATC Code N06AX16
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alventa XL 37.5 mg prolonged-release capsules, hard MHRA Approved
	Me-too status	Fix-Zar 37.5mg XR Capsule Invictus Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Source of pellets is not provided; source of pellets along with GMP certificate of that source, stability study of three batches of pellets and certificate of analysis of pellets are required. In case of imported pellets, requisite fee is also required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New) Source of pellets is M/s Vision Pharmaceuticals (Local)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP specification.	
871.	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	AVENT 16mg tablet
	Composition	Each film coated tablet contains: Candesartan Cilexetil……. 16mg
	Diary No. Date of R& I & fee	Dy No. 14605 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792395 dated 06-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code C09CA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan Cilexetil 16 mg Tablets - PL 35084/0002-9; MHRA Approved (for uncoated tablet).
	Me-too status	Cansaar 8mg Tablet (uncoated) M/s Pharmatec Pakistan Karachi
	GMP status	Last GMP inspection conducted on 10-07-2019

	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Applied product is film coated tablet. Evidence of product approved in reference regulatory authority is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with requisite fee is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **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 for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New) • Formulation changed to uncoated tablet along with Rs.7500 fee.
	Remarks of the Evaluator[xxiii].	
	Decision: Approved as uncoated tablet with USP specification.	
872.	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	ZYTRIN 2mg tablet
	Composition	Each tablet contains: Terazosin (as Hydrochloride.$2H_20$)…… 2mg
	Diary No. Date of R& I & fee	Dy No. 14582 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789185 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terazosin 2 mg Tablets MHRA Approved PL 43870/0001
	Me-too status	Euzet 2mg Tablet Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 327th meeting of RB	**Deferred for submission of latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following:

		• Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) • Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with USP specification.	
873.	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	ZYTRIN 5mg tablet
	Composition	Each tablet contains: Terazosin (as Hydrochloride.$2H_20$)…… 5mg
	Diary No. Date of R& I & fee	Dy No. 14583 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789186 dated 07-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code G04CA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terazosin 5 mg Tablets MHRA Approved PL 43870/0002
	Me-too status	Euzet 5mg Tablet Trigon Pharmaceuticals (Private) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required.
	Decision of 327th meeting of RB	**Deferred for submission of latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with USP specification.	
874.	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	MEF tablets 500mg
	Composition	Each film coated tablet contains: Mefenamic acid…….500mg
	Diary No. Date of R& I & fee	Dy No. 14574 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789177 dated 07-03-2019.
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids ATC Code M01AG01

	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mefenamic acid 500 mg film-coated tablets MHRA Approved PL 13606/0258
	Me-too status	Megamef 500mg Tablet Mega Pharmaceuticals Limited
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 327th meeting of RB	**Deferred for submission of latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) • Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with BP specification.	
875.	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	RIFAREX tablet 550mg
	Composition	Each film tablet contains: Rifaxamin…….550mg
	Diary No. Date of R& I & fee	Dy No. 14579 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789182 dated 07-03-2019.
	Pharmacological Group	Antibiotics ATC Code A07AA11
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xifaxan 550 mg film coated tablets USFDA Approved
	Me-too status	Nyxia 550mg film coated tablet Pharmedic Laboratories (Pvt.) Ltd Lahore
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 327th meeting of RB	**Deferred for submission of latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General)

		Cream/Ointment/Gel (General) • Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved with Innovator's specification.	
876.	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) Capsule section (General)
	Brand Name +Dosage Form + Strength	OSPRA-PLUS Capsules 20/1100mg
	Composition	Each capsule contains: Omeprazole…….20mg Sodium bicarbonate …….1100mg
	Diary No. Date of R& I & fee	Dy No. 14576 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789179 dated 07-03-2019.
	Pharmacological Group	Proton pump inhibitors ATC Code A02BC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zegerid capsule USFDA Approved
	Me-too status	Outset Capsules GT Pharma (Pvt) Ltd., Lahore Reg. No. 86378
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years.
	Decision of 327th meeting of RB	**Deferred for submission of latest GMP inspection report conducted within last three years.**
	Reply of Applicant	Reply of applicant was submitted vide letter No. LP/RA-081/2023 dated 26-06-2023, stating the following: • Inspection for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) • Tablet Psychotropic (New)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with Innovator's specification.	
877.	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	LAXMAC tablet 60mg
	Composition	Each film coated tablet contains: Loxoprefen Sodium as Hydrate…….60mg
	Diary No. Date of R& I & fee	Dy No. 14571 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789174 dated 07-03-2019.
	Pharmacological Group	Analgesic, anti-inflammatory, anti-pyretic
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available for film coated tablet and applied composition
	Me-too status	Loxonin 60mg film coated tablet

		Evolution Pharmaceuticals (Pvt.) Ltd
	GMP status	Last GMP inspection conducted on 10-07-2019
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required. • Composition approved in PMDA Japan is Loxoprofen sodium hydrate (JP) 68.1mg (Brand name Kunihiro) whereas applied composition is Loxoprefen Sodium as Hydrate 60mg. Change in composition according to RRA is required along with relevant fee. • Applied product is film coated tablet. Evidence of product approved in PMDA, Japan is of uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with prescribed fee is required.
	Decision of 327th meeting of RB	**Deferred for following:** • **Change in formulation from film coated to uncoated tablet as available in reference regulatory authority, along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Change in composition from Loxoprefen Sodium as Hydrate 60mg to Loxoprofen sodium hydrate (JP) 68.1mg 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 (full fee of registration).** • **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 for grant of one additional section and renewal was conducted on 25-02-2021 and the panel had recommended the following sections: Tablet (General) Capsule (Cephalosporin) Dry Suspension (Cephalosporin) Capsule (General) Cream/Ointment/Gel (General) Tablet Psychotropic (New) • Change in composition and dosage form (film coated to uncoated tablet) along with Rs. 30,000/- fee.
	Remarks of the Evaluator[xxiii].	
	Decision: Approved as uncoated tablet with JP specification and following label claim: "Each tablet contains: Loxoprofen sodium hydrate…….68.1mg".	

Case no. 02 Registration applications for local manufacturing of (Veterinary) drugs (Form 5)

a. New cases

878.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603) Dry Powder Section (General) Veterinary
	Brand Name +Dosage Form + Strength	DIAREX ORAL POWDER
	Composition	Each gram contains: Neomycin sulphate (BP)…33.33mg Streptomycin sulphate (BP)… 33.33mg Sulphaguanidine (BP)… 0.33g

		Kaolin (BP)…0.33g Pectin (USP)… 33.33mg Bismuth Subnitrate (USP)…0.167g Vitamin A Acetate (BP)… 6,666.67 IU
	Diary No. Date of R& I & fee	Dy.No 32841 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 16359930
	Pharmacological Group	Antibiotic & Vitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	12g, 100g: Decontrolled
	Me-too status	Diarroban Oral Powder M/s. Star Labs, Lahore Reg. No. 026438
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	
	Decision: Approved. Firm shall submit Rs. 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications before issuance of registration letter.	
879.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603) Dry Powder Section (General) Veterinary
	Brand Name +Dosage Form + Strength	NUTRIGEST ORAL POWDER
	Composition	Each gram contains: Propionic Acid Calcium…250mg Propionic Acid Sodium…400mg Acetanilide…150mg Magnesium Oxide…125mg Iron II Sulphate…0.40mg Zinc Sulphate…0.10mg Magnesium Sulphate…0.20mg Copper Sulphate…0.45mg Cobalt Sulphate…0.40mg Sodium Molybedate…0.10mg Sodium Chloride…20mg
	Diary No. Date of R& I & fee	Dy.No 32842 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 2760880684
	Pharmacological Group	Minerals
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100g: Decontrolled
	Me-too status	Gestone Oral Powder M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 044911)
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	• Evidence of availability of Atomic Absorption Spectrophotometer for testing of metals is required.
	Decision: Deferred for submission of evidence of availability of Atomic Absorption Spectrophotometer for testing of metals. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
880.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603)
	Brand Name +Dosage Form + Strength	DEXA GCT INJECTION

	Composition	Each ml Contains: Gentamicin Sulphate ……..…60mg Tylosin Tartrate ……150mg Dexamethasone ……..…0.265mg Chlorpheniramine ……..…7.5mg
	Diary No. Date of R& I & fee	Dy.No 32843 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 1425829464
	Pharmacological Group	Antibiotic, Steroid, Anti-histamine
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Genta Combisone Injection (10ml, 20ml, 50ml, 100ml, 250ml), Leads Pharma, Islamabad. Reg. No. 046696.
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	• Evidence of approval of Veterinary Liquid Injectable (Steroidal) Section from CLB, DRAP is required. • Latest GMP inspection report conducted within a period of last three years is required. • As the applied formulation also includes Dexamethasone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
	Decision: Deferred for the following; • **Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following:** • **Evidence of approval of Veterinary Liquid Injectable (Steroidal) Section (Small volume parenterals) from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years.** • **Choice of only one pack size.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
881.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603)
	Brand Name +Dosage Form + Strength	ZOTAT IM INJECTION
	Composition	Each ml contains: Cyproterone…..350mg
	Diary No. Date of R& I & fee	Dy.No 32844 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 1370007004
	Pharmacological Group	Anti-androgens
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml: Decontrolled
	Me-too status	Not confirmed
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	• Cyproterone is a steroidal modulator of sex hormone. Application may be referred to EWG for veterinary drugs for clarity regrading classification of Cyproterone; whether it is a steroid only or a steroidal hormone, or otherwise.

		• Accordingly, evidence of required manufacturing facility is required. Firm has Liquid Injectable section (General) (Veterinary) but does not have section for manufacturing steroidal and/or hormonal liquid injectable. • 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 or in case of unavailability applicant shall apply on Form 5-D. • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for review of EWG on veterinary drugs for clarity regarding classification of Cyproterone; whether it is a steroid only or a steroidal hormone, or otherwise, and for submission of the following: • **Evidence of dedicated manufacturing facility for Veterinary Liquid Injectable (steroidal hormone) (small volume parenterals) and its approval thereof from CLB, DRAP (in case the EWG decides that the applied drug is a steroid hormone)** • **Latest GMP inspection report conducted within a period of last three years,** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) 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, .**	
882.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603)
	Brand Name +Dosage Form + Strength	Prednimine Injectable suspension
	Composition	Each ml contains: Prednisolone……..10mg Chlorpheniramine Maleate…..4mg
	Diary No. Date of R& I & fee	Dy.No 32845 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 096815862
	Pharmacological Group	Corticosteroid & antihistamine
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml vial: Decontrolled
	Me-too status	PREDINE INJECTION Reg. No. 043199 M/s Guyton Pharmaceuticals, Lahore.
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for review of EWG on veterinary drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Evidence of approval of Veterinary Liquid Injectable (Steroidal) (Small volume parenterals) Section from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
883.	Name and address of manufacturer / Applicant	Zakfas Pharmaceuticals (Pvt.) Ltd, 12-km Lutaf Abad Bosan Road, Multan. (DML No. 000603)

		Oral Liquid Veterinary Section
	Brand Name +Dosage Form + Strength	LEVAFOS GOLD SUSPENSION
	Composition	Each 1000mL contains: Triclabendazole ….. 3%w/v. Levamisole HCl…….. 6%w/v. Sodium Selenite 0.07%w/v. Cobalt Chloride 0.15%w/v.
	Diary No. Date of R& I & fee	Dy.No 32846 dated 02-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 1434422315
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml plastic bottle; Decontrolled
	Me-too status	Vermicide gold liquid (as provided by the firm) Each mL contains: Levamisole HCl ….. 3%w/v Oxyclozanide …….. 6%w/v Sodium Selenite 0.07%w/v Cobalt Chloride 0.15%w/v M/s Leads Pharma (Pvt) Ltd Reg. No. 043555
	GMP status	Panel inspection conducted on 15-06-2021 whereby renewal of DML and grant of one additional section was recommended.
	Remarks of the Evaluator[xxiii].	• Change the composition according to drug product already registered by DRAP and also provided as me-too by the applicant (Vermicide gold liquid; Reg. No. 043555), along with full fee of registration (PKR 30,000) prescribed vide S.R.O 496(I)/2023 dated 17-04-2023. • Evidence of testing facility for metals is required. • The composition of metoo provided by the firm is different from the applied composition, the firm may be asked to provide "Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, pack size, brand name and name of firm."
	Decision: Deferred for following: • **Evidence of testing facility for metals,** • **Latest GMP inspection report conducted within a period of last three years,** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, pack size, 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, .**	
884.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injection (General Antibiotic) Section
	Brand Name +Dosage Form + Strength	ENROFAR 20% INJECTION
	Composition	Each ml contains: Enrofloxacin…..200mg
	Diary No. Date of R& I & fee	Dy.No 31320 dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 531154388
	Pharmacological Group	Fluroquinolone antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml glass vial; Decontrolled

	Me-too status	Enras-20 Injection (10ml) M/s Zakfas Pharmaceutical (Pvt) Ltd Multan Reg. No. 057071 Enflox-20% Injection (50ml) M/s Univet Pharmaceuticals, Rawalpindi. Reg. No. 112216 Enropro 20% Injection (100ml) M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. Reg. No. 112252
	GMP status	GMP Inspection was conducted on 29-07-2022. The panel had concluded that the firm was GMP compliant on the day of inspection for the following sections: Veterinary Liquid Injection (General) Veterinary Liquid Injection (General Antibiotic) Veterinary Powder (General and General Antibiotic)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved. Firm shall select only one pack size before issuance of registration letter.	
885.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	MELO-FAR 20 INJECTION
	Composition	Each ml contains: Meloxicam……20mg
	Diary No. Date of R& I & fee	Dy.No 31319 dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 345915365932
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & Demanded Price	10ml, 100ml glass vial; Decontrolled
	Me-too status	Camrold 20 Liquid Injection (100ml) M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. Reg. No. 109006
	GMP status	As above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved for 100ml pack size only with BP specification as formulation in aforesaid volume in registred by DRAP.	
886.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	MIL-D-FAR INJECTION
	Composition	Each ml Contains: Calcium Gluconate…208.3mg Calcium D-Sacharate…10mg Magnesium Hypophosphite…53.3mg Magnesium Chloride…20mg Boric Acid…43.3mg Dextrose…200mg Vitamin B1…1mg Vitamin B2…0.7mg Vitamin B12…30mcg Nicotinamide…2mg
	Diary No. Date of R& I & fee	Dy.No 31318 dated 12-11-2021 Rs.30,000/- dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No.

		039497054842
	Pharmacological Group	Electrolytes/Minerals/Antidotes/Multivitamins
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	300ml vial; Decontrolled
	Me-too status	Not found in available record
	GMP status	As above
	Remarks of the Evaluator[xxiii].	• Firm was advised to provide, inter alia, the following vide letter No. F.2-1/2023/ PEC-DRAP (DD-PEC-XXIII) dated 04-07-2023: "Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, pack size, brand name and name of firm." Reply of applicant was submitted vide letter No. IZF/DRAP-PEC/JUL-23-04 dated 07-07-2023 (Dy No. 17153 dt 10-07-2023), stating **Mil-D Forte Injection (Reg. No. 007629) by M/s Star Laboratories, Lahore** as the me-too product. However, the same could not be confirmed from available database. Firm may be advised to provide some other me-too/ generic.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, pack size, brand name and name of firm.** • **Evidence of relevant manufacturing facility.** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
887.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	BUPRAFAR INJECTION
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 31321 dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No.49138137715
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	20ml, 50ml, 100ml glass vial; Decontrolled
	Me-too status	Bupralex Injection M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 033264 (Registered in all applied pack sizes i.e. 20ml, 50ml, 100ml)
	GMP status	As above
	Remarks of the Evaluator[xxiii].	
	Decision: Approved. Firm shall select any one pack size before issuance of registration letter.	
888.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceuticals (Pvt) Ltd. Plot No. 542 A-B, Sundar Industrial Estate, Lahore, Pakistan. (DML 000800) Veterinary Liquid Injectable Section (General)
	Brand Name +Dosage Form + Strength	MILFAR-C INJECTION
	Composition	Each ml Contains: Calcium Gluconate…208.3mg Calcium D Sacharate…10mg

		Magnesium Hypophosphite…53.3mg Magnesium Chloride…20mg Boric Acid…43.3mg Dextrose…200mg
	Diary No. Date of R& I & fee	Dy.No 31322 dated 12-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No.769136104014
	Pharmacological Group	Electrolytes/Minerals/Antidotes
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	300ml, 450ml glass vial; Decontrolled
	Me-too status	Milphone-C injection (300ml) M/s Star Laboratories, Lahore Reg. No. 003794
	GMP status	As above
	Remarks of the Evaluator[xxiii].	• Firm was advised to provide, inter alia, the following vide letter No. F.2-1/2023/ PEC-DRAP (DD-PEC-XXIII) dated 04-07-2023: "Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the applied fill volume** along with registration number, pack size, brand name and name of firm." Reply of applicant was submitted vide letter No. IZF/DRAP-PEC/JUL-23-05 dated 07-07-2023 (Dy No. 17152 dt 10-07-2023), stating **Milfone-C (Reg. No. 003794)** as the me-too product. According to the available office record, the me-too product is available in 300ml with different composition than the applied product. Accordingly, revision of pack size, change in master composition and label claim as follows according to product already approved by DRAP is required, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: Calcium Gluconate 65.83mg Calcium D Saccharase 3.33mg Magnesium Hypophosphate 16.67mg Magnesium Chloride 3.33mg Magnesium Hypophosphate 16.67mg Magnesium Chloride 3.33mg Boric Acid 14.1mcg Dextrose 66.67mcg"
	Decision: Deferred for submission of following: • **Confirmation of LVP manufacturing facility** • **Justfication of the applied formulation regarding the concentrations of ingredients per ml.**	
889.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd, Plot No.145, Industrial Triangle, Kahuta Road, Islamabad (DML 000296) Veterinary Oral Liquid Section (General)
	Brand Name +Dosage Form + Strength	METPHOR ORAL LIQUID
	Composition	Each ml Contains: Bromhexine…0.05mg Guaiphenesin…25mg Aminophylline…20mg Menthol…20mg
	Diary No. Date of R& I & fee	Dy.No 31948 dated 22-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 4711251793
	Pharmacological Group	Mucolytic, Expectorant, Bronchodilator

	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1L; Decontrolled
	Me-too status	Not provided
	GMP status	GMP inspection conducted on 03-08-2021 on the basis of which GMP compliance certificate No. F.3-19/2019-Addl. Dir. (QA&LT-I) dated 28-02-22 was issued.
	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: 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 response within 1 month after publication of the minutes, .**	
890.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd, Plot No.145, Industrial Triangle, Kahuta Road, Islamabad (DML 000296) Veterinary Oral Liquid Section (General)
	Brand Name +Dosage Form + Strength	GUAMET ORAL LIQUID
	Composition	Each ml contains: Aminophylline…150mg Bromhexine HCl…10.5mg Guaiphenesin…100mg Camphor…10mg Menthol…10mg
	Diary No. Date of R& I & fee	Dy.No 31949 dated 22-11-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 4537813497
	Pharmacological Group	Mucolytic, Expectorant, Bronchodilator
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1L; Decontrolled
	Me-too status	Not provided
	GMP status	GMP inspection conducted on 03-08-2021 on the basis of which GMP compliance certificate No. F.3-19/2019-Addl. Dir. (QA&LT-I) dated 28-02-22 was issued.
	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: 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 response within 1 month after publication of the minutes, .**	
891.	Name and address of manufacturer / Applicant	M/s Bio-Oxime Pharmaceuticals, Plot. No.31, 32 Millat Garment City, Dry Port Road, Faisalabad (DML 000812) Veterinary Oral Powder Section (General)
	Brand Name +Dosage Form + Strength	FLOTETRA WATER SOLUBLE POWDER
	Composition	Each gm Contains: Florfenicol…150mg Oxytetracycline HCl…150mg
	Diary No. Date of R& I & fee	Dy.No 32859 dated 15-12-2021; PKR 30,000/-vide Deposit Slip No. 16721295
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications

	Pack size & Demanded Price	500g, 1000g jar; Decontrolled
	Me-too status	Floxybar 30 Water Soluble Powder (100g, 500g, 1000g, 2500g) M/s Baariq Pharmaceuticals, Lahore. Reg. No. 072601
	GMP status	DML renewal inspection conducted on 24-02-2021. The panel had recommended the renewal of DML for following two sections: Veterinary Oral Powder Section (General) Veterinary Oral Liquid Section (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. **Firm shall submit Rs. 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications before issuance of registration letter.**	
892.	Name and address of manufacturer / Applicant	M/s Bio-Oxime Pharmaceuticals, Plot. No.31, 32 Millat Garment City, Dry Port Road, Faisalabad (DML 000812) Veterinary Oral Powder Section (General)
	Brand Name +Dosage Form + Strength	FOS-T WATER SOLUBLE POWDER
	Composition	Each mg contains: Calcium Fosfomycin…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 32858 dated 15-12-2021 Fee paid PKR 30,000/-vide Deposit Slip No. 0831839841
	Pharmacological Group	Antibiotic, electrolytes
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	25g,50g,100g,160g,500g, 1kg, 20kg; Decontrolled
	Me-too status	Fosfomax Oral Powder M/s Biogen Pharma, Rawat Reg. No.063808
	GMP status	DML renewal inspection conducted on 24-02-2021. The panel had recommended the renewal of DML for following two sections: Veterinary Oral Powder Section (General) Veterinary Oral Liquid Section (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with following label claim: **Each mg contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **Firm shall submit Rs. 30,000 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in label claim and finished product specifications before issuance of registration letter.**	
893.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB AMPROL-F ORAL POWDER
	Composition	Each Gram contains: Amprolium HCl Eq. to Amprolium…200mg Furaltadone HCl Eq. to Furaltadone…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 29975 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 41286788215

	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	Amprodone Water Soluble Powder Reg. No. 46574 M/s Noa Hemis Pharmaceuticals, Karachi
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• The applied formulation includes Furaltadone; show cause has been issued to other firms having registered formulation containing the salt Furaltadone. • Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Amprolium HCl…….. 200mg Furaltadone HC……..200mg" • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Rejected due to presence of Furaltadone in applied formulation as Registration Board in its 308th meeting decided on the recommendation of Expert Working Group on Veterinary Drugs to issue show cause notices to all registered veterinary drugs containing Furaltadone due to strong potential of causing genotoxicity, cytotoxicity and possible residual effects. **The Board further advised the concerned section to place the products already registred in above formulation for issuance of show cause notices for cancellation of registration.**	
894.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB LINCOMIX-4 ORAL POWDER
	Composition	Each 100gm contains: Lincomycin HCl Eq. to Lincomycin…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 29974 dated 03-11-202; Rs.30,000/- vide Deposit Slip No.803769350
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	Lincosel-40 Oral Powder Reg. No. 089826 M/s Selmore Pharmaceuticals (Pvt) Limited, 36 Km, Multan Road, Lahore.
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gm contains: Lincomycin HCl Eq. to Lincomycin…400mg" • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following:	

	• **Evidence of section approval issued by Licensing Division, DRAP** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows:** **"Each gram contains:** **Lincomycin HCl Eq. to Lincomycin…400mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
895.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	MG KILLER ORAL POWDER
	Composition	Each gram contains: Oxytetracycline HCl Eq. to Oxytetracycline…200mg Tylosin Tartrate Eq. to Tylosin…100mg Bromhexine HCl Eq. to Bromhexine…5mg Streptomycin Sulphate Eq. to Streptomycin…20mg Colistin Sulphate Eq. to Colistin…500,000IU
	Diary No. Date of R& I & fee	Dy.No 29973 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No.74196145725
	Pharmacological Group	Antibacterial and Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Not stated
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	Not confirmed
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Composition of me-too product provided by the firm is different from that of the applied product. 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. • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Finished product specifications are required.
	Decision: Deferred for commnets of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already regisrred formulation if any will treated in line with commnets/ recommendation of Ministry of Food Security.	
896.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB DOX 50 ORAL POWDER
	Composition	Each gram contains: Doxycycline HCl Eq. to Doxycycline…500mg
	Diary No. Date of R& I & fee	Dy.No 29976 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 91728963423
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	D FORT-50 Oral Powder Reg. No. 80963 M/s Kohinoor Industries, Sahiwal
	GMP status	Last GMP inspection conducted on 07-10-2019

	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Doxycycline HCl…..…500mg" • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -** **Doxycycline HCl…..…500mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
897.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB NEODOX-20 ORAL POWDER
	Composition	Each gram contains: Doxycycline HCl Eq. to Doxycycline…200mg Neomycin Sulphate Eq. to Neomycin…200mg
	Diary No. Date of R& I & fee	Dy.No 29972 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 56690347106
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	DOXY & NEO water soluble powder Reg. No. 63823 M/s Attabak Pharmaceuticals, Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
898.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB NEO CHLORTIN-B ORAL POWDER
	Composition	Each gram contains: Neomycin Sulphate Eq. to Neomycin…70mg Colistin Sulphate Eq. to Colistin…4mg Chlortetracycline HCl Eq. to Chlortetracycline…80mg Bromhexine HCl Eq. to Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 29970 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 907794963

	Pharmacological Group	Antibacterial and Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	Z-CNC PLUS Water Soluble Powder Reg. No. 80943 M/s Zoic International, Lahore
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years 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 OR submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for pre-approval change for equivalency and adjustment of weight as per salt factor according to the product already registered by DRAP/me-too status provided by the applicant as follows: Each gram contains: - Neomycin Sulphate…70mg Colistin Sulphate……4mg Chlortetracycline HCl…80mg Bromhexine HCl…..5mg
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -** **Neomycin Sulphate…70mg** **Colistin Sulphate……4mg** **Chlortetracycline HCl…80mg** **Bromhexine HCl…..5mg "** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
899.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB AMPROL-90 ORAL POWDER
	Composition	Each gram contains: Amprolium HCl Eq. to Amprolium…900mg
	Diary No. Date of R& I & fee	Dy.No 29971 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 3466453964
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	MAK Amprolium Soluble Powder Reg. No. 63609 M/s Medicure Labs, Karachi
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required

		• Latest GMP inspection report conducted within a period of last three years 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 OR submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for pre-approval change for equivalency and adjustment of weight as per salt factor according to the product already registered by DRAP/me-too status provided by the applicant as follows: Each gram contains:- Amprolium HCl ……900mg
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains:-** **Amprolium HCl ……900mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
900.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB LINCOAMOXITIN-B ORAL POWDER
	Composition	Each 1gm contains: Colistin Sulphate Eq. to Colistin…500,000IU Lincomycin HCl Eq. to Lincomycin…50mg Amoxycillin Trihydrate Eq. to Amoxycillin….100mg Bromhexine HCl Eq. to Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 29982 dated 03-11-2021 Rs.30,000/- vide Deposit Slip No. 66250895
	Pharmacological Group	Antibacterial and Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Colab Water Soluble Powder Reg. No. 079839 By M/s Decent Pharma, Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019
	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 OR submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for pre-approval change for equivalency and adjustment of weight as per salt factor according to the product already registered by DRAP/me-too status provided by the applicant as follows: Each gram contains:- Colistin Sulphate……500,000 IU Lincomycin HCl…….50mg Amoxycillin trihydrate…100mg Bromhexine HCl…….5mg • Evidence of section approval issued by Licensing Division, DRAP is required

		• Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -** **Colistin Sulphate……500,000 IU** **Lincomycin HCl…….50mg** **Amoxycillin trihydrate…100mg** **Bromhexine HCl…….5mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
901.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-NEOCOMOX ORAL POWDER
	Composition	Each gram contains: Amoxycillin Trihydrate Eq. to Amoxycillin…100mg Colistin Sulphate Eq. to Colistin…50mg Neomycin Sulphate Eq. to Neomycin…200mg
	Diary No. Date of R& I & fee	Dy.No 29983 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 334604183
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	NEO AC water soluble powder Reg. No. 079844 of M/s Decent Pharma, Islamabad.
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years 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 OR submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for pre-approval change for equivalency and adjustment of weight as per salt factor according to the product already registered by DRAP/me-too status provided by the applicant as follows: Each gram contains: - Amoxycillin as trihydrate ……100mg Colistin Sulphate……...50mg Neomycin Sulphate …….200 mg
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -** **Amoxycillin as trihydrate ……100mg** **Colistin Sulphate……....50mg**	

	Neomycin Sulphate …….200 mg" **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
902.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB FLOROX ORAL POWDER
	Composition	Each gram contains: Oxytetracycline HCl Eq. to Oxytetracycline…150mg Florfenicol…150mg
	Diary No. Date of R& I & fee	Dy.No 29980 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 615419562
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	OXY-FLORO Water Soluble Powder Reg. No. 80726 M/s Intervac Pharma, Lahore.
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Revision of label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Oxytetracycline HCl…150mg Florfenicol…150mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows:** **"Each gram contains: -** **Oxytetracycline HCl…150mg** **Florfenicol…150mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
903.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-LINCOMIX 1.1 ORAL POWDER
	Composition	Each gram contains: Lincomycin HCl Eq. to Lincomycin…11mg
	Diary No. Date of R& I & fee	Dy.No 29981 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No. 092770998
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Linco Premix 1100 Water Soluble Powder Reg. No. 75703 M/s Attabak Pharmaceuticals, Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019

	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Revision of label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Lincomycin HCl …11mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows:** **"Each gram contains: -** **Lincomycin HCl …11mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
904.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB AMOXITIN EXTRA ORAL POWDER
	Composition	Each gram contains: Amoxycillin Trihydrate Eq. to Amoxycillin…500mg Colistin Sulphate Eq. to Colistin…500,000IU Dextrose Anhydrous …1g
	Diary No. Date of R& I & fee	Dy.No 29978 dated 03-11-2021 ; Rs.30,000/- vide Deposit Slip No. 6149109575
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Euromox-50 Water Soluble Powder Reg. No. 80156 M/S DECENT Pharma, Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Revision of label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Amoxycillin Trihydrate… 500mg Colistin Sulphate… 500,000IU Dextrose Anhydrous (qasr) …1g"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -**	

	Amoxycillin Trihydrate… 500mg **Colistin Sulphate… 500,000IU** **Dextrose Anhydrous (qasr) …1g"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
905.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB ALS-50 ORAL POWDER
	Composition	Each gram contains: Amoxycillin as Trihydrate Eq. to Amoxycillin…100mg Lincomycin as HCl Eq. to Lincomycin…50mg Streptomycin 2HCL Eq. to Streptomycin…50mg
	Diary No. Date of R& I & fee	Dy.No 29979 dated 03-11-2021; Rs.30,000/- vide Deposit Slip No.36564698
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Alspectomix Water Soluble Powder Reg. No. 080155 M/S. Decent Pharma, Plot # 30, Street # Ss-3, National Industrial Zone, Rawat, Islamabad.
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Change in master formulation and revision of label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: - Amoxycillin as Trihydrate .....100mg Lincomycin As HCl…….50mg Streptomycin 2HCl ...50mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in master formulation and revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains: -** **Amoxycillin as Trihydrate .....100mg** **Lincomycin as HCl……..50mg** **Streptomycin 2HCl ...50mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
906.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB NICOSTREP ORAL POWDER
	Composition	Each Gram contains: Chlorteracycline HCl…200mg Neomycin Sulphate…60mg Streptomycin Sulphate…20mg Colistin Sulphate…10mg
	Diary No. Date of R& I & fee	Dy.No 29977 dated 03-11-2021; Rs.30,000/- vide Deposit

		Slip No. 805051975
	Pharmacological Group	Antibacterial and Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Streptochlor Water Soluble Powder Reg. No. 80738 M/s Baariq Pharmaceuticals, Lahore
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• As the applied formulation is a combination of four antibiotics, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Evidence of section approval issued from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
907.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-GALA ORAL POWDER
	Composition	Each gram contains: Amoxycillin Trihydrate Eq. to Amoxycillin…50mg Lysozyme HCl Eq. to Lysozyme…10mg Guaifenesin…35mg
	Diary No. Date of R& I & fee	Dy.No 33163 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No.7164129202
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form 5
	Finished Product Specification	Not mentioned
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Amoxy Add Water Soluble Powder M/s Samyang Anipharm Co., Seoul, Korea Reg. No. 069649
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Provide rationality and solubility of formulation as similar product was deferred for same in 326th meeting of Registration Board held from 14th to 16th March, 2023 • Provide finished product specifications. • Change dosage form from oral powder to water soluble powder, change master formulation and revise label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Amoxicillin Trihydrate…. 50gm Lysozyme Chloride . …….. 10gm Guaifenesin …….. ….…….35gm"

		• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Finished product specifications** • **Rationality of formulation as similar product was deferred for same in 326th meeting of Registration Board** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in dosage form from oral powder to water soluble powder, change in master formulation and revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains:** **Amoxicillin Trihydrate…. 50gm** **Lysozyme Chloride . …….. 10gm** **Guaifenesin …….. ….…….35gm"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
908.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-TYLOFUR ORAL POWDER
	Composition	Each gram contains: Tylosin Tartrate Eq. to Tylosin…60mg Furaltadone HCl Eq. to Furaltadone…150mg Bromhexine HCl Eq. to Bromhexine…5mg Erythromycin Thiocyanate Eq. to Erythromycin…40mg
	Diary No. Date of R& I & fee	Dy.No 33164 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 3292392855
	Pharmacological Group	Antibiotic and mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Tylovit e.f plus powder M/s Leads Pharma (Pvt) Ltd., Islamabad Reg. No. 044950
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • The applied formulation includes Furaltadone; show cause has been issued to other firms having registered formulation containing the salt Furaltadone. • Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: • Each gram contains: - Tylosin tartrate ……. 60mg Furaltadone HCl …….. 150mg Bromhexine HCl…… 05mg. Erythromycin thiocyanate 40mg
	Decision: Rejected due to presence of Furaltadone as Registration Board in its 308th	

	meeting decided on the recommendation of Expert Working Group on Veterinary Drugs to issue show cause notices to all registered veterinary drugs containing Furaltadone due to strong potential of causing genotoxicity, cytotoxicity and possible residual effects.	
909.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-NEOVIT ORAL POWDER
	Composition	Each 1000gram contains: Oxytetracycline HCl Eq. to Oxytetracycline…250mg Neomycin Sulphate Eq. to Neomycin…100mg Furaltadone HCl Eq. to Furaltadone…250mg Sodium Sulphate…60mg Vitamin A…2500IU Vitamin D3…500IU Vitamin E…1mg Vitamin C…100mg
	Diary No. Date of R& I & fee	Dy.No 33165 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 00716836262
	Pharmacological Group	Antibiotic and Multivitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	AR TNF 100 Oral Powder M/s Mallard Pharmaceuticals, Multan Reg. No. 53963
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • The applied formulation includes Furaltadone; show cause has been issued to other firms having registered formulation containing the salt Furaltadone. • Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Oxytetracycline HCl …250mcg Neomycin Sulphate …100mg Furaltadone HCl…250mg Sodium Sulphate…60mg Vitamin A…2500IU Vitamin D3…500IU Vitamin E…1mg Vitamin C…100mg"
	Decision: Rejected due to presence of Furaltadone as Registration Board in its 308th meeting decided on the recommendation of Expert Working Group on Veterinary Drugs to issue show cause notices to all registered veterinary drugs containing Furaltadone due to strong potential of causing genotoxicity, cytotoxicity and possible residual effects.	
910.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-OLAVIT ORAL POWDER
	Composition	Each gram contains: Olanquindox…100mg Vitamin A…600IU

		Vitamin D3…400IU Vitamin E…50IU
	Diary No. Date of R& I & fee	Dy.No 33162 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 1513922799
	Pharmacological Group	Antibiotic and Multivitamin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	OLADOX Oral Powder Reg. No. 63810 M/S Biogen Pharma, Rawat
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Rectify typographical error in name of API as follows, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Olaquindox…100mg Vitamin A…600IU Vitamin D3…400IU Vitamin E…50IU"
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Evidence of section approval issued from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years,** • **Submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for rectification of typographical error in name of API as follows:** **"Each gram contains:** **Olaquindox…100mg** **Vitamin A…600IU** **Vitamin D3…400IU** **Vitamin E…50IU"** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
911.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB AMCOLIN A & K ORAL POWDER
	Composition	Each gram contains: Amprolium HCl Eq. to Amprolium…166mg Sulphaquinoxaline Sodium Eq. to Sulphaquinoxaline…166mg Colistin Sulphate Eq. to Colistin…500,000IU Vitamin A…5000IU Vitamin K3…5mg
	Diary No. Date of R& I & fee	Dy.No 33157 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 74548550
	Pharmacological Group	Antiprotozoal, Antibiotic, Multivitamins
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	EMRICIDE-AK Oral Powder M/s Hawk Bio Pharma, Islamabad

		Reg. No. 078396
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Amprolium HCl …166mg Sulphaquinoxaline Sodium …166mg Colistin Sulphate …500,000IU Vitamin A…5000IU Vitamin K3…5mg" • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains:** **Amprolium HCl …166mg** **Sulphaquinoxaline Sodium …166mg** **Colistin Sulphate …500,000IU** **Vitamin A…5000IU** **Vitamin K3…5mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
912.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB PROCOL Z ORAL POWDER
	Composition	Each gram contains: Procaine Penicillin…12mg Streptomycin Sulphate Eq. to Streptomycin…36mg Colistin Sulphate Eq. to Colistin…60,000IU Zinc Bacitracin…52mg
	Diary No. Date of R& I & fee	Dy. No 33156 dated 21-12-2021; Rs. 30,000/- vide Deposit Slip No. 0305920554
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Not mentioned
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Zeptocol Water Soluble Powder Reg. No. 080962 M/s Selmore Pharmaceuticals, Lahore
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • As the applied formulation is a combination of four antibiotics, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.

		• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Procaine Penicillin……12mg Streptomycin Sulphate …36mg Colistin Sulphate…60,000IU Zinc Bacitracin…52mg"
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Evidence of section approval issued from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each gram contains:** **Procaine Penicillin……12mg** **Streptomycin Sulphate …36mg** **Colistin Sulphate…60,000IU** **Zinc Bacitracin…52mg"** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
913.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-SORBVIT ORAL POWDER
	Composition	Each gram contains: Methnamine Mandelate…900mg Vitamin B1…7mg Vitamin C…1mg Sorbitol…50mg
	Diary No. Date of R& I & fee	Dy.No 33166 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 54619903
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg; Decontrolled
	Me-too status	Vety-Flush Powder Reg. No.019938 M/s Vety-Care, Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Rectify typographical error in name of API as follows, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Methenamine Mandelate…900mg Vitamin B1…7mg Vitamin C…1mg Sorbitol…50mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,**	

	• **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change of finished product specifications and rectification of typographical error in name of API as follows:** **"Each gram contains:** **Methenamine Mandelate…900mg** **Vitamin B1…7mg** **Vitamin C…1mg** **Sorbitol…50mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
914.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-FOSFO ORAL POWDER
	Composition	Each gram contains: Fosfomycin Calcium Eq. to Fosfomycin…200mg Tylosin Tartrate Eq. to Tylosin…100mg Fructose…180mg Sodium Phosphate Eq. to Sodium…150mg Magnesium Sulphate Eq. to Magnesium…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 33167 dated 21-12-2021 ;Rs.30,000/- vide Deposit Slip No. 8979453502
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 5kg, 20kg: Decontrolled
	Me-too status	Fosfotyl Powder M/s Leads Pharma, Islamabad Reg. No. 78240
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each gram contains: Fosfomycin Calcium …200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP as follows:** **"Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg"** **The Board further decided that the applicant shall submit response within 1 month after**	

	publication of the minutes, .	
915.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-ORASOUL ORAL LIQUID
	Composition	Each ml contains: Ammonium Chloride…650mg Methionine…100mg Sorbitol…50mg Vitamin A…2,500,000 IU Vitamin C…100mg
	Diary No. Date of R& I & fee	Dy.No 33161 dated 21-12-2021 ;Rs.30,000/- vide Deposit Slip No.116901105
	Pharmacological Group	Multivitamins and Expectorant
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml; Decontrolled
	Me-too status	Aminoflash Oral Liquid M/S. Baariq Pharmaceuticals, Lahore Reg. No. 080732
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
916.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB VIT-E PLUS ORAL LIQUID
	Composition	Each ml contains: Vitamin C…40mg Vitamin E…200mg Selenium…25mg
	Diary No. Date of R& I & fee	Dy.No 33160 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 87916049148
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml; Decontrolled
	Me-too status	Soluvit E Plus Oral Liquid Reg. No. 57046 M/s LEADS Pharma Islamabad
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• The master formulation includes water as solvent along with three APIs. Vitamin E is not soluble in water. The master formulation and manufacturing method need to be revised to add solubilizer for dissolving Vitamin E. • Revision in label claim and master formulation is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023:

		"Each ml contains: Vitamin C…40mg Vitamin E…200mg Selenium (as Sodium Selenite)…25mg" • Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each ml contains:** **Vitamin C…40mg** **Vitamin E…200mg** **Selenium (as Sodium Selenite) …25mg"** • **Change in master formulation and method of manufacturing to include solubilizer for Vitamin E.** • **evidence of availability of Atomic Absorption Spectrophotometer for testing of metals.** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
917.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB BRO-10 ORAL LIQUID
	Composition	Each ml contains: Bromhexine HCl Eq. to Bromhexine…10mg
	Diary No. Date of R& I & fee	Dy.No 33159 dated 21-12-2021 ;Rs.30,000/- vide Deposit Slip No. 4193288024
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml; Decontrolled
	Me-too status	Bromosol Oral Liquid 10% M/s. Intervac (Pvt) Ltd., Sheikhupura Reg. No. 080725
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required. • Revision in label claim is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains:- Bromhexine HCl……10mg"
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each ml contains:-**	

	Bromhexine HCl……10mg" **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
918.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000426)
	Brand Name +Dosage Form + Strength	SB-ENGOPHYLLIN ORAL LIQUID
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…40mg Guaiphenesin…100mg
	Diary No. Date of R& I & fee	Dy.No 33158 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 508564398487
	Pharmacological Group	Antibiotic, Bronchodilator, Expectorant
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml; Decontrolled
	Me-too status	Enrophylin Oral Liquid M/s Baariq Pharmaceuticals, Lahore Reg. No. 80730
	GMP status	Last GMP inspection conducted on 07-10-2019
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Latest GMP inspection report conducted within a period of last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Latest GMP inspection report conducted within a period of last three years** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
919.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20km Ferozepur Road, Lahore (DML No.00736) Liquid Injectable Vial (General) Veterinary section
	Brand Name +Dosage Form + Strength	EG-ATRO INJECTION
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 33155 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 15666300
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & Demanded Price	50ml amber colored glass vial; Decontrolled
	Me-too status	Atrovet Injection Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 034577 (10ml,25ml,50ml)
	GMP status	Inspection for DML renewal was conducted on 03-02-2023 whereby the panel had recommended the renewal for Liquid Injectable Vial (General) Veterinary section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
920.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20km Ferozepur Road, Lahore (DML No.00736) Liquid Injectable Vial (General) Veterinary section
	Brand Name +Dosage Form + Strength	EG-OXY-10 INJECTION

	Composition	Each ml contains: Oxytetracycline…100mg
	Diary No. Date of R& I & fee	Dy. No 33154 dated 21-12-2021; Rs. 30,000/- vide Deposit Slip No. 78640627506
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100ml amber colored glass vial; Decontrolled
	Me-too status	Oxyline 10% Injection M/s. Intervac (Pvt) Ltd., Sheikhupura Reg. No. 072656(10ml,20ml,50ml, 100ml)
	GMP status	Inspection for DML renewal was conducted on 03-02-2023 whereby the panel had recommended the renewal for Liquid Injectable Vial (General) Veterinary section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
921.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20km Ferozepur Road, Lahore (DML No.00736) Liquid Injectable Vial (General) Veterinary section
	Brand Name +Dosage Form + Strength	EG-OXY-20 INJECTION
	Composition	Each ml contains: Oxytetracycline…200mg
	Diary No. Date of R& I & fee	Dy. No 33153 dated 21-12-2021; Rs. 30,000/- vide Deposit Slip No. 18840946132
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100ml amber colored glass vial; Decontrolled
	Me-too status	Oxyline 20% Injection M/s. Intervac (Pvt) Ltd., Sheikhupura Reg. No. 072657(10ml,20ml,50ml, 100ml)
	GMP status	Inspection for DML renewal was conducted on 03-02-2023 whereby the panel had recommended the renewal for Liquid Injectable Vial (General) Veterinary section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
922.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20km Ferozepur Road, Lahore (DML No.00736) Liquid Injectable Vial (General) Veterinary section
	Brand Name +Dosage Form + Strength	EG-FLUNIXIN-5 INJECTION
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 33152 dated 21-12-2021 ;Rs.30,000/- vide Deposit Slip No. 2096794224
	Pharmacological Group	Veterinary NSAID
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	50ml amber colored glass vial; Decontrolled
	Me-too status	Maxin Injection M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reg. No. 043576(10ml,20ml,50ml, 100ml)
	GMP status	Inspection for DML renewal was conducted on 03-02-2023 whereby the panel had recommended the renewal for Liquid Injectable Vial (General) Veterinary section

	Remarks of the Evaluator[xxiii].	
	Decision: Approved with following label claim: **Each ml contains:** **Flunixin as Meglumine…50mg** **Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim before issuance of registration letter.**	
923.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20km Ferozepur Road, Lahore (DML No.00736) Liquid Injectable Vial (General) Veterinary section
	Brand Name +Dosage Form + Strength	EG-MEPRA-5 INJECTION
	Composition	Each ml contains: Mepyramine Maleate…50mg
	Diary No. Date of R& I & fee	Dy.No 33151 dated 21-12-2021; Rs.30,000/- vide Deposit Slip No. 056326755416
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml amber colored glass vial; Decontrolled
	Me-too status	Mepro-Vee Injection M/s Venus Pharma, Lahore Reg. No. 017063 (Pack size 10ml, 30ml, 50ml)
	GMP status	Inspection for DML renewal was conducted on 03-02-2023 whereby the panel had recommended the renewal for Liquid Injectable Vial (General) Veterinary section
	Remarks of the Evaluator[xxiii].	
	Decision: Deferred for commnets of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already regisrred formulation if any will treated in line with commnets/ recommendation of Ministry of Food Security.	
924.	Name and address of manufacturer / Applicant	M/s Jfrin Pharmaceutical Laboratories. Plot No. 16,17 & 20, Hub Industrial Trading Estate, Hub, Balochistan (DML No. 000580)
	Brand Name +Dosage Form + Strength	JFCYNO-12 INJECTION
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 33457 dated 22-12-2021; Rs.30,000/- vide Deposit Slip No. dated 3765567213
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished Product Specification	Not provided
	Pack size & Demanded Price	100ml glass vials; Decontrolled
	Me-too status	Cyanowim-1000mcg Injection 100ml M/s Wimits Pharmaceuticals, Lahore. Reg. No.102042
	GMP status	GMP inspection was conducted on 02-06-2021 whereby GMP level/compliance was rated "good"
	Remarks of the Evaluator[xxiii].	• Evidence of section approval issued by Licensing Division, DRAP is required • Finished product specifications are required
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Finished product specifications** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes,**	

925.	Name and address of manufacturer / Applicant	M/s Jfrin Pharmaceutical Laboratories. Plot No. 16,17 & 20, Hub Industrial Trading Estate, Hub, Balochistan (DML No. 000580)
	Brand Name +Dosage Form + Strength	Jfoxymeg injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 33456 dated 22-12-2021; Rs.30,000/- vide deposit Slip No. 959732467635
	Pharmacological Group	Antibiotic, anti-inflammatory
	Type of Form	Form-5
	Finished Product Specification	Not stated
	Pack size & Demanded Price	100ml glass vials; Decontrolled
	Me-too status	OTC Forte LA Injection (100ml) M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. Reg. No. 113551
	GMP status	GMP inspection was conducted on 02-06-2021 whereby GMP level/compliance was rated "good"
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains:- Oxytetracycline HCl …300mg Flunixin as Meglumine ……..20mg" • Finished product specifications are required • Evidence of section approval issued by Licensing Division, DRAP is required
	Decision: Deferred for submission of the following: • **Evidence of section approval from CLB, DRAP,** • **Finished product specifications** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows according to product already approved by DRAP:** **"Each ml contains: -** **Oxytetracycline HCl …300mg** **Flunixin as Meglumine …….20mg"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
926.	Name and address of manufacturer / Applicant	M/s Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir (DML No. 000652) Veterinary Oral Liquid (General) Section
	Brand Name +Dosage Form + Strength	Nobienro 25%(w/v) Liquid
	Composition	Each ml contains: Enrofloxacin Base…250mg
	Diary No. Date of R& I & fee	Dy.No 33454 dated 22-12-2021; Rs.30,000/- vide Deposit Slip No. 75427084952
	Pharmacological Group	Fluroquinolone antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml,500ml,1000ml bottle; Decontrolled
	Me-too status	Flunix Liquid 25% M/s Leads Pharma (Pvt) Ltd Reg. No. 046657
	GMP status	Report of GMP inspection conducted on 16-11-2018 is

		provided.
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit fee (PKR 7500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of finished product specifications and copy of latest GMP inspection report conducted within a period of last three years before issuance of registration letter.	
927.	Name and address of manufacturer / Applicant	M/s Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir (DML No. 000652) Veterinary Liquid Vials Injection (General) Section
	Brand Name +Dosage Form + Strength	Nobipulmocin Injection
	Composition	Each ml solution contains: Tilmicosin…300mg
	Diary No. Date of R& I & fee	Dy.No 33453 dated 22-12-2021; Rs.30,000/- submitted vide Deposit Slip No. 4751290318
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Pulmocine Injection M/s Leads Pharma (Pvt) Ltd Reg. No. 058845 (Pack size: 10ml, 20ml,50ml,100ml)
	GMP status	GMP inspection was conducted on 02-06-2021 whereby GMP level/compliance was rated "good"
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required. • Change of finished product specifications to USP Specs is required along with Rs. 7500/- fee.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report conducted within a period of last three years** • **Rs. 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications from Manufacturer's Specifications to USP Specifications.**	
928.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Primec Plus Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 30252 dated 05-11-2021; Rs.30,000/- vide Deposit Slip No. 939667363526
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Active Plus Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore Regna. 033251 Pack size 10ml, 50ml, 100ml.
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report conducted within a period of last three years.**	

929.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Primec Plus Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 30253 dated 05-11-2021; Rs.30,000/- vide Deposit Slip No.7109264505
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Active Plus Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore Regna. 033251 Pack size 10ml, 50ml, 100ml.
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: Copy of latest GMP inspection report conducted within a period of last three years.	
930.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Primec Plus Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 30254 dated 05-11-2021; Rs.30,000/- vide Deposit Slip No 7023736005
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Active Plus Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore Regna. 033251 Pack size 10ml, 50ml, 100ml.
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: Copy of latest GMP inspection report conducted within a period of last three years.	
931.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Pri-Osteovit Injection 100ml
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E (acetate)…20mg
	Diary No. Date of R& I & fee	Dy.No 34225 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 71813830939
	Pharmacological Group	Vitamins

	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml Glass vials; Decontrolled
	Me-too status	VITAL-3 INJECTION Reg. No. 049635 M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (10ML,20ML,50ML,100ML)
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report conducted within a period of last three years.** • **Fee (PKR 7500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change of finished product specifications.**	
932.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Trocid 34 Injection 10ml
	Composition	Each ml Contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 34226 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 30599941162
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP Specifications
	Pack size & Demanded Price	10ml glass vial
	Me-too status	Zodax Injection M/s Zakfas Pharmaceuticals (Pvt) Ltd, Multan. Reg. No. 063567 (10ml,20ml,50ml,100ml)
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report conducted within a period of last three years.**	
933.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Pri-Cyanofos Injection 10ml
	Composition	Each ml Contains: Toldimphos Sodium…200mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 34227 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 4390103071
	Pharmacological Group	Vet Nutritional supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml Glass vial; Decontrolled
	Me-too status	Not available in applied pack size
	GMP status	Not provided
	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 in the applied PACK SIZE i.e. 10ml is required.

		• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Deferred for submission of the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in the applied PACK SIZE i.e. 10ml** • **Latest GMP inspection report against inspection conducted within the last three years** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
934.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Ketoflame 10 Injection 20ml
	Composition	Each ml Contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 34223 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 930536178837
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject 10% Injection Reg. No. 043141 M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (10ml,20ml,50ml,100ml)
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Latest GMP inspection report conducted within a period of last three years** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
935.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Pri-Buquone Injection 20ml
	Composition	Each ml Contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 34224 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No.911829334910
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20ml Glass vial, Decontrolled
	Me-too status	Bupralex Injection M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 033264 (Pack sizes 20ml, 50ml, 100ml)
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter:	

	• **Copy of latest GMP inspection report conducted within a period of last three years.**	
936.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Pri-Metaprim Injection 20ml
	Composition	Each ml Contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 34222 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 4877240026
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	TRYTON INJECTION Reg. No. 035183 GUYTON PHARMACEUTICALS, LAHORE (10ML,20ML,50ML,100ML)
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report conducted within a period of last three years.**	
937.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial Area, I-10/3, Islamabad (DML No. 000392) Liquid Section
	Brand Name +Dosage Form + Strength	TPC 20% Liquid
	Composition	Each ml Contains: Thiamphenicol…200mg
	Diary No. Date of R& I & fee	Dy.No 32458 dated 10-12-2021; Rs.30,000/- vide Deposit Slip No.22852406516
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Thiam Rold 20% oral liquid M/S Haarolds Pharmaceuticals (Pvt) Ltd, AJK. Reg. No.109060
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	Firm has approval of liquid section. It is not clear if the section is for manufacturing *oral liquids for veterinary use.* Therefore, evidence of approval of Oral liquid (general) Veterinary section from Licensing Division, DRAP is required.
	Decision: Approved.	
938.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial Area, I-10/3, Islamabad (DML No. 000392) Liquid Section
	Brand Name +Dosage Form + Strength	TPC 25% Liquid
	Composition	Each ml Contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 32459 dated 10-12-2021; Rs.30,000/- vide Deposit

		Slip No.301923981587
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml ; Decontrolled
	Me-too status	THIAM ROLD 25% ORAL LIQUID M/S Haarolds Pharmaceuticals (Pvt) Ltd, AJK. Reg. No.109059
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	• Evidence of approval of Oral liquid (general) Veterinary section issued by Licensing Division, DRAP is required
	Decision: Deferred for submission of the following: • **Evidence of approval of *Oral liquid (general) Veterinary section* from Licensing Division, DRAP** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
939.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial Area, I-10/3, Islamabad (DML No. 000392) Liquid Section
	Brand Name +Dosage Form + Strength	P-Flox Oral Liquid
	Composition	Each 100ml Contains: Pefloxacin…10gm
	Diary No. Date of R& I & fee	Dy.No 32460 dated 10-12-2021; Rs.30,000/- vide Deposit Slip No. 25594064099
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml,500ml,1L
	Me-too status	CIPSIN ORAL LIQUID M/s Vetrox Pharma, Toba Tek Singh. Reg No.112363
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	• Evidence of approval of Oral liquid (general) Veterinary section issued by Licensing Division, DRAP is required • Revision in label claim is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: Each 100ml Contains: - Pefloxacin Methanesulfonate……13.960gm (Pefloxacin Base…..10.00gm)
	Decision: Deferred for submission of the following: • **Evidence of approval of *Oral liquid (general) Veterinary section* from Licensing Division, DRAP** • **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision in label claim as follows according to product already approved by DRAP:** **"Each 100ml Contains: -** **Pefloxacin Methanesulfonate……13.960gm (Pefloxacin Base….10.00gm)"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
940.	Name and address of	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial

	manufacturer / Applicant	Area, I-10/3, Islamabad (DML No. 000392) Oral Powder (General) Veterinary Section
	Brand Name +Dosage Form + Strength	Neo Le Powder
	Composition	Each gm Contains: Neomycin Sulphate…720mg
	Diary No. Date of R& I & fee	Dy.No 32461 dated 10-12-2021; Rs.30,000/- vide Deposit Slip No.521401765
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	500g, 1kg, 2.5kg, 5kg
	Me-too status	Neo 720 Water Soluble Powder Prix Pharmaceutica (Pvt) Ltd., Lahore Reg. No.049516
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Firm shall submit Rs. 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications before issuance of registration letter.	
941.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial Area, I-10/3, Islamabad (DML No. 000392) Liquid Section
	Brand Name +Dosage Form + Strength	DMG TST Liquid
	Composition	Each 1000ml Contains: Tylosin Tartrate…50gm Sulphamethoxypyradiazine…50gm Trimethoprim…10gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 32462 dated 10-12-2021; Rs.30,000/- vide Deposit Slip No. 26288445032
	Pharmacological Group	Antibiotic, Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	500ml,1L, 2.5L, 5L; Decontrolled
	Me-too status	COMPLI SHELL LIQUID M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. Reg. No.63882
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	• Evidence of approval of Oral liquid (general) Veterinary section issued by Licensing Division, DRAP is required • Revision in label claim is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each 1000ml Contains: - Tylosin Tartrate…….50g Sulphamethoxypyradiazine sodium..50g Trimethoprim……..10g Bromhexine HCl……..5g"
	Decision: Deferred for submission of the following: • **Evidence of approval of *Oral liquid (general) Veterinary section* from Licensing Division, DRAP**	

	• **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision in label claim as follows according to product already approved by DRAP:** **"Each 1000ml Contains: -** **Tylosin Tartrate……..50g** **Sulphamethoxypyradiazine sodium...50g** **Trimethoprim……..10g** **Bromhexine HCl……..5g"** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
942.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd.81-A, Street # 6, Industrial Area, I-10/3, Islamabad (DML No. 000392) Oral Powder (General) Veterinary Section
	Brand Name +Dosage Form + Strength	Ampro 100 Oral Powder
	Composition	Each mg Contains: Amprolium HCl…0.9mg
	Diary No. Date of R& I & fee	Dy.No 32463 dated 10-12-2021; Rs.30,000/- vide Deposit Slip No. 122993297
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	500g, 1kg; Decontrolled
	Me-too status	Amprobar Water Soluble Powder M/s Baariq Pharmaceuticals, Lahore. Reg. No.073955
	GMP status	GMP inspection was conducted on 17-05-2023 and the firm was concluded to be GMP compliant
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP Specifications.	
943.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat. (DML No. 00698) Dry Powder Veterinary Section
	Brand Name +Dosage Form + Strength	Ampromax Powder
	Composition	Each mg Powder Contains: Amprolium HCl…0.9mg
	Diary No. Date of R& I & fee	Dy.No 32630 dated 13-12-2021; Rs.30,000/- vide Deposit Slip No.55632756223
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	500g, 1kg; Decontrolled
	Me-too status	Amprobar Water Soluble Powder M/s Baariq Pharmaceuticals, Lahore. Reg. No.073955
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with USP Specifications.	
944.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat. (DML No. 00698) Dry Powder Veterinary Section

	Brand Name +Dosage Form + Strength	D-SULPHA 3 POWDER
	Composition	Each 1000gm Powder Contains: Sulphachlorpyridazine Sodium…150gm Sulphaquinoxaline Sodium…120gm Sulphadiazine Sodium…80gm Diaveridine HCl…40gm Vitamin A…30,000 IU Vitamin K3…3gm
	Diary No. Date of R& I & fee	Dy.No 32631 dated 13-12-2021; Rs.30,000/- vide Deposit Slip No. 657252758486
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg, 2.5kg,5kg,10kg; Decontrolled
	Me-too status	Me-too provided by the firm (Reg. No. 075628) has different composition than applied product.
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	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: Deferred for submission of the following: • **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 response within 1 month after publication of the minutes, .**	
945.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat. (DML No. 00698) Oral Liquid Syrup Veterinary Section
	Brand Name +Dosage Form + Strength	THIAM-P LIQUID
	Composition	Each ml Contains: Thiamphenicol…200mg
	Diary No. Date of R& I & fee	Dy.No 32632 dated 13-12-2021; Rs.30,000/- vide Deposit Slip No.12338357284
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml, 150ml,500ml, 1L,5L,10L; Decontrolled
	Me-too status	Thiam Rold 20% oral liquid M/S Haarolds Pharmaceuticals (Pvt) Ltd, AJK. Reg. No.109060
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
946.	Name and address of	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS

	manufacturer / Applicant	2, National Industrial Zone, Rawat. (DML No. 00698) Dry Powder Veterinary Section
	Brand Name +Dosage Form + Strength	Lincos 400 Powder
	Composition	Each Gram Contains: Lincomycin HCl Eq. to Lincomycin…400mg
	Diary No. Date of R& I & fee	Dy.No 32633 dated 13-12-2021 Rs.30,000/- Deposit slip No.65983935176
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg, 2.5kg,5kg,10kg,25kg; Decontrolled
	Me-too status	LINCOSEL-40 ORAL POWDER M/s Selmore Pharmaceuticals, Lahore Reg. No.089826
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	• Change of specifications from Innovator's Specifications to USP Specifications along with Rs. 7500 fee is required.
	Decision: Approved. Firm shall submit Rs. 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change of specifications from Innovator's Specifications to USP Specifications.	
947.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat. (DML No. 00698) Dry Powder Veterinary Section
	Brand Name +Dosage Form + Strength	RESPILIN-CT POWDER
	Composition	Each 1000gm contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…100gm Chlortetracycline HCl Eq. to Chlortetracycline Base…300gm
	Diary No. Date of R& I & fee	Dy.No 32634 dated 13-12-2021; Rs.30,000/- vide Deposit Slip No.353398143579
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg,5kg,10kg,25kg; Decontrolled
	Me-too status	SB TIACLOR ORAL POWDER M/s SB Pharma Reg. No.048223
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
948.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat. (DML No. 00698) Dry Powder Veterinary Section

	Brand Name +Dosage Form + Strength	RESPILIN POWDER
	Composition	Each 100gm powder contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…45gm
	Diary No. Date of R& I & fee	Dy.No 32635 dated 13-12-2021; Rs.30,000/- vide Deposit Slip No.4713551472
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg,5kg,10kg,25kg; Decontrolled
	Me-too status	SB TIAMULIN ORAL POWDER M/s SB Pharma Reg. No.048221
	GMP status	GMP inspection conducted on 15-04-2021 on the basis of which GMP compliance certificate No. F.3-72/2021-Addl. Dir. (QA&LT-I)/3 dated 30-04-21 was issued for the following sections: Oral Powder (Veterinary) (General & Penicillin) Liquid Injectable (Veterinary) (General & Penicillin) Liquid (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
949.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd. 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke. (DML No. 000929) Oral Liquid Veterinary Section
	Brand Name +Dosage Form + Strength	NEO-PEFLOX ORAL LIQUID
	Composition	Each 100ml Contains: Pefloxacin Methanesulfonate 13.960 gm Eq. to Pefloxacin Base…10gm
	Diary No. Date of R& I & fee	Dy.No 33766 dated 27-12-2021; Rs.30,000/- vide Deposit Slip No.1706766665
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1L, 5L, 2.5L, 10L, 25L; Decontrolled
	Me-too status	CIPSIN ORAL LIQUID M/s Vetrox Pharma, Toba Tek Singh. Reg No.112363
	GMP status	Not applicable as DML was granted in 2021
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
950.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad (DML No. 000766) Liquid Injectable (Veterinary) (General) Section
	Brand Name +Dosage Form + Strength	ADOCIN INJECTION
	Composition	Each ml contains: Danofloxacin as Mesylate 31.722mg Eq. to Danofloxacin…25mg
	Diary No. Date of R& I & fee	Dy.No 33992 dated 29-12-2021; Rs.30,000/- vide Deposit Slip No. 12362089
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications

	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	DFLOX INJECTION M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 088087 (50ml)
	GMP status	GMP inspection conducted on 09-05-2022 on the basis of which GMP compliance certificate No. F.3-98/2022-Addl. Dir. (QA&LT-I)-60 dated 12-09-22 was issued for the following sections: Oral liquid Syrup (Veterinary) (General) Oral Dry Powder (Veterinary) (General) Oral Powder (Veterinary) (General) Oral liquid (Veterinary) (General) Oral Powder(Veterinary) (Penicillin) Liquid Injectable (Veterinary) (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 50ml pack size.	
951.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad (DML No. 000766) Oral liquid (Veterinary) (General) Section
	Brand Name +Dosage Form + Strength	ALTANFESI ORAL LIQUID
	Composition	Each ml contains: Doxycycline HCl…200mg Tylosin Tartrate…100mg Guaifenesin…200mg Aminophylline…80mg
	Diary No. Date of R& I & fee	Dy.No 33991 dated 29-12-2021; Rs.30,000/- vide Deposit Slip No. 79895094
	Pharmacological Group	Antibiotic, expectorant, bronchodilator
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml, 100ml,150ml,250ml,500ml,1L,2.5L, 5L; Decontrolled
	Me-too status	Tyco-G Oral Liquid M/s Attabak Pharmaceuticals, Islamabad Reg. No. 075704
	GMP status	As above
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved with following label claim: **Each ml contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Guaifenesin…200mg** **Aminophylline…80mg** **Firm shall submit Rs. 30,000 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in label claim and finished product specifications before issuance of registration letter.**	
952.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad (DML No. 000766) Liquid Injectable (Veterinary) (General) Section
	Brand Name +Dosage Form + Strength	FLOXY INJECTION
	Composition	Each ml contains: Flunixin as Magnesium Salt…20mg Oxytetracycline as HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 33994 dated 29-12-2021; Rs.30,000/- vide Deposit Slip No. 7740065085
	Pharmacological Group	NSAID, Antibiotic
	Type of Form	Form 5

	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Duasol Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 033254 (10ml,20ml,50ml)
	GMP status	As above
	Remarks of the Evaluator[xxiii].	• Revision of pack size, change in master composition and label claim as follows *according to product already approved by DRAP*, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: Oxytetracycline (As HCl) …300mg Flunixin Meglumine ……..20mg"
	Decision: Deferred for revision of pack size, change in master composition and label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: **"Each ml contains:** **Oxytetracycline (As HCl) …300mg** **Flunixin Meglumine ……..20mg" (Pack size 50ml)** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
953.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad (DML No. 000766) Oral Powder (Veterinary) (General) Section
	Brand Name +Dosage Form + Strength	NEFOXY ORAL POWDER
	Composition	Each mg contains: Neomycin Sulphate…150mcg Florfenicol…100mcg Oxytetracycline HCl…300mcg
	Diary No. Date of R& I & fee	Dy.No 33990 dated 29-12-2021; Rs.30,000/- vide Deposit Slip No. 8464225980
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100mg,200mg,500mg,1kg,2.5kg, 5kg, 10kg, 20kg, 25kg; Decontrolled
	Me-too status	E-Col Water Soluble Powder M/s Evergreen Pharmaceuticals, Lahore. Reg. No. 081733
	GMP status	As above
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Firm shall submit fee Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications before issuance of registration letter.	
954.	Name and address of manufacturer / Applicant	M/s Decent Pharma. Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad Oral liquid (Veterinary) (General)
	Brand Name +Dosage Form + Strength	VITAPLEX ORAL SOLUTION
	Composition	Each ml contains: Vitamin A…4000 IU Vitamin D3…800 IU Vitamin E…1.6mg Vitamin B1…2mg Vitamin B2…1mg

		Vitamin B6...1mg Vitamin B12...1mcg Vitamin C...1mg Vitamin K3...1mg Calcium Pantothenate...5mg Nicotinamide...5mg Folic Acid...100mcg DL-Methionine...10mg Choline Chloride...500mg Lysine HCl...1mg Biotin...25mcg
	Diary No. Date of R& I & fee	Dy.No 33993 dated 29-12-2021; Rs.30,000/- vide Deposit Slip No.
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml,500ml,1L,2.5L, 10L, 20L; Decontrolled
	Me-too status	Energizer Oral Solution M/s Biogen Pharma, Rawat Chak Beli Road, Rawat. Reg. No. 063814
	GMP status	As above
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Firm shall submit fee Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications before issuance of registration letter.	
955.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Aerosol (Veterinary) Section
	Brand Name +Dosage Form + Strength	CTC Spray
	Composition	Each Container Contains: Chlorteracycline HCl…3.210gm
	Diary No. Date of R& I & fee	Dy.No 34218 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 683464555861
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	211ml, 325ml; Decontrolled
	Me-too status	Reg. No.043110 CTC SPRAY M/s PRIX PHARMACEUTICA, KARACHI (211ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required for assessing the GMP compliance of Aerosol section.
	Decision: Approved. Firm shall submit copy of latest GMP inspection report for Aerosol section conducted within a period of last three years and fee Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications before issuance of registration letter.	
956.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Aerosol (Veterinary) Section
	Brand Name +Dosage Form + Strength	Frontline Spray
	Composition	Each 100ml Contains: Fipronil…0.25gm

	Diary No. Date of R& I & fee	Dy.No 34221 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No.34466944993
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml, 250ml; Decontrolled
	Me-too status	Not verified from database
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required for assessing the GMP compliance of Aerosol section. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for submission of following: • **Latest GMP inspection report for Aerosol section conducted within a period of last three** • **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 response within 1 month after publication of the minutes, .**	
957.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Aerosol (Veterinary) Section
	Brand Name +Dosage Form + Strength	Oxysone Spray
	Composition	Each ml Contains: Oxytetracycline HCl…5mg Hydrocortisone…1.60mg
	Diary No. Date of R& I & fee	Dy.No 34220 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No.8640004829
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Reg. No.071079 CORTISEL SPRAY M/s SELMORE PHARMACEUTICAL (PVT) LTD., LAHORE (150ML,250ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required for assessing the GMP compliance of Aerosol section.
	Decision: Deferred for clarification regarding salt form of hydrocortisone used in the applied formulation. The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .	
958.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Aerosol (Veterinary) Section
	Brand Name +Dosage Form +	Teravetz 2.5% Aerosol Spray

	Strength	
	Composition	Each ml Contains: Oxytetracycline…25mg Gentian Violet…5mg
	Diary No. Date of R& I & fee	Dy.No 34219 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No.84220071191
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml, 125, 150ml,200ml, 250ml,300ml
	Me-too status	Teravetz 2.5 % Aerosol Spray Reg. No.102201 M/S. Vetz Pharmaceuticals (Private) Limited. Kotri Sindh.
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• Latest GMP inspection report conducted within a period of last three years is required for assessing the GMP compliance of Aerosol section.
	Decision: Approved. Firm shall submit following before issuance of registration letter: • **Copy of latest GMP inspection report for Aerosol section conducted within a period of last three years.**	
959.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	I-Alpha Pre Injection 10ml
	Composition	Each 100ml Contains: 9-Alpha-Fluro Prednisolone…0.2gm
	Diary No. Date of R& I & fee	Dy.No 34074 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 45869980443
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	10ml- Decontrolled
	Me-too status	Not provided
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE along with registration number, brand name and name of firm is required. • As the applied formulation also includes Prednisolone, the application may be 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 for submission of the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE 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, .	
960.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Thipesing Injection 50ml
	Composition	Each ml Contains: Thiamphenicol…200mg Tylosin…57.5mg Prednisolone Acetate…5mg
	Diary No. Date of R& I & fee	Dy.No 34072 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 81671906212
	Pharmacological Group	Antibiotic; steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	TRIOX-P INJECTION Reg. No. 069638 M/s S.J & G FAZUL ELLAHIE (PVT) LIMITED, KARACHI (20ML, 50ML, 100ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	•
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
961.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Laphenra-35 Injection 50ml
	Composition	Each ml Contains: Prednisolone Acetate…25mg Chlorpheniramine Maleate…10mg
	Diary No. Date of R& I & fee	Dy.No 34071 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.0973612285
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Reg. No.057084 Predmine Injection M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore (5ML,10ML,20ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be 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.	
962.	Name and address of	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML

	manufacturer / Applicant	No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Laphenra-14 Injection 10ml
	Composition	Each ml Contains: Prednisolone Acetate…10mg Chlorpheniramine Maleate…4mg
	Diary No. Date of R& I & fee	Dy.No 34070 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.697809101378
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Reg No.049642 Solomin Injection Selmore Pharmaceuticals (Pvt) Ltd., Lahore (10ml, 20ml, 50ml, 100ml)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
963.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Acetosol-25 DS Injection 50ml
	Composition	Each ml Contains: Prednisolone Acetate…25mg
	Diary No. Date of R& I & fee	Dy.No 34079 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 37937955963
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Reg No.033291 PREDNIVET INJECTION 50ML REX PHARMACEUTICAL PAKISTAN, KARACHI
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. • Change in Specifications to BP Specifications along with Rs.7500/- fee is required
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of following: • **Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications from Innovators' Specifications to BP Specifications** **The Board further decided that the applicant shall submit the response within 1 month**	

	after publication of the minutes, .	
964.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Acetosol-25 DS Injection 10ml
	Composition	Each ml Contains: Prednisolone Acetate…25mg
	Diary No. Date of R& I & fee	Dy.No 34078 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.4359180281
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Reg, No 035091 Predison Injection 2.5%. Manhattan Pharma, Karachi Injectio (10ml, 50ml, 250ml)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. • Change in Specifications to BP Specifications along with Rs.7500/- fee is required
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of following: • **Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications from Innovators' Specifications to BP Specifications** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
965.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Acetosol DS Injection 50ml
	Composition	Each ml Contains: Prednisolone Acetate…10mg
	Diary No. Date of R& I & fee	Dy.No 34077 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 633071869
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Not provided in approved pack size
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic

		requirement keeping in view safety, efficacy and quality parameters. • Change in Specifications to BP Specifications along with Rs.7500/- fee is required • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE along with registration number, brand name and name of firm is required.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of following: • **Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications from Innovators' Specifications to BP Specifications,** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE i.e. 50ml 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, .**	
966.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	I-Alpha Pre Injection 50ml
	Composition	Each 100ml Contains: 9-Alpha-Fluro Prednisolone…0.2gm
	Diary No. Date of R& I & fee	Dy.No 34075 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.7257792120
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Abicorten Injectable Solution 50ml Reg. No.020756 M/s Prix Pharma Lahore
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be 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.	
967.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Thipesing Injection 100ml
	Composition	Each ml Contains: Thiamphenicol…200mg Tylosin…57.5mg Prednisolone Acetate…5mg
	Diary No. Date of R& I & fee	Dy.No 34073 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 535565870
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Reg. No. 069638 TRIOX-P INJECTION M/s S.J & G FAZUL ELLAHIE (PVT) LIMITED, KARACHI (20ML, 50ML, 100ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be 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.	
968.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Acetosol Injection 10ml
	Composition	Each ml Contains: Prednisolone Acetate…10mg
	Diary No. Date of R& I & fee	Dy.No 34076 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.4991714565
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Not provided in applied pack size
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters. • Change in Specifications to BP Specifications along with Rs.7500/- fee is required • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE along with registration number, brand name and name of firm is required.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of following: • **Rs.7500 prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in specifications from Innovators' Specifications to BP Specifications,** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied PACK SIZE i.e. 10ml 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, .**	
969.	Name and address of	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post

	manufacturer / Applicant	Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Burqon 5% Injection 100ml
	Composition	Each ml Contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 34132 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 259433728
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Bupralex Injection M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 03326 (Pack size 20ml, 50ml,100ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 100 ml pack size.	
970.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Burqon 5% Injection 50ml
	Composition	Each ml Contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 34131 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.48941980426
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Bupralex Injection M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 033264 (Pack sizes 20ml, 50ml, 100ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 50ml pack size.	
971.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Nixyl 20% Injection 50ml
	Composition	Each ml Contains: Nitroxynil…200mg
	Diary No. Date of R& I & fee	Dy.No 34137 dated 30-12-2021; Rs.30,000/- vide Deposit

		Slip No.794802310
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Troxy-20% Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 034596 (10ML, 20ML, 50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
972.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Nixyl 34% Injection 100ml
	Composition	Each ml Contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 34140 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.8521647657
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Tronox-340 injection 100ml M/s. Nawal Pharmaceuticals, Rawalpindi. Regna. 99041
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved in 100 ml pack size	
973.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	NIXYL 34% INJECTION 50ML
	Composition	Each ml Contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 34139 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 493416663883
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Troxy-34% Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 034597

		(10ML, 20ML, 50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 50ml pack size.	
974.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	NIXYL 20% INJECTION 100ML
	Composition	Each ml Contains: Nitroxynil…200mg
	Diary No. Date of R& I & fee	Dy.No 34138 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.1212780284
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP Vet Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Tronox-200 injection 100ml M/s. Nawal Pharmaceuticals, Rawalpindi. Regna. 99040
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved in 100ml pack size.	
975.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	DECTIN 1% INJECTION 50ml
	Composition	Each ml Contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 34129 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.32372373508
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml;Decontrolled
	Me-too status	ECTOMEC 10 INJECTION 50ML M/S. PRIX PHARMACEUTICA (PVT) LTD, LAHORE. Reg, No. 080758
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	

	Decision: Approved in 50ml pack size.	
976.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	DECTIN 1% INJECTION 100ML
	Composition	Each ml Contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 34130 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 873582390555
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	DORAMEC-DMG INJECTION Reg. No.043544 M/s LEADS PHARMA (PVT) LTD., ISLAMABAD. (50ML, 100ML, 250ML, 500ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 100ml pack size.	
977.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Marcin 10% Injection 100ml
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 34136 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.8210339213
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Reg. No 099432 Marbo-Vetz 10% Injection (100ml) M/s Vetz Pharmaceuticals (Private) Limited, Kotri Sindh.
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 100ml pack size.	
978.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Marcin 10% Injection 100ml
	Composition	Each ml Contains: Marbofloxacin…100mg

	Diary No. Date of R& I & fee	Dy.No 34136 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.8210339213
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Reg. No 099432 Marbo-Vetz 10% Injection (100ml) M/s Vetz Pharmaceuticals (Private) Limited, Kotri Sindh.
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision:Deleted being duplicate of product at sr no 977	
979.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Marcin 10% Injection 50ml
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 34135 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 25055286855
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Marcin injection 50ml vial Regna. 088117 M/s. Mylab (Pvt) Ltd, Bahawalpur.
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved in 50ml pack size.	
980.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Pecticin Injection 50ml
	Composition	Each ml Contains: Lincomycin HCl…50mg Spectinomycin as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 34111 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.3941406961
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Spectolin Injection

		M/s Noble Pharma, Mirpur, Azad Kashmir Reg. No. 75706 (50ml,100ml,500ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: - Lincomycin HCl…...50mg Spectinomycin HCl……100mg"
	Decision: Approved in 50ml pack size. Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter: **"Each ml contains: -** **Lincomycin HCl…...50mg** **Spectinomycin HCl……100mg".**	
981.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Pecticin Injection 500ml
	Composition	Each ml Contains: Lincomycin HCl…50mg Spectinomycin as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 34134 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.037317312713
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	500ml, Decontrolled
	Me-too status	Spectolin Injection M/s Noble Pharma, Mirpur, Azad Kashmir Reg. No. 75706 (50ml,100ml,500ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: - Lincomycin HCl…...50mg • Spectinomycin HCl……100mg"
	Decision: Deferred for submission of following: • **Relevant manufacturing facility (LVP)**	

	• **Full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter:** **"Each ml contains: -** **Lincomycin HCl…...50mg** **Spectinomycin HCl……100mg".** **The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .**	
982.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Pecticin Injection 100ml
	Composition	Each ml Contains: Lincomycin HCl…50mg Spectinomycin as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 34133 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 42031879657
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Spectolin Injection M/s Noble Pharma, Mirpur, Azad Kashmir Reg. No. 75706 (50ml,100ml,500ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: - Lincomycin HCl…...50mg Spectinomycin HCl……100mg"
	Decision: Approved. Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter: **"Each ml contains: -** **Lincomycin HCl…...50mg** **Spectinomycin HCl……100mg".**	
983.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Pecticin Injection 50ml
	Composition	Each ml Contains: Lincomycin HCl…50mg Spectinomycin as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 34111 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.3941406961
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications

	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Spectolin Injection M/s Noble Pharma, Mirpur, Azad Kashmir Reg. No. 75706 (50ml,100ml,500ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: - Lincomycin HCl…...50mg Spectinomycin HCl……100mg"
	Decision: Deleted being duplicate entry at Sr. No. 980.	
984.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Xylasin 2% Injection 50ml
	Composition	Each ml Contains: Xylazine as HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 34115 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.53449770710
	Pharmacological Group	Sedative and analgesic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	50ml Type 1 Glass vial; Decontrolled
	Me-too status	I-XAZINE INJECTION Reg. No. 062067 M/s INTERNATIONAL PHARMA LABS., LAHORE. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision in label claim and master formulation is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: Each ml Contains: Xylazine HCl…20mg
	Decision: Approved in 50ml pack size. Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter: **"Each ml contains:** **Xylazine HCl…20mg".**	
985.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424)

		Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Xylasin 2% Injection 100ml
	Composition	Each ml Contains: Xylazine as HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 34116 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.38426972710
	Pharmacological Group	Sedative and analgesic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100ml Type 1 Glass vial; Decontrolled
	Me-too status	I-XAZINE INJECTION Reg. No. 062067 M/s INTERNATIONAL PHARMA LABS., LAHORE. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision in label claim and master formulation is required as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: Each ml Contains: Xylazine HCl…20mg
	Decision: Approved with 100ml pack size. Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter: **"Each ml contains:** **Xylazine HCl…20mg".**	
986.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Oxymep 10% Injection 50ml
	Composition	Each ml Contains: Phenoxy-2-Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 34117 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 92791338
	Pharmacological Group	Appetite enhancer
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Hepasel Injection Reg.No.046518 M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (30ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•

	Decision: Approved.	
987.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Oxymep 10% Injection 100ml
	Composition	Each ml Contains: Phenoxy-2-Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 34118 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 812992176894
	Pharmacological Group	Appetite enhancer
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Hepasel Injection Reg.No.046518 M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (30ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
988.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Sufrim 48% Injection 100ml
	Composition	Each ml Contains: Sulphadiazine…400mg Trimethoprim…80mg
	Diary No. Date of R& I & fee	Dy.No 34128 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.13136540
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP VET Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	TRYTON INJECTION Reg. No. 035183 GUYTON PHARMACEUTICALS, LAHORE (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
989.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Sufrim 48% Injection 50ml

	Composition	Each ml Contains: Sulphadiazine…400mg Trimethoprim…80mg
	Diary No. Date of R& I & fee	Dy.No 34127 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 4602663269
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP Vet Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	TRYTON INJECTION Reg. No. 035183 GUYTON PHARMACEUTICALS, LAHORE (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
990.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Fenicol 30% Injection 100ml
	Composition	Each ml Contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 34126 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.3594758055
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	FOLAK INJECTION Reg. No. 075797 M/S. A & K PHARMACEUTICAL, FAISALABAD. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
991.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Fenicol 30% Injection 50ml
	Composition	Each ml Contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 34125 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.96827810013
	Pharmacological Group	Antibiotic; Decontrolled
	Type of Form	Form 5

	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	FOLAK INJECTION Reg. No. 075797 M/S. A & K PHARMACEUTICAL, FAISALABAD. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
992.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Sulpha 33.3% Injection 500ml
	Composition	Each ml Contains: Sulphadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 34124 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 916271432
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	EPLADINE INJECTION Reg.No.002021 M/s EPLA LAB LTD KARACHI (100ML, 500ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Deferred for confirmation of manufacturing facility for Large Volume Parenterals.	
993.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Unimycin 10% Injection 100ml
	Composition	Each ml Contains: Lincomycin as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 34112 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.768120968619
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	JP Specifications
	Pack size & Demanded Price	100ML; Decontrolled
	Me-too status	LINCOMYCIN INJECTION 100ML Reg. No.048147 M/s GENOME PHARMA, ISLAMABAD
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of

		which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	• Revision of label claim as follows according to product already approved by DRAP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: - Lincomycin hydrochloride…. 100mg"
	Decision: Approved. Firm shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision of label claim as follows before issuance of registration letter: **"Each ml contains: -** **Lincomycin hydrochloride…. 100mg".**	
994.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Meprine 5% Injection 50ml
	Composition	Each ml Contains: Mepyramine Maleate…50mg
	Diary No. Date of R& I & fee	Dy.No 34119 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.26962723696
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Mepro-Vee Injection M/s Venus Pharma, Lahore Reg. No. 017063 (Pack size 10ml, 30ml, 50ml)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters in food-producing species. Firm shall also clarify the target species for the applied formulation. The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .	
995.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Meprine 5% Injection 100ml
	Composition	Each ml Contains: Mepyramine Maleate…50mg
	Diary No. Date of R& I & fee	Dy.No 34120 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.5684269531
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	I-MEPA INJECTION Reg. No 48206 INTERNATIONAL PHARMA LABS., LAHORE. (10ML,25ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters in food-producing species. Firm shall also clarify the target species for the applied formulation. The Board further decided that the applicant shall submit response within 1 month after publication of the minutes, .	
996.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Kamcin 10% Injection 50ml
	Composition	Each ml Contains: Kanamycin Sulphate Eq. to Kanamycin Base…100mg
	Diary No. Date of R& I & fee	Dy.No 34121 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.420173888998
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	Unimycin 50ml; Decontrolled
	Me-too status	KANAMYCINE INJECTION Reg, No. 41233 M/s INTERNATIONAL PHARMA LABS., LAHORE. (10ML,50ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
997.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Kamcin 10% Injection 100ml
	Composition	Each ml Contains: Kanamycin Sulphate Eq. to Kanamycin Base…100mg
	Diary No. Date of R& I & fee	Dy.No 34122 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.73164495
	Pharmacological Group	100ml; Decontrolled
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	KANAMYCINE INJECTION

		Reg, No. 41233 M/s INTERNATIONAL PHARMA LABS., LAHORE. (10ML,50ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
998.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Sulpha 33.3% Injection 100ml
	Composition	Each ml Contains: Sulphadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 34123 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.9754312597
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	SULFADOX INJECTION Reg.No.035185 M/s GUYTON PHARMACEUTICALS, LAHORE. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
999.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Imonate 12% Injection 50ml
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 34113 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.7016586611
	Pharmacological Group	50ml; Decontrolled
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	IMIDO-G INJECTION Reg. No.035187 M/s GUYTON PHARMACEUTICALS, LAHORE. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections:

		Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1000.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals.14-km, Adyala Road, Post Office Daghal, Rawalpindi (DML No. 000424) Liquid Injection Vial (Veterinary) Section
	Brand Name +Dosage Form + Strength	Imonate 12% Injection 100ml
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 34114 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.3957344659
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	IMIDO-G INJECTION Reg. No.035187 M/s GUYTON PHARMACEUTICALS, LAHORE. (10ML,20ML,50ML,100ML)
	GMP status	GMP inspection conducted on **04-11-2021** on the basis of which GMP compliance certificate No. F.3-76/2021-Addl. Dir. (QA&LT-I)-33 dated 06-12-21 was issued for the following sections: Oral Dry Powder (Veterinary) Section Liquid (Veterinary) Section Liquid Injection Vial (Veterinary) Section
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	

Case no. 03 Registration applications of newly granted DML (Veterinary)

a. New cases

1001.	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-1% Oral Liquid
	Composition	Each ml Contains: Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 14689 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No. 74858954887
	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,2500ml, 5000ml; Decontrolled
	Me-too status	Mucorox 10 Oral Solution M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. Reg. No.111266
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1002.	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-5% Oral Liquid
	Composition	Each ml Contains: Bromhexine HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 14691 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.72162070727
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml,5000ml; Decontrolled
	Me-too status	Brombar-5 Oral Liquid M/s Baariq Pharmaceuticals, Lahore Reg. No. 73947
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Applicant shall submit fee (PKR 7,500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications, before issuance of registration letter.	
1003.	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
	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: 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, .	
1004.	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	Bro Ment P-30 Oral Liquid
	Composition	Each ml Contains: Menthol…20mg Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 14694 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.246998980251
	Pharmacological Group	Antitussive, 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,2500ml, 5000ml; Decontrolled
	Me-too status	Bromo Rox Oral Liquid Reg No.111278 M/S. Vetrox Pharmaceutical Pvt Ltd, 12-Km Toba Jhang Road, Near M-4 Interchange,Toba Tek Singh.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1005.	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	Bro Ment P-60 Oral Liquid
	Composition	Each ml Contains: Menthol…40mg Bromhexine HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 14695 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.34410364368
	Pharmacological Group	Antitussive, mucolytic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Bromo-Plus Liquid M/s Elegance Pharmaceutical, Chak Belli, Rawalpindi Reg No 073917
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Applicant shall submit fee (PKR 7,500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications, before issuance of registration letter.	
1006.	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	Enro Poul-10 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 14696 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.827009467908
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 500 ml,1000 ml, 25000ml, 5000ml; Decontrolled
	Me-too status	ENRORIQ-10 ORAL LIQUID Reg. No.079813 M/S. BAARIQ PHARMACEUTICALS, PLOT # 600, SUNDER INDUSTRIAL ESTATE, SUNDER RAIWIND ROAD, LAHORE
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•

	Decision: Approved.	
1007.	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	ENRO POUL-20 ORAL LIQUID
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 14697 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.985262836151
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 500 ml,1000 ml, 5000ml; Decontrolled
	Me-too status	Roxitrill-20 Oral Solution Reg. No 111268 M/s Vetrox Pharmaceutical Pvt Ltd,Toba Tek Singh.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1008.	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	Enro Poul-25 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…250mg
	Diary No. Date of R& I & fee	Dy.No 14684 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.83687733242
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml,2500ml, 5000ml; Decontrolled
	Me-too status	Roxitrill-25 Oral Solution Reg. No 111269 M/s Vetrox Pharmaceutical Pvt Ltd,Toba Tek Singh.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Applicant shall submit fee (PKR 7,500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications, before issuance of registration letter.	
1009.	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	ENRO STIN-2 ORAL LIQUID
	Composition	Each 100ml Contains: Enrofloxacin…20gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 14698 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.6734400485
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications

	Pack size & Demanded Price	100 ml,250ml,500 ml,1000 ml,2.5L,5L, 10L, 25L; Decontrolled
	Me-too status	Maxen Liquid Reg No. 075749 M/S. D-Maarson Pharmaceuticals, Rawat, Islamabad
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1010.	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	Enro Stin-5 Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…25gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 14687 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.29218566606
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250ml,500 ml,1000 ml,2.5L,5L, 10L, 25L; Decontrolled
	Me-too status	Reg. No.111273 QUINOROX-250 ORAL SOLUTION M/S. VETROX PHARMACEUTICAL PVT LTD, TOBA TEK SINGH.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1011.	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	Enro Stin-1 Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…100mg Colistin Sulphate…480,000IU
	Diary No. Date of R& I & fee	Dy.No 14688 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.706607122642
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml, 250ml, 500 ml,1000 ml,2500ml, 5000ml, 10L, 25L; Decontrolled
	Me-too status	Reg No 074068 Coliflox Oral Liquid M/S. Decent Pharma, Rawat, Islamabad.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1012.	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 +	FLORI SH-10 ORAL SOLUTION

	Strength	
	Composition	Each ml Contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 14680 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.925291914
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 500 ml,1000 ml, 5000ml; Decontrolled
	Me-too status	Fenrox 10 Oral Solution Reg No.111274 M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1013.	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	FLORI SH-23 ORAL SOLUTION
	Composition	Each 1000ml Contains: Florfenicol…230gm
	Diary No. Date of R& I & fee	Dy.No 14683 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.525322338767
	Pharmacological Group	Antibiotic
	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,2500, 5000ml; Decontrolled
	Me-too status	Baflor-23 Oral Solution Reg No 071096 & Fenrox 23 Oral Solution Reg No.111276 M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1014.	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	Flori SH-25 Oral Solution
	Composition	Each ml Contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 14682 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.0111566912
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100 ml,250 ml,500 ml,1000 ml, 5000ml; Decontrolled
	Me-too status	Fenrox Forte Oral Solution Reg No.111277 M/s Vetrox Pharmaceutical Pvt Ltd,

		Toba Tek Singh. Reg No 111277
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1015.	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	FLORISTIN-10 ORAL SOLUTION
	Composition	Each ml Contains: Florfenicol…1mg Colistin Sulphate…25mg
	Diary No. Date of R& I & fee	Dy.No 14681 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.9333075106
	Pharmacological Group	Antibiotic
	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,2500ml, 5000ml; Decontrolled
	Me-too status	Co-Flor Liquid Reg No 078326 M/s Wimits Pharmaceuticals, Lahore.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1016.	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	FLORISTIN-25 ORAL SOLUTION
	Composition	Each ml Contains: Florfenicol…250mg Colistin Sulphate…500,000IU
	Diary No. Date of R& I & fee	Dy.No 14678 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.3200020010
	Pharmacological Group	Antibiotic
	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,2500ml, 5000ml; Decontrolled
	Me-too status	Flocol Liquid Reg. No. 074082 M/S. D-Maarson Pharmaceuticals, Rawat, Islamabad.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1017.	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	Floristin-23 Oral Solution
	Composition	Each ml Contains: Florfenicol…230gm Colistin Sulphate…500,000IU
	Diary No. Date of R& I & fee	Dy.No 14679 dated 12-06-2023; Rs.30,000/- vide Deposit

		Slip No.748568954887
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml,2500ml, 5000ml; Decontrolled
	Me-too status	Fenicol-23 Oral Solution Reg. No. 080731 M/s Baariq Pharmaceuticals, Lahore
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved. Applicant shall submit fee (PKR 7,500) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change in finished product specifications, before issuance of registration letter.	
1018.	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-25 Oral Liquid
	Composition	Each ml Contains: Tilmicosin Phosphate Eq. to Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 14686 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.581909274
	Pharmacological Group	Antibiotic
	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	Tilmicobak Oral Liquid Reg. No. 075706 Each 100ml Contains: - Tilmicosin Phosphate...25g M/S. Attabak Pharmaceuticals, Islamabad.
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	• Revision of salt form in label claim as follows according to product already approved by DRAP, along with full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: Tilmicosin Phosphate...250mg"
	Decision: Approved. Applicant shall submit full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for revision label claim as follows, before issuance of registration letter: **"Each ml contains:** **Tilmicosin Phosphate...250mg"**	
1019.	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
	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: 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.	
1020.	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	Pe Poul Oral Liquid
	Composition	Each 100ml Contains: Pefloxacin Methane Sulfonate 13.960mg Eq. to Pefloxacin Base…10gm
	Diary No. Date of R& I & fee	Dy.No 14693 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.5715728176
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	500 ml,1000 ml,2500ml, 5000ml, 10L,25L; Decontrolled
	Me-too status	CIPSIN ORAL LIQUID M/s Vetrox Pharma, Toba Tek Singh. Reg No.112363
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
1021.	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	POUL CIN T ORAL LIQUID
	Composition	Each ml Contains: Enrofloxacin…75mg Sulphamethoxypyridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 14692 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.01430015294
	Pharmacological Group	Antibiotic
	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	Ensufic Liquid Reg No. 088140 M/S. Biorific Pharma, Islamabad

	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	• As the applied formulation is a combination of four antibiotics, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
	Decision: Deferred for review of EWG on veterinary drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1022.	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	Sulpha Prim Oral Suspension
	Composition	Each ml Contains: Sulphadiazine…400mg Trimethoprim…80mg
	Diary No. Date of R& I & fee	Dy.No 14677 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.34451220048
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP Vet Specifications
	Pack size & Demanded Price	100 ml,250 ml, 450 ml,500 ml,1000 ml,5000ml; Decontrolled
	Me-too status	Reg. No.010699 TRIKAIL SUSPENSION M/s KAILGON AGRO KARACHI
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	• Applicant has given BP Vet finished product specifications. Applied product monograph is not available in BP Vet. Change of specifications is required from BP (Vet) to Innovator's Specifications along with submission of PKR 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Approved. Firm shall submit PKR 7500 fee prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 for change of specifications from BP (Vet) to Innovator's Specifications, before issuance of registration letter.	

Case no. 04 Registration applications for imported (Veterinary) drugs (Form 5A)

a) New cases

1023.	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: 13/11/2023 Status: To sell drugs as a Distributor
	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 : 33037 Dated 16-12-2021
	Fee including differential fee	Rs : 150,000 Deposit Slip No. 4814325825

	Brand Name +Dosage Form + Strength	OXYTETRACYCLINE 10% Solution for Injection for veterinary use
	Composition	Oxytetracycline as dihydrate ……100 mg/ml
	Finished Product Specification	Not mentioned
	Pharmacological Group	Antibacterial for systemic use-Tetracyclines
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml brown glass vials
	International availability	Not applicable
	Me-too status	Terrasym PVP-100 injection Each ml contains: Oxytetracycline HCl 100mg M/s Symans Pharmaceuticals, Lahore (Pack size: 10ml, 30ml, 50ml) Reg. No. 022749 Oxytron 100 Injection M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Pack size:100ml) Reg. No. 113564
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICALPRODUCT** (BD/2018/No. of Certificate 248688 dated **06-02-2018**) **Certified by:** Ministry of Agriculture Nature and Foods, The Netherlands (Scanned copy attested by Embassy of Pakistan and MOFA of country of origin) **Product License No. REG NL 1227** **Issued on:** 09/05/1990 **Proof of free sale in country of origin:** Confirmed from CoPP. **GMP CERTIFICATE:** Facilities and operations conform to GMP as recommended by WHO; GMP Certificate No. NL/V17/0018; confirmed from CoPP **SOLE AGENCY CONTRACT AGREEMENT** Dated: 05-05-2017
	Remarks of the Evaluator[xxiii]	• Scanned copy of Sole Agency Contract Agreement is attached. Original attested agreement is required. • Submitted copy of COPP was valid at the time of submission. • Submit Finished Product Specifications (Product monograph of me-too is available in USP) • Revise composition as follows according to product already approved by DRAP & as given in CoPP, along with submission of full fee of registration (PKR 30,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023: "Each ml contains: Oxytetracycline HCl…. 100mg"

	Decision: Deferred for: • **Submission of original, notarized Sole Agency Contract Agreement,** • **Submission of original, legalized valid CoPP,** • **Submission of Finished Product Specifications** • **Revision of composition as follows according to product already approved by DRAP & as given in CoPP, along with submission of full fee of registration (PKR 150,000) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023:** **"Each ml contains:** **Oxytetracycline HCl…. 100mg"** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1024.	Name and address of Applicant	M/s Vety Care (Pvt) Ltd, Plot No. 77 Street No. 6, I-10/3, Industrial Area, Islamabad.
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Syntex S.A, 7458, Luis De Sarro 501-(B1838DQK), Luis Guillon-Buenos Aires, Argentina
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 32248 Dated 25-11-2021
	Fee including differential fee	Rs : 150,000 Deposit Slip No. 60050194247
	Brand Name +Dosage Form + Strength	CYCLASE 250mcg/ml Injectable Solution for veterinary use
	Composition	Each ml contains: Cloprostenol (as Sodium)…263mcg
	Finished Product Specification	Not mentioned
	Pharmacological Group	Luteolytic agent
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	Not given
	International availability	Not applicable
	Me-too status	Not confirmed from available office record; not provided by applicant
	Detail of certificates attached	Original, valid, legalized/notarized CoPP, Free Sales certificate, Sole Agency agreement and GMP certificate are not attached.
	Remarks of the Evaluator[xxiii]	• Clarify the name and address of marketing authorization holder • Legalized, valid GMP of manufacturer is not attached • Legalized, valid Free sales certificate is not attached • Original sole agency agreement on letterhead of principal is required. • Valid, legalized CoPP is required. • Label needs to be changed in accordance with The Drugs (Labeling and Packing Rules), 1986. • Submit 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.
	Decision: Deferred for clarification regarding name and address of marketing authorization holder and submission of following: • **Valid Drug Sales License of applicant** • **Legalized, valid GMP of manufacturer**	

	• **Legalized Free sales certificate of applied product in the country of origin** • **Original, notarized sole agency agreement on letterhead of principal** • **Valid, legalized CoPP** • **Revised label in accordance with The Drugs (Labeling and Packing Rules), 1986.** • **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.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1025.	Name and address of Applicant	M/s Vety Care (Pvt) Ltd, Plot No. 77 Street No. 6, I-10/3, Industrial Area, Islamabad.
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Syntex S.A, 7458, Luis De Sarro 501-(B1838DQK), Luis Guillon-Buenos Aires, Argentina
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 32247 Dated 25-11-2021
	Fee including differential fee	Rs : 150,000 Deposit Slip No. 65145331171
	Brand Name +Dosage Form + Strength	GONASYN Intramuscular Injection for veterinary use
	Composition	Each 100ml contains: Gonadorelin Acetate…0.005g
	Finished Product Specification	Not mentioned
	Pharmacological Group	Progonadotropin
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	Not stated
	International availability	Not applicable
	Me-too status	Not confirmed from available office record; not provided by applicant
	Detail of certificates attached	Original, valid, legalized/notarized CoPP, Free Sales certificate, Sole Agency agreement and GMP certificate are not attached.
	Remarks of the Evaluator[xxiii]	• Clarify the name and address of marketing authorization holder • Legalized, valid GMP of manufacturer is not attached • Leaglized, valid Free sales certificate is not attached • Original sole agency agreement on letterhead of principal is required. • Valid, legalized CoPP is required. • Label needs to be changed in accordance with The Drugs (Labeling and Packing Rules), 1986. • Submit 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.

	Decision: Deferred for clarification regarding name and address of marketing authorization holder and submission of following: • **Valid Drug Sales License of applicant** • **Legalized, valid GMP of manufacturer** • **Legalized Free sales certificate of applied product in the country of origin** • **Original, notarized sole agency agreement on letterhead of principal** • **Valid, legalized CoPP** • **Revised label in accordance with The Drugs (Labeling and Packing Rules), 1986.** • **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.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1026.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32050 Dated 23-11-2021
	Fee including differential fee	Rs. 75,000 Deposit Slip No. 69546034807
	Brand Name +Dosage Form + Strength	FLOFENICOL 20% ORAL SOLUTION
	Composition	Each ml contains: Florfenicol…200mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml,100ml, 150ml, 250ml,500ml, 1L, 2L, 5L
	International availability	Florfenicol 20% Oral Reg. No.THQ-119-XK Registered in Vietnam Validity: 23-11-2022
	Me-too status	Floricol Liquid M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. Reg. No. 073936 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement**

		Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of

		the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 09219320350. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1027.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam

	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32060 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 232268028
	Brand Name +Dosage Form + Strength	PRO-CRD COMPLEX 30/20 WATER SOLUBLE POWDER
	Composition	Each gram powder contains: - Tylosin Tartrate…….200mg Doxycycline HCl……...400 mg Colistin Sulphate…....1MIU Bromhexine HCl…….10 mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g, 500g, 1kg, 5kg, 20kg, 25kg
	International availability	PRO-CRD Complex 30/20 Reg. No.THQ-220-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	MONODOXWATER SOLUBLE POWDER M/s BAARIQ PHARMACEUTICALS, LAHORE Reg. No. 087142
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label

		• Differential fee of Rs.75000 vide Deposit slip No. 528225379. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1028.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32058 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 66484026
	Brand Name +Dosage Form + Strength	Para Plus Oral Powder
	Composition	Each 100gm Contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm

		Sodium Bicarbonate…12.5gm Vitamin E…12.5gm"
	Finished Product Specification	Not stated
	Pharmacological Group	Antipyretic, Multivitamin
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg,25kg
	International availability	Para plus Reg. No.THQ-185-XK Registered in Vietnam Validity: 25-02-2022
	Me-too status	Parascorbic powder M/s Baariq Pharmaceuticals, Lahore. Reg. No. 087190
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified.

		• Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 24778999902. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product

		• Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1029.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32059 Dated 23-11-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 43403191338
	Brand Name +Dosage Form + Strength	Tilmicosin Oral Solution
	Composition	Each ml Contains: Tilmicosin Phosphate…250mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 150ml, 250ml,500ml, 1L, 2.5L

	International availability	Tilmicosin Reg. No.THQ-137-XK Registered in Vietnam Validity: 24-3-2022
	Me-too status	Tilmicobak Oral Liquid M/s Attabak Pharma. Reg.No.075706
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-

		DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 48617838. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1030.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32061 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 5035508680
	Brand Name +Dosage Form + Strength	Pro-Lamox-C WSP
	Composition	Each 100gm Contains: Amoxicillin Trihydrate…20gm Colistin Sulphate…50MIU
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	Pro-Lamox-C Reg. No.THQ-221-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Fagomox M/s Farm Aid Group Reg. No. 087189
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist

		Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for*

		oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use. • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 973258620415. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.

	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
1031.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32062 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 474201420
	Brand Name +Dosage Form + Strength	Pro-Cefo Injection
	Composition	Each ml Contains: Ceftiofur as HCl…50mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Pro-Cefo Injection Reg. No.THQ-239-XK Registered in Vietnam Validity: 18-12-2022
	Me-too status	Exefur Injection M/s SJ&G FazulEllahie Reg. No. 063704 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam

		No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Cephalosporin Injectables* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production*

		line of Beta lactam in the forms of powder, granule for oral use. • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 5425865744. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer *for the relevant manufacturing facility/production line i.e. Cephalosporin Injectables*.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1032.	Name and address of Applicant	M/s Al-Habib Agencies.

		Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32063 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 9365242748
	Brand Name +Dosage Form + Strength	Pro-Liso 4.4% Feed Premix Powder
	Composition	Each 100gm Contains: Lincomycin HCl…4.4gm
	Finished Product Specification	Not stated; Lincomycin HCl soluble powder is available in USP
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,500g, 1kg,10kg, 5kg, 25kg
	International availability	Pro-Liso 4.4% THQ-222-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Lincos-P Powder M/s A&K Pharmaceuticals. Reg. No. 049667 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam

		& manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the

		final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 251517196. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1033.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32054 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 224432818225
	Brand Name +Dosage Form + Strength	Super T.D Man-70% WSP

	Composition	Each 100gm Powder Contains: Doxycycline Hyclate Eq. to 800gm of Doxycycline…923.32gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g,250g,500g, 1kg, 5kg,20kg, 25kg
	International availability	Super T.D Man -70% Reg. No.THQ-224-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Doxyral 80% powder M/s Orient Animal Health Reg. No. 082504 (30ml,50ml,100ml,500ml,1 Liter,2.5 Liter,5 Liter,10 Liter)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label

		• Differential fee of Rs.75000 vide Deposit slip No. 54195176543. Following are still required from the applicant: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1034.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32053 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 3266953570
	Brand Name +Dosage Form + Strength	Super Lamox-70% WSP
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…700gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic

	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50g,100g, 250g,500g, 1kg, 5kg, 10kg
	International availability	Super Lamox-70% Reg. No.THQ-223-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Primox 70% WSP M/s Prix Pharma Reg. No. 074032
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder for solution.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required

		• Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 0156607334. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.

		• Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer**. • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1035.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32064 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 468627042483
	Brand Name +Dosage Form + Strength	ProZSB Plus Powder
	Composition	Each 1000gm Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years

	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	ProZSB Plus Reg. No.THQ-219-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	PSB 100 M/s Epla Labs Reg. No. 013257
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided.

		• Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 2515097727. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.

		• Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1036.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32052 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 74459177223
	Brand Name +Dosage Form + Strength	Flunixin 5% Injection
	Composition	Each ml Contains: Flunixin Meglumine…50mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled

	Pack size	50ml
	International availability	Flunixin 5% Injection Reg. No.THQ-149-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Maxin Injection M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reg. No. 043576(10ml,20ml,50ml, 100ml)
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP

		(DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 973993467. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)

	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1037.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32056 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 5803348191
	Brand Name +Dosage Form + Strength	Proaminovit Injection
	Composition	Each ml Contains: Dextrose (Glucose)...50mg Calcium Chloride...2mg Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate...7.5mg L-Histidine HCl...0.02mg DL-Methionine...0.525mg L-Tryptophan...0.175mg L-Cysteine HCl...0.02mg L-Threonine...0.35mg L-Isoleucine...0.525mg L-Arginine HCl...1.425mg L-Phenylalanine...0.35mg L-Valine...0.525mg L-Lysine...0.525mg L-Leucine...0.6mg Monosodium Glutamate...0.08mg Riboflavin...0.05mg D-Panthenol...0.1mg Pyridoxine HCl...0.1mg Nicotinamide...3mg Thiamine HCl...0.1mg

	Finished Product Specification	Not stated
	Pharmacological Group	Multivitamims
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	250ml
	International availability	Pro Amino Vit Reg. No.THQ-90-XK Registered in Vietnam Validity: 23-11-2022
	Me-too status	Could not be verified from available database
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986.

		• Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 79993318292. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product

		• Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)
	Decision: Deferred for submission of the following: • **Provision of legalized Free Sale Certificate indicating the product is licensed and on marlet in country of origin as submitted Free Sale indicates the product is not licensed and is for export only.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**	
1038.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32055 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 24737481
	Brand Name +Dosage Form + Strength	Enrofloxacin 10% Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…50MIU
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 500ml, 1L, 5L
	International availability	Enrofloxacin 10% THQ-164-XK Registered in Vietnam

		Validity: 20-05-2021
	Me-too status	Reg No.074080 AMTIN-C ORAL LIQUID M/S. D-MAARSON PHARMACEUTICALS, PLOT # 17, STREET SS-2, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP

		(DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 346346776. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)

	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1039.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32051 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 20964369
	Brand Name +Dosage Form + Strength	Fos-T Oral Powder
	Composition	Each 1000gm Contains: Fosfomycin Calcium…200gm Tylosin Tartrate…100gm Fructose 1,6 Diphosphate…180gm Sodium Phosphate…150gm Magnesium Sulphate…100gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg,25kg
	International availability	Fos T Reg. No.THQ-182-XK Registered in Vietnam Validity: 13-07-2023
	Me-too status	Reg. No.113592 FAS-FO 73 POWDER M/s Eterna Pharma (Pvt) Ltd., Plot # 99,100,101&198- C, Sector D1, Old Industrial Estate, Mirpur, AJK.
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist

		Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not 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 is required. If me-too is available, differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for

		five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Me-too status provided • Differential fee of Rs.75000 vide Deposit slip No. 57653080426. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)

	Decision: Deferred for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1040.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32057 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 4446146165
	Brand Name +Dosage Form + Strength	Pollo-CRD Plus Oral Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Colistin Sulphate…450MIU Bromhexine HCl…5gm Streptomycin Sulphate…36gm
	Finished Product Specification	Not stated
	Pharmacological Group	Mucolytic, Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 20kg,25kg
	International availability	Pollo-CRD Plus Reg. No.THQ-218-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Reg No.071069 PULMODOX-S POWDER ATTABAK PHARMACEUTICAL, ISLAMABAD.
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only**

		GMP certificate: For Non-Betalactam solutions (injection and Oral) and powder for oral use Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required. • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for

		five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 79682450386. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP)

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1041.	Name and address of Applicant	M/s Mian Traders. Railway Road Morre Eminabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Lamons, S.A. Pol. Mecanova.C/Ricard Calvet Serra, Naves 27-28. 25190 Lleida-Spain
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Spain
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32721 Dated 01-12-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 5010680460
	Brand Name +Dosage Form + Strength	DOXICICLINA 250mg/ml Lamons Oral solution for administration in drinking water
	Composition	Each ml contains: Doxycycline (Hyclate)…250mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibacterial for systemic use
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1L, 5L
	International availability	Product is freely available in Spain, as verified online. Product is not registered in other countries, as claimed by the principal.
	Me-too status	Not confirmed
	Detail of certificates attached	Original or copy of legalized CoPP, Free Sales certificate, GMP of principal manufacturer and sole agency certificate are not attached
	Remarks of the Evaluator[xxiii]	• Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer are required. • Copy of valid DSL 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. • Finished Product Specifications are required. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Name & address of marketing authorization holder in the country of origin needs to be clarified.

	Decision: Deferred for submission of following: • **Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer** • **Original, Valid notarized sole agency certificate** • **Copy of valid DSL** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished Product Specifications** • **Revised label in accordance with The Drugs (Labelling and Packing) Rules, 1986.** • **Name & details of marketing authorization holder in the country of origin.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1042.	Name and address of Applicant	M/s Mian Traders. Railway Road Morre Eminabad, Gujranwala, Punjab, Pakistan
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Lamons, S.A. Pol. Mecanova.C/Ricard Calvet Serra, Naves 27-28. 25190 Lleida-Spain
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Spain
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32720 Dated 01-12-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 86296688206
	Brand Name +Dosage Form + Strength	Clorviogen Lamons 2% Suspension for Cutaneous Spraying
	Composition	Each gram Contains: Chlorteracycline HCl…20mg
	Finished Product Specification	Not stated
	Pharmacological Group	Antibacterial for cutaneous use
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	200ml
	International availability	Product is freely available in Spain, as verified online.
	Me-too status	Not confirmed
	Detail of certificates attached	Original or copy of legalized CoPP, Free Sales certificate, GMP of principal manufacturer and sole agency certificate are not attached
	Remarks of the Evaluator[xxiii]	• Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer are required. • Copy of valid DSL 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. • Finished Product Specifications are required. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Name & address of marketing authorization holder in the country of origin needs to be clarified

	Deferred for submission of following: • **Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer** • **Original, Valid notarized sole agency certificate** • **Copy of valid DSL** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished Product Specifications** • **Revised label in accordance with The Drugs (Labelling and Packing) Rules, 1986.** • **Name & details of marketing authorization holder in the country of origin.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**	
1043.	Name and address of Applicant	M/s Prix Pharmaceutica. 26 Abbot Road, Lahore, 54000, Pakistan
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Fatro S.P.A. Via Emilia, 285-40064 Ozzano dell'Emilia (Bologna)-Italy
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Italy
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No. 33989 Dated 29-12-2021
	Fee including differential fee	Rs.150,000 Deposit Slip No. 5566930933
	Brand Name +Dosage Form + Strength	Wondercef Powder & Solvent for Solution for Injection
	Composition	Each Vial Contains: Ceftiofur Sodium Eq. to Ceftiofur (lyophilized powder)…4200mg Solvent: Water for Injection (EP)….80ml Strength after reconstitution: 50mg/ml
	Finished Product Specification	Not stated
	Pharmacological Group	Antibacterial for systemic use
	Shelf life	Powder: 2 years Solvent: 4 years
	Demanded Price	Decontrolled
	Pack size	Not specified
	International availability	N/A
	Me-too status	Not confirmed
	Detail of certificates attached	Original or copy of legalized CoPP, Free Sales certificate, GMP of principal manufacturer and sole agency certificate are not attached
	Remarks of the Evaluator[xxiii]	• Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer are required. • Copy of valid DSL 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. • Finished Product Specifications are required. • Pack size needs to be specified. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Name & details of marketing authorization holder in the country of origin needs to be clarified. • Real time and accelerated stability studies results are required according to Zone IVA.

	Deferred for submission of following: • **Valid, legalized CoPP, Free Sales Certificate and GMP certificate of the manufacturer.** • **Copy of valid DSL** • **Original, Valid notarized 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** • **Finished Product Specifications** • **Applied pack size** • **Revised label in accordance with The Drugs (Labelling and Packing) Rules, 1986.** • **Name & details of marketing authorization holder in the country of origin** • **Real time and accelerated stability studies results according to Zone IVA.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**

Agenda of Deputy Director (PE&R) (Mr. Muneeb Ahmed Cheema)

Priority/ New Molecules

1044.	**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:** 002 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 15-08-2022 **Status:** by way of wholesaler **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	M/s Exirnanosina, Unit 7, F1. 4, No. 94, Fathi Shaghagi St., Jahanmehr St., Shahid Gomnam Ave., Fatemi Sq., Tehran, Iran.
	Name, address of manufacturer(s)	M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# 665/113187) issued by Iran Food & Drug Administration dated 21-02-2021. • Free Sale status: The COPP endorses the free sale status of the applied product in Iran. • GMP status: The COPP endorses the GMP status of the manufacturer. • Firm has submitted Legalized GMP certificate (Certificate No. 665/44522) issued by Iran Food & Drug Administration dated 09-02-2022 for M/s Exirnanosina, Pardis Science & Technology Park, Damavand Road, Tehran, I.R. Iran	
	Details of letter of authorization / sole agency agreement • Original Legalized Sole Agency Declaration (NOC) issued dated 18-07-2021 by M/s Exirnanosina in name of M/s Gene-Tech Laboratories for SinaDoxosome Injection, has been submitted. • Another agreement between the M/s Zhejiang Hengdian Apeola I&E Co., & M/s Shandong Luoxin Pharmaceutical Group Stock Co; Ltd has also been submitted declaring M/s Zhejiang Hengdian Apeola I&E Co the formal sole distributor of the applied 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 20055 dated 13-07-2022
	Details of fee submitted	Rs.150,000/- dated 27-06-2022
	The proposed proprietary name / brand name	SinaDoxosome 20mg/ 10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	(Injectable Nanoliposomal Doxorubicin Hydrochloride) Each 10ml Vial Contains: Doxorubicin HCl…….20mg
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	L01DB01 — Anthracycline topoisomerase inhibitor
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Doxulip 20mg Injection of M/s Revive Pharmakon, Lahore (Reg.087684)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Synbias Pharma ltd., Kreplischikov Street 181, 83085, Donetsk, Ukraine. Firm has submitted copy of GMP certificate (Certificate No. SD20150377) issued by Shandong Food and Drug Administration in the name of M/s Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd.
	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 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.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of

		drug product, specifications, analytical procedures, 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 of Caelyx injection has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	Type I glass vial
	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 for 18 months.

Remarks of Evaluator:

Section#	Observations	Firm's response
	A contract agreement has been submitted b/w Nano Daru Pajuhan Pardis Iran and Genetech Laboratories Karachi. This need to be clarified because another sole agency authorization in your name has also been submitted by the manufacturer i.e. M/s Exirnanosina Company.	
1.3.5	Copy of valid DSL of the applicant shall be submitted.	
1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board shall be submitted.	
2.3	Information submitted in Table for literary references for drug product is not correct. Revised information shall be submitted along with reference from pharmacopoeia.	
3.2.S.2.1	Details of drug substance manufacturer declared in section 1.6.5 are different from that declared in section 3.2.S.2.1.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Exirnanosina shall be submitted.	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the M/s Exirnanosina) shall be submitted.	
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by M/s Exirnanosina used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical Ingredient manufacture.	
3.2.P.1	Qualitative composition of applied formulation is different from that of the innovator drug product. Clarification shall be submitted in this regard.	
3.2.P.2.2.1	Justification shall be submitted for the limit &	

	results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	
3.2.P.2.5	Submit compatibility studies with the proposed diluent for dilution.	
3.2.P.3.2	Qualitative composition of applied formulation is different from that of the innovator drug product. Clarification shall be submitted in this regard.	
3.2.P.5.1	• Justification need to be submitted for referring the USP monograph because the applied liposomal formulation is not available in the same. • Justification shall be submitted for the limit of pH test with reference to Innovator product • Justification shall be submitted for not including test of related substance in drug product specifications with reference to pharmacopoeial monograph. • Justification shall be submitted for variation of limit of Endotoxin test with reference to Innovator product .	
3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.	
3.2.P.8.3	• Justification shall be submitted for the limit & results of pH test reported in the stability studies. • Justification shall be submitted for not performing test of related substances in stability studies. • Significant change in the results of Assay test has been reported in the accelerated stability studies of batch no. SD00209601. Justification shall be submitted in this regard. • Out of specification results for of Assay test has been reported in the accelerated stability studies of batch no. SD00209602. Justification shall be submitted in this regard. • Long term stability studies of 18months has been submitted only whereas long term stability study shall be submitted till claimed shelf life.	

Decision: Deferred for submission of above cited shortcomings.

1045.	**Name, address of Applicant / Importer**	AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block -2 Clifton Karachi.
	Details of Drug Sale License of importer	**License No:** No. DHODSK (Drug)/-139/- 290 dated 04.05.2023 **Address:** C-50, Block -2 Clifton Karachi **Address of Godown:** Plot No. 208/1 Sector 23 Korangi Indusial Area Karachi. **Validity:** 20.04.2023 to 19.04.2028 **Status:** Drug Sale License by way of Whole Sale
	Name and address of marketing authorization holder (abroad)	AstraZeneca AB, Gartunavagen, Soderralje SE-151 85 Sweden. (also responsible for batch release in EU, quality control, primary and secondary packaging)

	Name, address of manufacturer(s)	Same as marketing authorization holder.
	Name of exporting country	Sweden
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized CoPP issued by European Medicine Agency vide Certificate No. 01/23/177895 indicating that product has market authorization and actually on market in exporting country. **GMP:** Legalized GMP certificate bearing No. 6.2.1-2021-050663 is submitted issued by Swedish Medical Product Agency based on inspection conducted 01.10.2021 valid till three years which indicated address AstraZeneca AB, Gartunavagen, Soderralje 152 57Sweden. Which is different form the address provided on CPP mentioned above
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s AstraZeneca AB SE -151 85 Soderralje Sweden which is wholly owned subsidiary of the parent company AstraZeneca PLC located at Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 OAA United Kingdom.
	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. 12725 dated 23.05.2023
	Details of fee submitted	PKR /-: 75000/- dated 12.05.2023
	The proposed proprietary name / brand name	**TAGRISSO 40mg Film Coated Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Osemertinib as Mesylate …..40mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent: Protein Kinase Inhibitor ATC Code: L01EB04
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack of 30's
	Proposed unit price	To be submitted at the time of price fixation
	The status in reference regulatory authorities	EMA (EEA), PMDA Japan, USFDA
	For generic drugs (me-too status)	Not available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	Lonza AG Lonzastrasse 3930 Visp Switzerland & Dottikon Exclusive Synthesis AG Hembrunnsstrasse

		17 5605 Dottikon Switzerland
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 commercial batches of API stored at long-term, accelerated and stressed (thermal and photolytic) storage conditions. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I Glass Vial 10ml Type I Glass Ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has stability data at following conditions: 25°C/60% RH real time for 36 months 30°C/75% RH real time for 36 months 40°C/75% RH accelerated conditions for 6 months Based on above 36-month, a shelf-life is applied by the firm for Tagrisso 40mg film-coated tablets when stored in Alu foil-foil blister packs. The following product labelling should be used: 'Store below 30°C'.
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		
1046.	**Name, address of Applicant / Importer**	AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block -2 Clifton Karachi.
	Details of Drug Sale License of importer	**License No:** No. DHODSK (Drug)/-139/- 290 dated 04.05.2023 **Address:** C-50, Block -2 Clifton Karachi **Address of Godown:** Plot No. 208/1 Sector 23 Korangi Indusial Area Karachi. **Validity:** 20.04.2023 to 19.04.2028 **Status:** Drug Sale License by way of Whole Sale
	Name and address of marketing authorization holder (abroad)	AstraZeneca AB, Gartunavagen, Soderralje SE-151 85 Sweden. (also responsible for batch release in EU, quality control, primary and secondary packaging)
	Name, address of manufacturer(s)	Same as marketing authorization holder.

	Name of exporting country	Sweden
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized CoPP issued by European Medicine Agency vide Certificate No. 01/23/177895 indicating that product has market authorization and actually on market in exporting country. **GMP:** Legalized GMP certificate bearing No. 6.2.1-2021-050663 is submitted issued by Swedish Medical Product Agency based on inspection conducted 01.10.2021 valid till three years which indicated address AstraZeneca AB, Gartunavagen, Soderralje 152 57Sweden. Which is different form the address provided on CPP mentioned above
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s AstraZeneca AB SE -151 85 Soderralje Sweden which is wholly owned subsidiary of the parent company AstraZeneca PLC located at Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 OAA United Kingdom.
	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. 12726 dated 23.05.2023
	Details of fee submitted	PKR /-: 75000/- dated 12.05.2023
	The proposed proprietary name / brand name	**TAGRISSO 80mg Film Coated Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Osemertinib as Mesylate …..80mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent: Protein Kinase Inhibitor ATC Code: L01EB04
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack of 30's
	Proposed unit price	To be submitted at the time of price fixation
	The status in reference regulatory authorities	EMA (EEA), PMDA Japan, USFDA
	For generic drugs (me-too status)	Not available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	Lonza AG Lonzastrasse 3930 Visp Switzerland & Dottikon Exclusive Synthesis AG Hembrunnsstrasse 17

		5605 Dottikon Switzerland
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 commercial batches of API stored at long-term, accelerated and stressed (thermal and photolytic) storage conditions. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I Glass Vial 10ml Type I Glass Ampoule
	Stability study data of drug product, shelf life and storage conditions	Firm has stability data at following conditions: 25°C/60% RH real time for 36 months 30°C/75% RH real time for 36 months 40°C/75% RH accelerated conditions for 6 months Based on above 36-month, a shelf-life is applied by the firm for Tagrisso 80mg film-coated tablets when stored in Alu foil-foil blister packs. The following product labelling should be used: 'Store below 30°C'.
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		
1047.	**Name, address of Applicant / Importer**	AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block -2 Clifton Karachi.
	Details of Drug Sale License of importer	**License No:** No. DHODSK (Drug)/-139/- 290 dated 04.05.2023 **Address:** C-50, Block -2 Clifton Karachi **Address of Godown:** Plot No. 208/1 Sector 23 Korangi Indusial Area Karachi. **Validity:** 20.04.2023 to 19.04.2028 **Status:** Drug Sale License by way of Whole Sale
	Name and address of marketing authorization holder (abroad)	AstraZeneca UK Limited, 600 Capability Green, Luton, LU13LU United Kingdom
	Name, address of manufacturer(s)	**Manufacturer:** Vetter Pharma-Fertigung GmbH & Co KG Schuetzenstrasses 87 and 99-101 Ravensburg, D-88212 Germany

		Packager: AstraZeneca UK Limited, Charter Way, Silk Road Business Park Macclesfield Cheshire SK10 2NA UK
	Name of exporting country	UK
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Legalized CPP issued by MHRA bearing No. PP10175693 indicates that FASLODEX 250mg Solution for Injection is licensed and is actually on the market in the exporting country. **GMP:** Legalized GMP certificate bearing No. UK MIA 17901 Insp GMP/GDP/IMP 17901/10117-0049 issued by MHRA UK based on inspection conducted on 02.08.2022 of AstraZeneca UK Limited, Charter Way, Silk Road Business Park Macclesfield Cheshire SK10 2NA UK indicates compliance with GMP requirements. Copy of GMP Certificate vide No. DE_BW_01_GMP_2020_0077 based on inspection conducted on 24.04.2020 of Vetter Pharma-Fertigung GmbH & Co KG Schuetzenstrasses 87 and 99-101 Ravensburg, D-88212 Germany indicates compliance with GMP regulation but was valid till 23.04.2023.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted by M/s AstraZeneca UK Limited Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 OAA United Kingdom in name of AstraZeneca Pharmaceuticals Pakistan Private Limited C-50, Block - 2 Clifton 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
	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. 12726 dated 23.05.2023
	Details of fee submitted	PKR /-: 75000/- dated 12.05.2023
	The proposed proprietary name / brand name	**FASLODEX 250mg Solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One Prefilled Syringe contains: Fulvestrant ….250mg/5ml
	Pharmaceutical form of applied drug	Solution for Injection in Prefilled Syringe
	Pharmacotherapeutic Group of (API)	Endocrine Therapy: Antioestrogens ATC Code: L02BA03
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	Pack of 2 PFS 2 safety Needles
	Proposed unit price	To be submitted at the time of price fixation
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	Minakem High Potent SA Rue Fonds Jean Paque, 8 Mont Saint Guibert 1435 Belgium Ajinomoto Omnichem N.V. Cooppallaan B-9230 Wetteren Belgium
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 4 batches of drug substance at 5°C ± 3°C for 24 months. The accelerated stability data is conducted at 25°C ± 2°C / 60 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Single use prefilled syringe
	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 25°C ± 2°C / 60 ± 5% RH for 6 months. Real time stability studies conducted at 5°C ± 3°C for 48 months Firm has requested 48months shelf life
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		
1048.	**Name, address of Applicant / Importer**	**M/s Pfizer Pakistan Limited**
	Details of Drug Sale License of importer	**License No: 029** **Address:** 12-Dockyard Road, West Wharf, Karachi, Pakistan **Address of Godown:** NA **Validity:** 25-02-2023. **Status:** Drug License by way of Wholesale **Renewal:** Firm has submitted a receipt of renewal.

	Name and address of marketing authorization holder (abroad)	Biohaven Pharmaceuticals Ireland DAC, 6th Floor, South Bank House, Barrow Street, Dublin, D04 TR29, Ireland
	Name, address of manufacturer(s)	**Manufacture, Quality Control & Primary Packaging by:** **Catalent UK Swindon Zydis Limited,** Frankland Road, Blagrove, Swindon, SN5 8RU UNITED KINGDOM **Primary (labelling blister printing):** **Anderson Brecon (UK) Limited** Units 2-7, Wye Valley Business Park, Brecon Road, Hay-On-Wye, Hereford, HR3 5PG, United Kingdom **Secondary packaging and Batch Release by:** **Millmount Healthcare Limited,** Block 7 City North Business Campus, Stamullen Ireland
	Name of exporting country	Ireland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 10/22/176156) dated 28-10-2022 issued by European Medicine Agency (EMA) for NURTEC Oral Lyophilisate (Rimegepant) 75mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection on risk-based approach.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from MAH 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 ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.
	Details of fee submitted	PKR 75,000/-: 04-11-2022
	The proposed proprietary name / brand name	**NURTEC Oral Lyophilisate (Rimegepant) 75mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each oral lyophilizate contains Rimegepant sulfate, equivalent to 75mg Rimegepant
	Pharmaceutical form of applied drug	Oral Lyophilisate
	Pharmacotherapeutic Group of (API)	Analgesics, calcitonin gene-related peptide (CGRP) antagonists, ATC code: N02CD06
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	2x1 (unit dose), 8x1 (unit dose) & 16x1 (unit dose),

	Proposed unit price	To be submitted later to Pricing Section for fixation of prices.
	The status in reference regulatory authorities	NURTEC Oral Lyophilisate 75mg **(USFDA, EMA & MHRA** Approved).
	For generic drugs (me-too status)	Not Applicable – Originator Product
	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 and drug product
	Name, address of drug substance manufacturer	Anthem Biosciences Private Limited (Unit-1) No. 49, F1 & F2 Canara Bank Road Bommasandra Industrial Area, Phase I Bommasandra, Bengaluru, Karnataka 560099 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 as well as real time conditions. Based on the stability data available from long-term and accelerated storage and as per ICH Q1E, the proposed retest period for the drug substance is 48 months, when stored in the intended container closure system at 20 to 25 °C with excursions permitted from 15 to 30 °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	Not Applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	The drug product container closure is a perforated unit dose blister system consisting of a five-layer blister film, heat-sealed with an aluminium lidding foil. Only the PVC (polyvinyl chloride) layer of the film and the heat seal layer of the foil come into direct contact with the dosage form. The aluminium layer of the foil prevents the printing ink from interacting with the

		dosage form.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted the stability protocol and testing regime for the GMP registration batches, and process validation batches. The stability studies include standard ICH conditions: 25 °C/60% RH, 30 °C/65% RH (optional, intermediate storage condition), 30 °C/75% RH, and 40 °C/75% RH. Based on the available long-term stability data on clinical and registration batches mentioned above, the Applicant proposes a shelf-life of 48 months.
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		
1049.	**Name, address of Applicant / Importer**	**M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Karachi, Pakistan.**
	Details of Drug Sale License of importer	**License No: 015** **Address:** 15 West Wharf, Dockyard Road, Karachi. **Address of Godown: C-21, SITE, Karachi** **Validity: 19-01-2028**. **Status:** License to sell drugs as wholesale. **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Novartis Pharma Schweiz AG, 6343 Risch, Switzerland.
	Name, address of manufacturer(s)	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein CH-4332, Switzerland.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP certificate (No. 22003210) dated 20-07-2022 issued by Swiss medic for Scemblix 20mg Film-coated Tablet. The CoPP confirms free sale status of the product in exporting country as well as GMP compliant status of manufacturer. GMP: Firm has submitted legalized copy of GMP of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted original & legalized letter of authorization for Scemblix 20mg Film-coated Tablet. The letter confirms that the manufacturer appoints M/s Novartis Pharma (Pakistan) Limited as representative, sole agent & marketing authorization holder 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. : 479 dated 05-01-2023

	Details of fee submitted	PKR 75,000/-: 13-12-2022
	The proposed proprietary name / brand name	Scemblix 20mg Film-coated Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Asciminib Hydrochloride eq. to Asciminib…….20mg
	Pharmaceutical form of applied drug	Film-coated Tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent, Protein Kinase Inhibitors ATC
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack size will be furnished along-with MRP
	Proposed unit price	Proposed MRP per pack shall be furnished later
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	As Firm is innovator of product hence submitted QOS as per ICH guidelines. 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	Novartis Pharma Schweizarhalle AG, Rothausstrasse, 4133, Pratteln, 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)	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 30degree / 75% RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Tablets packed in HDPE bottles with desiccant
	Stability study data of drug product, shelf	Based on the stability data accelerated and real time the

	life and storage conditions	proposed shelf life and storage conditions for Zone IV-a is as under: Shelf life: 24months Storage conditions: Don't store above 30°C
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		
1050.	**Name, address of Applicant / Importer**	**M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Karachi, Pakistan.**
	Details of Drug Sale License of importer	**License No: 015** **Address:** 15 West Wharf, Dockyard Road, Karachi. **Address of Godown: C-21, SITE, Karachi** **Validity: 19-01-2028**. **Status:** License to sell drugs as wholesale. **Renewal: NA**
	Name and address of marketing authorization holder (abroad)	Novartis Pharma Schweiz AG, 6343 Risch, Switzerland.
	Name, address of manufacturer(s)	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein CH-4332, Switzerland.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP certificate (No. 22003210) dated 20-07-2022 issued by Swiss medic for Scemblix 20mg Film-coated Tablet. The CoPP confirms free sale status of the product in exporting country as well as GMP compliant status of manufacturer. GMP: Firm has submitted legalized copy of GMP of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted original & legalized letter of authorization for Scemblix 20mg Film-coated Tablet. The letter confirms that the manufacturer appoints M/s Novartis Pharma (Pakistan) Limited as representative, sole agent & marketing authorization holder 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. : 480 dated 05-01-2023
	Details of fee submitted	PKR 75,000/-: 13-12-2022
	The proposed proprietary name / brand name	Scemblix 40mg Film-coated Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Asciminib Hydrochloride eq. to Asciminib…….40mg

	Pharmaceutical form of applied drug	Film-coated Tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agent, Protein Kinase Inhibitors ATC
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack size will be furnished along-with MRP
	Proposed unit price	Proposed MRP per pack shall be furnished later
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	As Firm is innovator of product hence submitted QOS as per ICH guidelines. 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	Novartis Pharma Schweizarhalle AG, Rothausstrasse, 4133, Pratteln, 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)	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 30degree / 75% RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Applicable
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Tablets packed in HDPE bottles with desiccant
	Stability study data of drug product, shelf life and storage conditions	Based on the stability data accelerated and real time the proposed shelf life and storage conditions for Zone IV-a is as under: Shelf life: 24months Storage conditions: Don't store above 30°C
Evaluation by PEC:		
Decision: Approved as per policy of inspections of manufacturer abroad.		

Routine Cases

1051.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, 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. 3338 dated 03.02.2022
	Details of fee submitted	PKR 75,000/-dated 20/01/2022
	The proposed proprietary name / brand name	Coldene-P Caplets 500/25mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each caplet contains: Paracetamol……...500mg Diphenhydramine HCl……25mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	N02BE51 (Paracetamol, Combinations excluding Psycholeptics).
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	10's, 20's and 30's
	Proposed unit price	As per S.R.O.
	The status in reference regulatory authorities	TYLENOL PM EXTRA STRENGTH, Johnson & Johnson Consumer Inc., USA.
	For generic drugs (me-too status)	Not Available
	GMP status of the Finished product manufacturer	The firm was inspected and conclusion of inspection was: Overall the firm was found to be operating at a very good level of cGMP compliance at the time of inspection.
	Name and address of API manufacturer.	**Paracetamol:** M/s Saakh Pharma (Pvt.) Ltd., C-7/1 North Western Industrial Zone Port Qasim Karachi. **Diphenhydramine Hydrochloride:** M/s Supriya Life science Ltd., A-5/2 Lote Parshuram Industrial Area MIDC Taluka Ked District Ratnagiri Maharashtra India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of drug substances and drug product is submitted.

	Module III (Drug Substance)	Official monograph of Paracetamol (USP/BP), Diphenhydramine Hydrochloride (USP/BP) is present respectively. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests impurities, specifications, analytical procedures and its validation, batch analyses and justification of specification, reference standard, container closure system and stability studies of all drug substances.
	Stability studies	Firm has submitted stability study data of 3 batches of the following drug substance at both accelerated as well as real time conditions: **1.Paracetamol** (Batch No.18GN60001, Batch No.18GN60002, and Batch No.18GN60003) Accelerated: 40˚C ± 2˚C / 75% ± 5% RH (for 6 months) Real time: 30˚C ± 2˚C / 65% ± 5%RH (for 24 months) **2. Diphenhydramine Hydrochloride** (Batch No. SLLDPH/0514024, Batch No. SLLDPH/0514025 and Batch No. SLLDPH/0514026) Accelerated: 40˚C ± 2˚C / 75% ± 5% RH (for 6 months) Real time: 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 has been established against the TYLENOL PM EXTRA STRENGTH by performing quality tests (Assay, D. Time and Dissolution). CDP has been performed against the TYLENOL PM EXTRA STRENGTH in media Phosphate buffer.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Paracetamol:** M/s Saakh Pharma (Pvt.) Ltd., C-7/1 North Western Industrial Zone Port Qasim Karachi. **Diphenhydramine Hydrochloride:** M/s Supriya Life science Ltd., A-5/2 Lote Parshuram Industrial Area MIDC Taluka Ked District Ratnagiri Maharashtra India
API Lot No.	**Paracetamol** (Batch No.19GN60185) **Diphenhydramine Hydrochloride** (Batch No. SLL/DPH/0915051)
Description of Pack (Container closure system)	10’s, 20’s and 30’s Caplets packed in inner 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.	Trial 01	Trial 02	Trial 03
Batch Size	1500 Caplets	1500 Caplets	1500 Caplets
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	03-10-2019	03-10-2019	03-10-2019
No. of Batches	03		

Administrative Portion

	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate of Paracetamol No. 83/2020-DRAP(K) issued by DRAP Karachi valid till 23/06/2022. Copy of DML of Diphenhydramine HCl License No. 25-KD/129 issued by Food And Drug Administration Maharashtra valid till 31/03/2023.
	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted the following documents for the procurement of API with approval from DRAP. • **Paracetamol** Copy of commercial invoice No. PRT/2019/0179 dated 11/03/2019 is submitted. • **Diphenhydramine HCl** Copy of DML of Diphenhydramine HCl commercial invoice No. SLL/EXP/794/15-16 dated 06/11/2015 is submitted.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

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.**

1052.	**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

	Name and address of marketing authorization holder (abroad)	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin China.
	Name, address of manufacturer(s)	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin Chine
	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. 20210054 issued by Drug Administration of Heilongjiang Province China on 05.07.2021. Validity: 04.07.2023
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., Harbin China. and M/s AMB HK Enterprises (Pvt) Ltd. 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
	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. 32071 dated 23.11.2021
	Details of fee submitted	PKR /-: 150000/- dated 02.11.2021
	The proposed proprietary name / brand name	**SALBIN INHALER**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One metered dose contains: Salbutamol Sulpahte equivalent to 100 micrograms salbutamol.
	Pharmaceutical form of applied drug	Pressurized Inhalation Solution
	Pharmacotherapeutic Group of (API)	Selective beta 2 adrenoceptor agonists/ Bronchodilator
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	Pack of 1 Vial and 1ampoule of 10ml
	Proposed unit price	Rs. 268 for 1's
	The status in reference regulatory authorities	Salamol CFC-Free Inhaler (MHRA)
	For generic drugs (me-too status)	Ventolin Inhaler
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin China.
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities,

		specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 60 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, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Further the firm has submitted the aerodynamic assessment studies as per BP monograph requirement by Anderson Cascade Impactor.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is performed with Chinese product manufactured by Shangdong Jewin Pharmaceutical Co., Ltd China.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Aluminum Aerosol Cans & Medicinal Aerosol Valve Package
	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
	Decision in 323rd meeting: Deferred for submission of pharmaceutical equivalence with the Innovator.	
Remarks: The firm has submitted pharmaceutical equivalence studies with the Innovator i.e. Salbutamol Sulpahte Inhaler of GSK.		
Decision: Approved as per policy of inspections of manufacturer abroad.		

Agenda of Deputy Director (PE&R) (Mr. Salateen Waseem Philip)

CTD Routine cases

1053.	Name, address of Applicant / Marketing Authorization Holder	M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. **(DML # 000503)**
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. **(DML # 000503)**
	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. 15106 (dated: 15-06-2023)
	Details of fee submitted	PKR 30,000/-: dated: 07-06-2021 (Invoice # 25270890232)
	The proposed proprietary name / brand name	**Tablet Laruda 40 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lurasidone HCl …….. 40 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic
	Reference to Finished product specifications	Manufacture Specification
	Proposed Pack size	20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA* approved **Latuda®** by Sunovion Pharmaceuticals
	For generic drugs (me-too status)	**Lurisa®** by M/s Helix *(Reg # 089358)*
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 14th February 2025
	Name and address of API manufacturer.	**Lurasidone HCl** M/s Jiangsu Yongan Pharmaceutical Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China **GMP Certificate valid till 14/01/2024**
	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	**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 Lurisa tablets** by M/s Helix performing quality tests (appearance, identification, average weight, Assay, Dissolution).
	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	**Lurasidone HCl** M/s Jiangsu Yongan Pharmaceutical Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China **GMP Certificate valid till 14/01/2024**		
API Lot No.	0200-201909001		
Description of Pack (Container closure system)	Alu-Alu blister of 10's packed in printed unit carton further packed in a Master chipper.		
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-001**	**T-002**	**T-003**
Batch Size	4640 Tablets (0.19kg)	4640 Tablets (0.19kg)	4640 Tablets (0.19kg)
Manufacturing Date	09/2020	09/2020	09/2020
Date of Initiation	12/12/2020	12/12/2020	12/12/2020
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).	License tio import drug issued by DRAP Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance 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	Submitted.

	accelerated)	

Remarks of the Evaluator:

Observations	Reply of the firm
3.2.P.2.2.1 As per SPC of Latuda 40 mg tablet available on MHRA UK, each film-coated tablet contains lurasidone hydrochloride 40 mg equivalent to 37.2 mg lurasidone. Please justify that why the quantity of lurasidone hydrochloride 40.952mg / tablet in the composition of your applied formulation? Why carnuba wax is not in the composition of your product while it's available in the innovator product for film coating of tablets along with Opadry®?	There is a typographical error while mentioning the quantity of Lurasidone HCl in composition Section. The correct quantity has been used in the formulation with calculation as follows: **For 40mg eq. to 37.24 x 1.074 = 40 mg** Molecular weight of Lurasidone HCl is 529.14 Molecular weight of Lurasidone is 492.68 For coating, we have used the ingredients (PEG/Macrogol, HPMC & Titanium oxide) same as innovator brand available in UK with rand name of Latuda and the batch is pilot scale so we will use carnauba wax while manufacturing commercial batches. **Remarks of Evaluator:** The composition of applied formulation is same as per innovator brand composition provided on European medicine agency's assessment report **EMA/59804/2021 dated 23-07-2021.**
3.2.P.8 Please justify that why pharmaceutical equivalence studies and comparator dissolution profie have been done with local brand **Lurisa** instead of innovator brand **Latuda?**	Innovator brand **Latuda** is not available in Pakistan. Therefore, **Lurisa tablet** by M/s Helix, which is a registered drug product from DRAP, has been used for CDP and product development.

Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

1054.	Name, address of Applicant / Marketing Authorization Holder	M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. **(DML # 000503)**
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E., Super Highway, Karachi. **(DML # 000503)**
	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. 32413 dated 29/11/2021
	Details of fee submitted	PKR 30,000/-: dated 07/06/2021
	The proposed proprietary name / brand name	Laruda 80mg/Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lurasidone Hydrochloride 80 mg Equivalent to

		Lurasidone ……74.5mg
	Pharmaceutical form of applied drug	Light yellow coloured, round, biconvex, film coated tablet bisecting line on one side and other side is plain
	Pharmacotherapeutic Group of (API)	Atypical Antipsychotic
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	2 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Latuda 80mg tablet by Sunovion Pharmaceuticals, Inc, USFDA Approved.
	For generic drugs (me-too status)	Lurisa 80 mg Tablet by Helix Pharma (Pvt) Ltd., Reg. No. 089359
	GMP status of the Finished product manufacturer	New license granted on 30/09/2019 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	JIANGSU YONGAN PHARMACEUTICAL CO., LTD., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 lurasidone hydrochloride is not 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 impurity d, g & related substances (impurity a & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 101101,101201,101202 for Real time Batches:101101,101201,101202 for Accelerated
	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 Lurisa 80 mg Tablet by Helix Pharma (Pvt) Ltd.,	Pharmaceutical Equivalence have been established against the brand leader that is Lurisa 80 mg Tablet by Helix Pharma (Pvt) Ltd., (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Lurisa 80 mg Tablet by Helix Pharma (Pvt) Ltd., in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu yongan pharmaceutical co., ltd., no. 18, 237 provincial road, economic development zone, huaian, jiangsu province, china		
API Lot No.	0200-201909001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10'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:24 months Accelerated: 6 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	0.23 Kg	0.23 Kg	0.23 Kg
Manufacturing Date	09/2020	09-2020	09-2020
Date of Initiation	28-09-2020	28-10-2022	28-10-2022
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.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided Commercial invoice no. ZY19111101G/W, dated 11-11-2019
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

Decision of Board in 322nd meeting:
Registration Board deferred the case for submission of reply to the shortcomings within six months.

Shortcomings highlighted in 322nd meeting of RB

Observation	Reply of firm
1.3.5 Firm has provided GMP certificate based on the inspection and evaluation conducted on 30-09-2019. Which is valid until 29-09-2021. Valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be provided.	GMP certificate valid up to 14th February 2025.
1.5.2. Firm has mentioned label claim Lurisadone Hydrochloride …85.904 mg (Equivalent to Lurisadone ….80 mg). However, Innovator is using Lurisadone Hydrochloride…. 80 mg. Justification required.	Firm has corrected the typographical mistake and submitted the label claim as product available in RRA as under: Each film coated tablet contains: Lurasidone Hydrochloride 80 mg Equivalent to Lurasidone ..…74.5mg
1.6.5 Provided GMP Certificates of Drug Substance manufacturer is not traceable. Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be provided.	**Lurasidone HCl** M/s Jiangsu Yongan Pharmaceutical Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China **GMP Certificate valid till 14/01/2024**
3.2.P.2 As the qualitative composition of the formulation is not similar to innovator / reference product compatibility studies of the Drug Substance(s) with excipients shall be provided.	The composition of applied formulation is same as per innovator brand composition provided on European medicine agency's assessment report **EMA/59804/2021 dated 23-07-2021.**
3.2.S.4 In Analytical method of Drug Substance is missing along with Method Validation. Justification required for changing the method.	Submitted
3.2.S.4. Analytical Method validations studies for drug substances performed by Drug product manufacturer are missing.	Submitted
3.2.S.7. Data of real time stability of drug substances is provided for 12 months only. Whereas as per certificate of analysis firm is claiming shelf life of 02 years. Data for real time stability studies shall be submitted.	Submitted
3.2.P.2.2.1 Justification shall be submitted for not performing Pharmaceutical equivalence studies & CDP against the innovator product.	Innovator brand **Latuda** is not available in Pakistan. Therefore, **Lurisa tablet** by M/s Helix, which is a registered drug product from DRAP, has been used for CDP and product development.
• **3.2.P.8.1**In Stability Studies Batch size is 0.230 kg. Justification required. • In batch no. T-001, significant change of more than 5 % in assay has been observed in accelerated and real time stability data sheets.	Firm has re-submitted stability data sheet after correction of typographical error.
3.2.P.8.3 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. The firm has label claim of lurasidone HCl ……80mg

Decision: Approved with Innovator's specifications. Registration letter will be issued after submission

of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1055.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Munawar Pharma (Pvt) Ltd. 31,Km. Ferozpur road , Lahore**
	Name, address of Manufacturing site.	M/s Bio-Lab (Pvt) Ltd Plot # 145, Industrial triangle, kahuta road Islamabad Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	GMP status of the firm	GMP certificate of **M/s Bio-Lab (Pvt) Ltd** Valid up to 02-08-2023
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2015 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	dated 06-05-2021
	Details of fee submitted	**PKR 50,000/- Dated 18-05-2020**
	The proposed proprietary name / brand name	**Someper 20mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole magnesium trihydrate eq. 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 gelatin capsules
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Esomeprazole Capsules (USFDA Approved)
	For generic drugs (me-too status)	Nexum Capsules of M/s Getz Pharma, Karachi (Reg.No. 033890)
	Name and address of API manufacturer.	**M/s Vision Pharmeuticals (Pvt) Ltd, Islamabad.**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 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	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Esocue 20mg manufactured by Sandoz Novartis (Pakistan) Ltd. Firm has submitted CDP results of their product against the innovator's product **Esocue 20mg** 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	Vision Pharmaceuticals Pvt Ltd. Plot No. 22-23, Industrial Triangle area, kahuta road Islamabad Pakistan.		
API Lot No.	EMZ045499		
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 (Months)		
Batch No.	**1025**	**1030**	**1029**

Batch Size	140000 Capsules	140000 Capsules	2000 Capsules
Manufacturing Date	04-2018	05-2018	07-2018
Date of Initiation	11-05-2018	11-05-2018	11-08-2018
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)	Last Product Specific Inspection of the firm was conducted for Biozodex Capsules for which the inspection was conducted on 11-03-2020 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Area, equipment , personnel & utilities are as per GMP Compliance
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) dated 31-071-2019 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).	Firm has submitted copy of commercial invoice cleared on 04-03-2018 specifying 50Kg of Esomeprazole Magnesium pellets.
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:

Shortcomings	Reply of firm
Copies of the Drug Substance specifications and analytical procedures used for routine testing of the drug substance by both drug substance & drug product manufacturers.	Submitted
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 shall be submitted.	Submitted
Pharmaceutical equivalence Studies does not include complete testing of the drug product and the comparator product including the test recommended by innovator product as well as the tests recommended in general monographs of official pharmacopeia.	Submitted with complete tests as mentioned in monograph of USP specification.
Description of process validation including the proposed protocol shall be described in modules 2.3.P.3.5 and 3.2.P.3.5	Submitted
GMP inspection report of applicant	Submitted
Specification of drug product doesn't contain tests as recommended by USP monograph.	Submitted with complete testing

Justify analytical method based on UV spectrophotometric method for assay testing of omeprazole capsule while that mentioned in USP it is based on HPLC.	Data of chromatograms Submitted
Evidence of procurement of omeprazole pellets from local source required.	Submitted

Decision: Approved.

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

1056.	**Contract Manufacturing**	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Munawar Pharma (Pvt) Ltd. 31,Km. Ferozpur road , Lahore**
	Name, address of Manufacturing site.	M/s Bio-Lab (Pvt) Ltd Plot # 145, Industrial triangle, kahuta road Islamabad Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	GMP status of the firm	GMP certificate of **M/s Bio-Lab (Pvt) Ltd** Valid up to 02-08-2023
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 24-03-2015 specifying Capsule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 13165 dated 06-05-2021
	Details of fee submitted	**PKR 50,000/- Dated 18-05-2020** (Slip # 1936645)
	The proposed proprietary name / brand name	**Someper 40mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Esomeprazole magnesium trihydrate eq. 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 gelatin capsules
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Esomeprazole Capsules (USFDA Approved)
	For generic drugs (me-too status)	Nexum Capsules of M/s Getz Pharma, Karachi (Reg.No. 033890)
	Name and address of API manufacturer.	**M/s Vision Pharmeuticals (Pvt) Ltd, Islamabad.**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system 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 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	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Esocue 20mg manufactured by Sandoz Novartis (Pakistan) Ltd. Firm has submitted CDP results of their product against the innovator's product **Esocue 40mg** 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	Vision Pharmaceuticals Pvt Ltd. Plot No. 22-23, Industrial Triangle area, kahuta road Islamabad Pakistan.
API Lot No.	EMZ045499
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 (Months)

Batch No.	015	036	084
Batch Size	140000 Capsules	10000 Capsules	144000 Capsules
Manufacturing Date	06-2018	08-2018	12-2018
Date of Initiation	11-08-2018	12-11-2018	11-02-2019
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)	Last Product Specific Inspection of the firm was conducted for Biozodex Capsules for which the inspection was conducted on 11-03-2020 and the report was presented in 294th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Area, equipment , personnel & utilities are as per GMP Compliance
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) dated 31-071-2019 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).	Firm has submitted copy of commercial invoice cleared on 04-03-2018 specifying 50Kg of Esomeprazole Magnesium pellets.
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:

Shortcomings	Reply of firm
Copies of the Drug Substance specifications and analytical procedures used for routine testing of the drug substance by both drug substance & drug product manufacturers.	Submitted
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 shall be submitted.	Submitted
Pharmaceutical equivalence Studies does not include complete testing of the drug product and the comparator product including the test recommended by innovator product as well as the tests recommended in general monographs of official	Submitted with complete tests as mentioned in monograph of USP specification.

pharmacopeia.	
Description of process validation including the proposed protocol shall be described in modules 2.3.P.3.5 and 3.2.P.3.5	Submitted
GMP inspection report of applicant	Submitted
Specification of drug product doesn't contain tests as recommended by USP monograph.	Submitted with complete testing
Justify analytical method based on UV spectrophotometric method for assay testing of omeprazole capsule while that mentioned in USP it is based on HPLC.	Data of chromatograms Submitted
Evidence of procurement of omeprazole pellets from local source required.	Submitted

Decision: Approved.

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

Case No. 01 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, 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. **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**

1057.	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.**
	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	The firm has submitted results of pharmaceutical

	comparative dissolution profile	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		
19.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
20.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
21.	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**
22.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
23.	Compliance Record of HPLC software	Submitted

	21CFR & audit trail reports on product testing	
24.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.
Remarks of the Evaluator:		
Decision: 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.**		
1058.	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	Firm submitted inspection report dated 02-02-2023 GMP compliance "A"
	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

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 # SLL/E/18-19/868 Dated 6/11/2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	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 equivalence studies have been performed against a local brand **Ketasol** instead of Innovator brand	Ketasol has been chosen because it is a 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: 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.**

1059.	**Name, address of Importer**	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan *(Importer)***
	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)**	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name, address of manufacturer(s)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei 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. 20210508) dated 12-2021 issued by CCPIT for calcium gluconate for injection 1.0g/10ml. 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 01-12-2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Hebei tiancheng pharmaceutical Co. Ltd. The letter species that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan. The authorization letter is valid till 19-04-2027.
	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. 30458 Dated: 27-10-2022
	Details of fee submitted	PKR 150,030/-: 19-08-2022 Slip # (268219177)
	The proposed proprietary name / brand name	Calconate injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Calcium gluconate……1.0G/10ML
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Calcium salt
	Reference to Finished product specifications	BP
	Proposed Pack size	50 injections/ box

	Proposed unit price	20/vial i.e 1000/box
	The status in reference regulatory authorities	**USFDA** & MHRA Approved.
	For generic drugs (me-too status)	Locally registered and available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per 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	Heb Name: Zhejiang Ruibang Pharmaceutical Co., Ltd. Address: No. 578 Binhai ten road, Economic and Technological Development Zone, Wenzhou, Zhejiang, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25 ℃±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	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	USP type-I glass ampoule
	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 2 batches is for 12 months while the stability study data for 3rd batch is for 9 months only.
Evaluation by PEC:		
3.2.P.1 In the innovator product and other formulations approved in USFDA with BP specifications for FPP, each 10 ml of solution contains 940 or 950 mg of calcium gluconate, with an amount of calcium in		

the form of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. While in the formulation submitted by the manufacturer of applied drug product, each 10 ml of solution contains 1g of calcium gluconate and also containing calcium hydroxide. How will you justify the amount of calcium is not exceeding 1g in the formulation? What is the role of sodium gluconate in the formulation? Please also provide reference of product with same formulation and composition approved in countries with stringent regulatory control declared by WHO. **3.2.P.2.7** Please provide brand name of the medicinal product, formulation / composition and the address of manufacturer of the reference product used in Pharmaceutical equivalence studies.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
1060.	Name, address of Applicant / Marketing Authorization Holder	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	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. 30637 (dated: 30-10-2022)
	Details of fee submitted	PKR 30,000/-: dated: 21-10-2022 (Invoice # 6958787793)
	The proposed proprietary name / brand name	**Gluco Cal Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml ampoule contains: Calcium Gluconate …… 1 g (100mg/ml)
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	Calcium Salt
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	05 ampoules per pack 10 ampoules per pack 50 ampoules per pack
	Proposed unit price	PKR 1162.55/- per pack of 05 ampoules. PKR 2235.096/- per pack of 10 ampoules. PKR 11,160.48/- per pack of 50 ampoules.
	The status in reference regulatory authorities	*USFDA* approved formulation
	For generic drugs (me-too status)	Formulation approved for M/s Surge
	GMP status of the Finished product manufacturer	**GMP certificate valid till 13-02-2025**
	Name and address of API manufacturer.	**Calcium Gluconate** M/s Lianyungang Zhonghong Chemical Co. Ltd. Area B, Guannan Economic Development Zone, Lianyungang, Jiangsu, China

		GMP Certificate valid till 23-07-2023
	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	**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 Calcium Gluconate injection** by performing quality tests (appearance, identification, pH , Assay, BET, 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	**Calcium Gluconate** M/s Lianyungang Zhonghong Chemical Co. Ltd. Area B, Guannan Economic Development Zone, Lianyungang, Jiangsu, China.		
API Lot No.	21051202		
Description of Pack (Container closure system)	Clear glass ampoule, with red printing and red ring, arrange in PVC tray and packed in 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, 18 & 24 (Months)		
Batch No.	**CG-0121**	**CG-0221**	**CG-0321**

Batch Size	100 Ampoules	100 Ampoules	100 Ampoules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	01/01/2022	01/01/2022	01/01/2022
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).	3028/2021-DRAP dated 31-08-2021
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:

Observations	Reply of the firm
1.3.4 Please submit latest inspection report conducted within last 03 years **OR** fresh / valid GMP certificate of your manufacturing unit which should be in force till date.	Submitted
3.2.P.1.2 The strength/amount of API mentioned in your applied formulation doesn't match with the reference product.	Firm has provided reference product (MHRA product) with same formulation.
3.2.P.2.3 Please submit in tabulated form the results of all the quality tests mentioned in **USP Specifications** for the Pharmaceutical equivalence studies of the applied drug established with the innovator / reference / comparator product.	Submitted
3.2.P.3.2 Please justify the use of overage of 3% of API in the drug product.	We hereby declare overage in documents is typo error. We are and will not use overage in trial batches as well commercial scale batches.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1061.	Name, address of Applicant / Marketing Authorization Holder	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	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. 26859 (dated: 22-09-2022)
	Details of fee submitted	PKR 30,000/-: dated: 26-08-2022 (Invoice # 91168906098)
	The proposed proprietary name / brand name	**Cardoxin Injection 2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Digoxin …… 0.5 mg / 2ml
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	Cardiac Glycosides
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	05 ampoules per pack & 50 ampoules per pack
	Proposed unit price	PKR 12/- per ampoule PKR 60/- per pack of 05 ampoules PKR 600/- per pack of 50 ampoules
	The status in reference regulatory authorities	*USFDA and MHRA* approved formulation
	For generic drugs (me-too status)	**Lanoxin®** by M/s GSK
	GMP status of the Finished product manufacturer	**GMP certificate valid till 13-02-2025**
	Name and address of API manufacturer.	**Digoxin** M/s Vital Laboratories Pvt. Ltd. Plot # 1710, Phase III, G.I.D.C Estate, VAPI, Dist. Valsad, Gujarat, India **GMP Certificate valid till 03/07/2026**
	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 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 Lanoxin** by performing quality tests (appearance, identification, content uniformity, Sterility Test, pH, Assay,BET).
	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	**Digoxin** M/s Vital Laboratories Pvt. Ltd. Plot # 1710, Phase III, G.I.D.C Estate, VAPI, Dist. Valsad, Gujarat, India		
API Lot No.	DGN2107002		
Description of Pack (Container closure system)	Clear glass ampoule, with red printing and red ring, arrange in PVC tray and packed in 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, 18 & 24 (Months)		
Batch No.	**DG-0122**	**DG-0222**	**DG-0322**
Batch Size	1000 Ampoules	1000 Ampoules	1000 Ampoules
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	10/01/2022	10/01/2022	10/01/2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of	Not applicable

	the firm (if any)	
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 # HHM/2122/00258 dated 06-12-2021 10grams 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:

Observations	Reply
1.3.4 Please submit fresh / valid GMP certificate of your manufacturing unit which should be in force till date.	Submitted
5.6.5 Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Submitted
3.2.P.2.3 Please submit in tabulated form the results of all the quality tests **(BP Specifications)** of Pharmaceutical equivalence studies of the applied drug established with the innovator / reference/ comparator product.	Submitted
3.2.P.3.2 Please justify the use of overage of 2% of Digoxin in the drug product formulation with documented proof, for expected manufacturing loss during drug product manufacturing.	We hereby declare overage in documents is typo error. We are and will not use overage in trial batches as well commercial scale batches.
3.2.P.8 is spectrophotometer used for assay of drug product, compliant to 21 CFR part 1, to record absorbance spectra of the three stability batches? Please submit respective documents **(absorbance spectra)**, Raw data sheets of Assay calculations for the three stability batches.	Firm has submitted 21 CFR compliant documents along with absorbance spectra of analyte for the results of chemical assay of digoxin.
Documents for the procurement of API with approval from DRAP.	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.**		
1062.	Name, address of Applicant / Marketing Authorization Holder	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-km Off, G.T Road, Lahore. **(DML # 000805)**
	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. 26882 (dated: 12-08-2022)
	Details of fee submitted	PKR 30,000/-: dated: 29-06-2022 (Invoice # 87253650825)
	The proposed proprietary name / brand name	**Baj-bol Injection 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml ampoule contains: Labetalol HCl …… 50mg (5mg/ml)
	Pharmaceutical form of applied drug	Ampoule for injection
	Pharmacotherapeutic Group of (API)	α & β adrenergic antagonist
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10 x 10 ampoules & 10 x 5 ampoules per pack
	Proposed unit price	PKR 150/- per ampoule PKR 1500/- per pack
	The status in reference regulatory authorities	*TGA Australia* approved formulation
	For generic drugs (me-too status)	Formulation approved for M/s Zafa
	GMP status of the Finished product manufacturer	**GMP certificate valid till 13-02-2025**
	Name and address of API manufacturer.	**Labetalol HCl** The manufacturer: **PROCOS S.P.A.** **Address:** Via Matteotti, 249, CAMERI, 28062, Italy **GMP Certificate valid till 14-07-2024**
	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	**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 Labetalol injection by M/s Zafa** by performing quality tests (appearance, identification, pH , Assay, BET, 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	**Labetalol HCl** The manufacturer: **PROCOS S.P.A.** **Address:** Via Matteotti, 249, CAMERI, 28062, Italy **GMP Certificate valid till 14-07-2024**		
API Lot No.	0000282255		
Description of Pack (Container closure system)	Clear glass ampoule, with red printing and red ring, arrange in PVC tray and packed in 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: 6 months Accelerated: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**LL-0121**	**LL-0221**	**LL-0321**
Batch Size	200 Ampoules	200 Ampoules	200 Ampoules
Manufacturing Date	03/2021	03/2021	03/2021
Date of Initiation	18/03/2021	20/03/2021	20/03/2021
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).	1096/2021-DRAP 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 the Evaluator:

Observations	Reply of the firm
1.3.4 Please submit latest inspection report conducted within last 03 years **OR** fresh / valid GMP certificate of your manufacturing unit which should be in force till date.	Submitted
3.2.S.4.3 Please submit analytical Method Verification studies for Active Pharmaceutical Ingredient **(Labetalol HCl)** including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer **(M/s Bajwa Pharma).**	Submitted
3.2.P.2.3 Please submit in tabulated form the results of all the quality tests mentioned in **USP Specifications** for the Pharmaceutical equivalence studies of the applied drug established with the innovator / reference / comparator product.	Submitted
3.2.P.3.2 Please justify the use of overage of 2% of Labetalol HCl in the drug product.	We hereby declare overage in documents is typo error. We are and will not use overage in trial batches as well commercial scale batches.
3.2.P.8 For the three stability batches, please submit chromatograms and their calculations sheets / results sheets separately for the interval of months (0, 3 & 6 month) both accelerated and real time studies. Please resubmit Chromatograms with report template which should contain following three boxes. i. "**Sample information window"** containing sample ID *(sample / standard)*, Batch #, User ID, Data Processed time, Data Acquisition time, Instrument No.,	Firm has submitted chromatograms with report template containing sample information and peak tables with tailing factor and theoretical plates.

flow rate, wavelength and all necessary information as per 21 CFR Part 11. ii. Chromatogram with peak table. iii. Information about tailing factor & theoretical plates. Please submit stability sheets mentioning all the tests in the monograph of USP specifications for the three stability batches.	 Submitted
Documents for the procurement of API with approval from DRAP.	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 Molecule

1063.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Pvt. Ltd **(DML # 000504)** A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo Pvt. Ltd **(DML # 000504)** A-29, North Western Industrial Zone, Port Qasim, 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. 5806 (dated: 01-03-2023)
	Details of fee submitted	PKR 75,000/-: dated: 11-01-2023 (Invoice # 642868666670)
	The proposed proprietary name / brand name	**Colystyrene 4g / 9g Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Cholestyramine as anhydrous Cholestyramine (a basic anion-exchange resin) ……4gm
	Pharmaceutical form of applied drug	Oral Powder for Solution
	Pharmacotherapeutic Group of (API)	Bile Acid sequestrants
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10 x 10 ampoules & 10 x 5 ampoules per pack
	Proposed unit price	PKR 150/- per Sachet PKR 1500/- per pack
	The status in reference regulatory authorities	*MHRA* approved formulation

	For generic drugs (me-too status)	**Not applicable**
	GMP status of the Finished product manufacturer	GMP certificate valid till 22-06-2024
	Name and address of API manufacturer.	**Cholestyramine** Manufacturer: **Phaex Polymers Pvt. Ltd** **Address:** Plot # F 10, MIDC Murbad, District Thane 421401 Maharashtra, India **GMP Certificate valid till 24-03-2025**
	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 / 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. Questran by Sanofi Aventis** by performing quality tests (appearance, identification, Average weight, Assay).
	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	**Cholestyramine** Manufacturer: **Phaex Polymers Pvt. Ltd** **Address:** Plot # F 10, MIDC Murbad, District Thane 421401 Maharashtra, India. **GMP Certificate valid till 24-03-2025**
API Lot No.	RV # 272/20 (SB 45/06M/20)
Description of Pack (Container closure system)	White to off white powder with sweet orange taste packed in paper foil sachet further packed in printed unit carton along with information 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**22PD-0224-10-SB**	**22PD-0225-11-SB**	**22PD-0226-12-SB**
Batch Size	75 Sachet	75 Sachet	75 Sachet
Manufacturing Date	06/2022	06/2022	06/2022
Date of Initiation	30/06/2022	30/06/2022	30/06/2022
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).	Invoice # T/PR/318/2020-21 Dated 16-02-2021
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.

Shortcomings communicated to firm

Observations	Reply of the firm
1.5.6 The monograph of finished Pharmaceutical product is available in USP while firm has applied with Innovator specification. Therefore, firm is required to follow official pharmacopeia monograph ***(USP Specification)*** and submit the monograph accordingly along with requisite fee of PKR 7500/- for change of specifications.	Our product, Cholystyrene 4 gm Sachet (Cholestyramine), is developed according to the USP official Pharmacopeia monograph (the analytical procedure is attached for your reference), but in 1.5.6 there is a typo error, and moreover, we have submitted a deposit slip number of **866577032884** for an update of specification.

Remarks of the Evaluator:
The deposit slip number **866577032884** is a fee submission for Licensing Division dated 31-01-2022 while firm is required to submit a fresh fee for the purpose of change of specification of cholstyrene Sachet.

Observations	Reply of the firm
3.2.P.2.1.2 Please Justify that why Acacia,	In accordance with the public assessment report

Xanthan Gum & Propylene Glycol Alginate are not in the applied formulation while same are in the composition of the reference product **Questran.** The list of excipients in Questran are as follows: **Acacia, Citric acid anhydrous, Flavours, Polysorbate 80 Propylene glycol alginate & Sucrose.**	**(PL 18153/0004)** of cholstyramine 4g powder for oral suspension issued by the **Medical and Health Products Regulatory Agency, United Kingdom (UK)** the following excipients are recommended: aspartame, citric acid, silica, colloidal anhydrous, natural orange flavor, propylene glycol alginate, and xanthan gum. Moreover, we have selected these excipients after different trials, and it has been observed that trials with them produced the satisfactory physical and analytical results.

Remarks of the Evaluator:

It is pertinent to mention here that in **Section 1.5.9** of CTD, the applicant initially provided the reference product approved by USFDA for which, formulation / composition is totally different as compared to applied formulation of firm.

However, in the reply of the firm for the shortcomings, the reference product has been changed and now it is MHRA approved product. However, the formulation of applicant is still not matching with the formulation of reference product **(PL 18153/0004)** issued by MHRA. The details of the excipients in MHRA's approved reference product and applied formulation of firm are as under: -

Reference product	Applicant's product
Cholestyramine Aspartame Citric acid Silica, colloidal anhydrous Natural orange flavor Propylene glycol alginate Xanthan gum	Cholestyramine Sucrose 40 mesh Aspartame Citric Acid Anhydrous Orange flavor Colloidal Silicon Dioxide

During evaluation of **Section 3.2.P.2.2.1** of application for Formulation development, it has been observed that applicant manufactured two trials batches.

The trial batch with composition same as compared to **Questran** *(reference product)* was rejected by applicant due to high viscosity and pH. **Xanthan Gum** is the suspending agent in the formulation for viscosity.

While the batch selected by applicant to produce stability batches doesn't contain **Xanthan Gum** but contain **Aspartame** as a suspending agent to control viscosity. It is pertinent to mention here that **Aspartame** is used in Pharmaceuticals and Foods as a **Sweetener** while firm is claiming it as a suspending agent.

Applicant's formulation contains both **Sucrose and Aspartame.** Firm needs to clarify that

i. Why sucrose has been made part of formulation when Aspartame is 200 times more sweetener than sucrose?
ii. Please provide evidence and references for Aspartame to be used as suspending agent.
iii. Please justify how Aspartame can replace xanthan gum and Propylene glycol alginate to control viscosity?
iv. Why the rejected trial batch, whose composition was same as compared to **Questran** being not modified / revised to get formulation with preferred viscosity and pH?

Observations	Reply of the firm
3.2.P.7 QUESTRAN ® (Cholestyramine for Oral Suspension USP) is available as four grams of anhydrous cholestyramine resin contained in 9 grams of QUESTRAN Powder sachet **and include a 15 cc scoop**. Please clarify that why 15cc scoop has not been made part of your applied drug product?	**Questran** is available in four grams of anhydrous Cholestyramine resin contain nine grams of Questran Powder. Since this is a sachet, a scoop is not necessary.

Remarks of the Evaluator:
As per justification given by applicant it is clear that each sachet of 9gm contains one dose of cholestyramine resin 4 grams which was not reflected in **Section 1.5.3** of CTD for label claim. Therefore, scoop is not required.

Observations	Reply of the firm
3.2.P.8 please submit COA and documents for the procurement of API with approval from DRAP.	Submitted

Proceeding of the case:
During presentation of agenda, Evaluator informed that Firm has submitted the required fee for **Change in specification.** The reply of the firm was also discussed regarding composition of the product and clarification submitted by the firm.

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.**

1064.	Name, address of Applicant / Marketing Authorization Holder	M/s Ophth Pharma Private Limited. **(DML # 000488)** Plot # 241, Sector 24, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Ophth Pharma Private Limited. **(DML # 000488)** Plot # 241, Sector 24, Korangi Industrial Area, 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. 481 (dated: 05-01-2023)
	Details of fee submitted	PKR 30,000/-: dated: 02-12-2021 (Invoice # 19655239551)
	The proposed proprietary name / brand name	**PYLOCAR Eye Drops 2%w/v**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each unit contains: Pilocarpine HCl …… 20mg/ml (2% w/v)
	Pharmaceutical form of applied drug	Eye Drops
	Pharmacotherapeutic Group of (API)	Muscarinic Cholinergic agonist
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 x 5ml ampoules
	Proposed unit price	1 x 5ml ampoules = **PKR 225/-**

	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Same formulation Approved for Ethical Laboratories
	GMP status of the Finished product manufacturer	**GMP certificate valid up to 26-09-2023**
	Name and address of API manufacturer.	**Pilocarpine HCl** Manufacturer: **SOURCETECH Quimica LTDA** Rod. Veredor Abel Fabricio Dias, 3430. Pindamonhangaba –SP – 12402 – 020 Brazil. **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 Pilocar Eye drops by M/s Ethical Laboratories** 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	**Pilocarpine HCl** Manufacturer: **SOURCETECH Quimica LTDA** Rod. Veredor Abel Fabricio Dias, 3430. Pindamonhangaba –SP – 12402 – 020 Brazil. **GMP Certificate valid till 23-11-2024**
API Lot No.	Not provided

Description of Pack (Container closure system)	Primary container made of plastic dropper bottle, packed in printed unit caryton along with the leaflet, further packe din master 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
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).	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	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

3.2.S.4.3 Drug Product manufacturer **(Ophth Pharma)** is required to perform system suitability test for API, as per the monograph of **USP 2023** and submit chromatogram along with calculation to confirm that, **Resolution** is NLT 1.5 between isopilocarpine & pilocarpine.

3.2.P.2.4 Please submit in tabulated form the results of **USP Specification's** quality control tests for the pharmaceutical equivalence report of applied formulation vs **Pilocar eye drops by ethical Laboratories.**

Please also justify that why pharmaceutical equivalence studies have been conducted against a local brand **Pilocar** instead of innovator brand.

3.2.P.8 Please submit results of three stability batches as per following template of DRAP CTD guidelines

Please submit COA of the API used in product development and manufacturing of three stability batches

along with documents of approval of procurement from DRAP in case of import. For the three stability batches, please submit chromatograms and their calculations sheets / results sheets along with calculation formulas separately for the interval of months (0, 3 & 6 month) both accelerated and real time studies. Please resubmit Chromatograms with report template **(Injection summary report)** which should contain following three boxes. i. "**Sample information window"** containing sample ID *(sample / standard)*, Batch #, User ID, Data Processed time, Data Acquisition time, Instrument No. Instrument monogram on top, flow rate, wavelength and all necessary information as per 21 CFR Part 11. ii. Chromatogram with peak table with area / width/ height of the peaks, tailing factor & theoretical plates. As primary container of your finished Pharmaceutical product is LDPE (semipermeable container), please submit results for water loss studies as per USP Chapter 671.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

New Section / New License

M/s AGM Pharmaceuticals **(DML # 000948)** Eminabad Road, G.T. Road, Gujranwala, Pakistan has submitted copy of letter of grant of section dated 10-11-2021 specifying Tablet (General) section, Capsule (General) and Dry Powder Injectable (Cephalosporin).

1065.	**Name, address of Applicant / Marketing Authorization Holder**	M/s AGM Pharmaceuticals **(DML # 000948)** Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals **(DML # 000948)** 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 16404 dated 27-06-2023
	Details of fee submitted	PKR 30,000/- Dated 22-06-2023 (Slip # 9952605069)
	The proposed proprietary name / brand name	**AG-Zole 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Omeprazole (as enteric coated pellets) …. 20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	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	Losec 20mg Hard gastro-resistant capsules (MHRA Approved)
	For generic drugs (me-too status)	Omecap Capsule. of M/s Next Pharmaceutical (Reg. No. 084494)
	Name and address of API manufacturer.	**Source of Omeprazole delayed released pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 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 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. Batches: (OMP076, OMP073, OMP090)
	Module-III Drug Product:	Firm has submitted data of drug product including 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 **Risek capsule 20mg** manufactured by Getz Pharma Pakistan by performing quality test (s) ***(Identification, Uniformity of dosage unit, dissolution time, and assay).*** Firm has submitted CDP results of their product against the innovator's product Risek Capsule 20mg 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 validation study reports for drug substance as well as drug product including accuracy, precision, specificity etc.

STABILITY STUDY DATA

Manufacturer of API	**Source of Omeprazole delayed released pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 13-06-2024**
API Lot No.	OMP0727
Description of Pack (Container closure system)	White to off white enteric coated pellets filled in hard gelatin capsule shell no. 2 having transparent color body and light green color cap in Alu-Alu Blister further packed in a unit carton within 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.	**TRC004**	**TRC005**	**TRC006**
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	12/2021	12/2021	12/2021
Date of Initiation	18/12/2021	18/12/2021	18/12/2021
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. F.3-26/2019-Addl.Dir (QA&LT-1)-56 dated 22-08-2022 issued by DRAP 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).	Firm has submitted copy of local invoice having batch number OMP0727 and delivery challan number 900797 specifying 1.00Kg of Omeprazole enteric coated 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. 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:

Observations	**Reply of the firm**

3.2.P.8 Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Capsule Risek 20 mg,** instead of innovator brand **Losec.**	Comparative product sample was easily available at the time of trial batches manufacturing also this product was approved by DRAP Pakistan so we use that sample for pharmaceutical development studies and comparative dissolution 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.**

1066.	**Name, address of Applicant / Marketing Authorization Holder**	M/s AGM Pharmaceuticals **(DML # 000948)** Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals **(DML # 000948)** 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 16403 dated 27-06-2023
	Details of fee submitted	PKR 30,000/- Dated 22-06-2023 (Slip # 46835180)
	The proposed proprietary name / brand name	**AG-Zole 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Omeprazole (as enteric coated pellets) …. 40 mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	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	Losec 40mg Hard gastro-resistant capsules (MHRA Approved)
	For generic drugs (me-too status)	Omecap Capsule. of M/s Next Pharmaceutical (Reg. No. 084494)
	Name and address of API manufacturer.	**Source of Omeprazole delayed released pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 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 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. Batches: (OMP076, OMP073, OMP090)
	Module-III Drug Product:	Firm has submitted data of drug product including 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 **Risek capsule 40mg** manufactured by Getz Pharma Pakistan by performing quality test (s) ***(Identification, Uniformity of dosage unit, dissolution time, and assay).*** Firm has submitted CDP results of their product against the innovator's product Risek Capsule 20mg 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 validation study reports for drug substance as well as drug product including accuracy, precision, specificity etc.
STABILITY STUDY DATA		
Manufacturer of API	**Source of Omeprazole delayed released pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 13-06-2024**	

API Lot No.	OMP0727		
Description of Pack (Container closure system)	White to off white enteric coated pellets filled in hard gelatin capsule shell no. 2 having transparent color body and light green color cap in Alu-Alu Blister further packed in a unit carton within 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.	**TRC007**	**TRC008**	**TRC009**
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
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)	
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&LT-1)-56 dated 22-08-2022 issued by DRAP 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).	Firm has submitted copy of local invoice having batch number OMP0727 and delivery challan number 900797 specifying 1.00Kg of Omeprazole enteric coated 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. 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:

Observations	Reply of the firm
3.2.P.8 Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Capsule Risek 20 mg,** instead of innovator brand **Losec.**	Comparative product sample was easily available at the time of trial batches manufacturing also this product was approved by DRAP Pakistan so we use that sample for pharmaceutical development studies and comparative dissolution 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.**

1067.	Name, address of Applicant / Marketing	M/s AGM Pharmaceuticals **(DML # 000948)**

	Authorization Holder	Emanabad Road, G.T Road, Gujranwala.
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals **(DML # 000948)** Emanabad Road, G.T Road, Gujranwala.
	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. 16405 (dated: 27-06-2023)
	Details of fee submitted	PKR 30,000/-: dated: 22-06-2023 (Invoice # 672130197934)
	The proposed proprietary name / brand name	**Tablet Cetec 10 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Cetrizine Dihydrochloride ……. 10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	BP Specification
	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	*USFDA and MHRA* approved formulation
	For generic drugs (me-too status)	**Avec®** by M/s Platinum
	GMP status of the Finished product manufacturer	Central Licensing Board in its 283rd meeting held on 28th October 2021 granted DML # 000948 (formulation) with following sections. Tablet Section (General) Capsule Section (General) Dry powder injection (General)
	Name and address of API manufacturer.	**Cetrizine di-Hydrochloride** M/s Sreekara Organics Plot # 159/A, S.V. Co-operative Industrial Estate, IDA, Bollaram, Jinnaram Mandal, Sanga Reddy District, Telangana, India. **GMP Certificate valid till 24/04/2024**
	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 Rigix tablets** by M/s AGP performing quality tests (appearance, identification, average weight, Disintegration time, Assay, Dissolution).
	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	**Cetrizine di-Hydrochloride** M/s Sreekara Organics Plot # 159/A, S.V. Co-operative Industrial Estate, IDA, Bollaram, Jinnaram Mandal, Sanga Reddy District, Telangana, India. **GMP Certificate valid till 24/04/2024**		
API Lot No.	(CTZ09020) RM210012		
Description of Pack (Container closure system)	Packed in ALU-ALU Blister and 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**TRT-013**	**TRT-014**	**TRT-015**
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11/2021	11/2021	11/2021
Date of Initiation	22/11/2021	22/11/2021	22/11/2021
No. of Batches	03		

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

26.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
27.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # E00056 Dated 13-07-2021
28.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
29.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
30.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Observations	Reply of the firm
Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Submitted
3.2.P.8 Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Tablet Rigix,** instead of innovator brand **Zyrtec by Pfizer.**	For pharmaceutical development studies and comparative dissolution studies we have use the local brand i.e. Rigix because this brand was easily available in local market which is also registered by DRAP Pakistan. Zyrtec was not available at the time we were planning to perform pharmaceutical development 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.**

M/s Pharman Pharmaceuticals (Pvt) Ltd
Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala.

Central Licensing Board in its 286th meeting held on 11th May 2022 granted DML # 000958 (formulation) with following sections.

1. Tablet Section (General)
2. Capsule Section (General)
3. Oral Liquid Section (General)

1068.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. (DML # 000958)**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. **(DML # 000958)**
	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. 16138 (dated: 26-06-2023)
	Details of fee submitted	PKR 30,000/-: dated: 09-01-2023 (Invoice # 3839876908) & **PKR 30,000/-: dated: 04-07-2023** **(Invoice # 852093315515)**
	The proposed proprietary name / brand name	**Tablet Cipharm 250 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq. Ciprofloxacin …….. 250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA and MHRA* approved formulation
	For generic drugs (me-too status)	**Ciproxin®** by M/s Bayer
	GMP status of the Finished product manufacturer	Central Licensing Board in its 286th meeting held on 11th May 2022 granted DML # 000958 (formulation) with following sections. 1. Tablet Section (General) 2. Capsule Section (General) 3. Oral Liquid Section (General)
	Name and address of API manufacturer.	**Ciprofloxacin HCl** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/03/2026**
	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	**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 Novidat tablets** by M/s Sami performing quality tests (appearance, identification, average weight, Disintegration time, Assay, Dissolution).
	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	**Ciprofloxacin HCl** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/03/2026**		
API Lot No.	CPH2205063		
Description of Pack (Container closure system)	Packed in ALU-ALU Blister and 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**CP22-001**	**CP22-002**	**CP22-003**
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	14/05/2022	14/05/2022	14/05/2022
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).	API Locally manufactured
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:

Observations	Reply of the firm
1.1.b The fee submitted on 09th January 2023 is not acceptable for the dossier resubmitted for evaluation. Therefore, please deposit prescribed fee as per Schedule F of L R & A Rules 1976.	Firm has submitted prescribed fee of PKR 30,000/- vide deposit slip # 852093315515
1.3.1.a Please clarify that why the address of manufacturing site (Factory) mentioned on letter head of firm, is different from address of manufacturing site on DML # 000958 (Formulation).	The address mentioned on DML is as per land registry documents (Patwarkhana) while the address mentioned on letter head is the address that is commonly used by Courier companies / PTCL bills etc. for easy access and understanding.
1.6.5 Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Submitted
3.2.P.8 Please submit COA of API used in Product development and stability studies.	Submitted
Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Tablet Novidat,** instead of innovator brand **Ciproxin.**	We have performed the Pharmaceutical Development and comparative dissolution studies against the leading brand locally available. As per CTD guidance document studies can be carried out against reference / innovator product. Novidat is a well-established brand in the market so that is why we choose Novidat.
Please submit data / chromatograms for the first interval (18-05-2022) 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.**

1069.	Name, address of Applicant / Marketing Authorization Holder	M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. **(DML # 000958)**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. **(DML # 000958)**
	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. 16138 (dated: 26-06-2023)
	Details of fee submitted	PKR 30,000/-: dated: 09-01-2023 (Invoice # 3839876908) & **PKR 30,000/-: dated: 04-07-2023** **(Invoice #** 6603912916**)**
	The proposed proprietary name / brand name	**Tablet Cipharm 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq. Ciprofloxacin ……. 500 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA and MHRA* approved formulation
	For generic drugs (me-too status)	**Ciproxin®** by M/s Bayer
	GMP status of the Finished product manufacturer	Central Licensing Board in its 286th meeting held on 11th May 2022 granted DML # 000958 (formulation) with following sections. 4. Tablet Section (General) 5. Capsule Section (General) 6. Oral Liquid Section (General)
	Name and address of API manufacturer.	**Ciprofloxacin HCl** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/03/2026**
	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	**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 Novidat tablets** by M/s Sami performing quality tests (appearance, identification, average weight, Disintegration time, Assay, Dissolution).
	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	**Ciprofloxacin HCl** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/03/2026**		
API Lot No.	CPH2205063		
Description of Pack (Container closure system)	Packed in ALU-ALU Blister and 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**CP22-004**	**CP22-005**	**CP22-006**
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	16/05/2022	16/05/2022	16/05/2022
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).	API Locally manufactured
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:

Observations	Reply of the firm
1.1.b The fee submitted on 09th January 2023 is not acceptable for the dossier resubmitted for evaluation. Therefore, please deposit prescribed fee as per Schedule F of L R & A Rules 1976.	Firm has submitted prescribed fee of PKR 30,000/- vide deposit slip # 6603912916
1.3.1.a Please clarify that why the address of manufacturing site (Factory) mentioned on letter head of firm, is different from address of manufacturing site on DML # 000958 (Formulation).	The address mentioned on DML is as per land registry documents (Patwarkhana) while the address mentioned on letter head is the address that is commonly used by Courier companies / PTCL bills etc. for easy access and understanding.
1.6.5 Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Submitted
3.2.P.8 Please submit COA of API used in Product development and stability studies.	Submitted
Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Tablet Novidat,** instead of innovator brand **Ciproxin.**	We have performed the Pharmaceutical Development and comparative dissolution studies against the leading brand locally available. As per CTD guidance document studies can be carried out against reference / innovator product. Novidat is a well-established brand in the market so that is why we choose Novidat.
Please submit data / chromatograms for the first interval (18-05-2022) 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.**

1070.	Name, address of Applicant / Marketing Authorization Holder	M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. **(DML # 000958)**
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals (Pvt) Ltd Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, Gujranwala. **(DML # 000958)**
	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. 16137 (dated: 26-06-2023)
	Details of fee submitted	PKR 30,000/-: dated: 09-01-2023

		(Invoice # 233716913) & **PKR 30,000/-: dated: 04-07-2023** **(Invoice # 919879383255)**
	The proposed proprietary name / brand name	**Tablet PARASOL 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol …… 500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic & Antipyretic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	100's, 200's, 500's, 1000's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA and MHRA* approved formulation
	For generic drugs (me-too status)	**Panadol®** by M/s GSK
	GMP status of the Finished product manufacturer	Central Licensing Board in its 286th meeting held on 11th May 2022 granted DML # 000958 (formulation) with following sections. 7. Tablet Section (General) 8. Capsule Section (General) 9. Oral Liquid Section (General)
	Name and address of API manufacturer.	**Paracetamol BP** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/02/2026**
	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 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 Panadol tablets by performing quality tests (appearance, identification, average weight, Disintegration time, Assay, Dissolution).
	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	**Paracetamol BP** M/s Citi Pharma Limited 3.5 km, Head Baloki Road, Phool Nagar, Kasur. **GMP Certificate valid till 03/02/2026**		
API Lot No.	Lot # 6182110012W (RM-6495)		
Description of Pack (Container closure system)	Packed in Alu-Alu nliter and 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**PR22-001**	**PR22-002**	**PR22-003**
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	13/05/2022	13/05/2022	13/05/2022
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).	API Locally manufactured
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:	
1.1.b The fee submitted on 09th February 2023 is	Firm has submitted prescribed fee of PKR 30,000/- vide

not acceptable for the dossier resubmitted for evaluation. Therefore, please deposit prescribed fee as per Schedule F of L R & A Rules 1976.	deposit slip # 919879383255
1.3.1.a Please clarify that why the address of manufacturing site (Factory) mentioned on letter head of firm, is different from address of manufacturing site on DML # 000958 (Formulation).	The address mentioned on DML is as per land registry documents (Patwarkhana) while the address mentioned on letter head is the address that is commonly used by Courier companies / PTCL bills etc. for easy access and understanding.
Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Submitted
3.2.P.8 Please submit COA of API used in Product development and stability studies.	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.**

M/s Trivista Pharmaceuticals (DML # 000952) 8-km, Taxila Khanpur Road, District Haripur, KPK has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Capsule (General) approved in 285th CLB meeting dated 17th & 18th March 2022.

1071.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Trivista Pharmaceuticals **(DML # 000952)** 8-km, Taxila Khanpur Road, District Haripur, KPK.
	Name, address of Manufacturing site.	M/s Trivista Pharmaceuticals **(DML # 000952)** 8-km, Taxila Khanpur Road, District Haripur, KPK.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 29-04-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Capsule (General) approved in 285th CLB meeting dated 17th & a8th March 2022.
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14386 dated 08-06-2023
	Details of fee submitted	PKR 30,000/- Dated 30-05-2023 (Slip # 5371789834)
	The proposed proprietary name / brand name	**Esovista 20mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin capsule contains Esomeprazole Magnesium Trihydrate (enteric coated pellets) equivalent to Esomeprazole …….20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor

	Pharmaceutical form of applied drug	Capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 20mg Hard gastro-resistant capsules (USFDA approved)
	For generic drugs (me-too status)	Nexum Capsules 20 mg by M/s Getz
	Name and address of API manufacturer.	**Source of Esomeprazole enteric coated pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 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 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 of their product against **Esocue capsule 20mg** manufactured by M/s Sandoz by performing quality test (s) ***(Identification, Uniformity of dosage unit, dissolution time, and assay)*.** Firm has submitted CDP results of their product against the **Esocue capsule 20mg** manufactured by M/s Sandoz in 3 dissolution mediums. 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 validation study reports for drug substance as well as drug product including accuracy, precision, specificity etc.

STABILITY STUDY DATA

Manufacturer of API	**Source of Esomeprazole enteric coated pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 13-06-2024**		
API Lot No.	EMZ046406		
Description of Pack (Container closure system)	Blue/orange colored hard gelatin capsules shell size 2 filled with almost white to off white colored round shaped enteric coated pellets.		
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.	**PFT22E001**	**PFT22E002**	**PFT22E003**
Batch Size	5000 Capsules	5000 Capsules	5000 Capsules
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	15/05/2022	15/05/2022	15/05/2022
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.	M/s Vision Pharma , Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased with invoices of M/s Vison 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 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:

3.2.P.8 Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand, i.e. **Capsule Resocue 20 mg,** instead of innovator brand **Nexium** by Astrazeneca**.**
COA for the **Lot # EMZ046406 of API** used in product development and manufacturing of stability batches.

Proceeding of the case.

During presentation of agenda, the evaluator informed that firm has submitted reply of shortcomings and application is complete as per DRAP guidelines for CTD application.

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.

1072.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Trivista Pharmaceuticals **(DML # 000952)** 8-km, Taxila Khanpur Road, District Haripur, KPK.
	Name, address of Manufacturing site.	M/s Trivista Pharmaceuticals **(DML # 000952)** 8-km, Taxila Khanpur Road, District Haripur, KPK.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML issued on 29-04-2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 29-04-2022 specifying Tablet (General) section, Capsule (General) approved in 285th CLB meeting dated 17th & a8th March 2022.
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 14387 dated 08-06-2023
	Details of fee submitted	PKR 30,000/- Dated 30-05-2023 (Slip # 59430880)
	The proposed proprietary name / brand name	**Esovista 40mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin capsule contains Esomeprazole Magnesium Trihydrate (enteric coated pellets) equivalent to Esomeprazole …….40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Pharmaceutical form of applied drug	Capsules
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium 40mg Hard gastro-resistant capsules (USFDA approved)
	For generic drugs (me-too status)	Nexum Capsules 40 mg by M/s Getz
	Name and address of API manufacturer.	**Source of Esomeprazole enteric coated pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 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 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 of their product against **Esocue capsule 20mg** manufactured by M/s Sandoz by performing quality test (s) ***(Identification, Uniformity of dosage unit, dissolution time, and assay)*.** Firm has submitted CDP results of their product against the **Esocue capsule 40mg** manufactured by M/s Sandoz in 3 dissolution mediums. 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 validation study reports for drug substance as well as drug product including accuracy, precision, specificity etc.

STABILITY STUDY DATA	
Manufacturer of API	**Source of Esomeprazole enteric coated pellets** M/s Vision Pharmaceuticals (Pvt.) Ltd. **(DML # 000806)** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. **GMP valid up to 13-06-2024**
API Lot No.	EMZ046406
Description of Pack	Blue/orange colored hard gelatin capsules shell size 2 filled with almost white

(Container closure system)	to off white colored round shaped enteric coated pellets.		
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.	**PFT22E004**	**PFT22E005**	**PFT22E006**
Batch Size	5000 Capsules	5000 Capsules	5000 Capsules
Manufacturing Date	05/2022	05/2022	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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Vision Pharma , Islamabad
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased with invoices of M/s Vison 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 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:

3.2.P.8 Please justify that why pharmaceutical development studies and comparative dissolution studies have been performed against Local Brand i.e. **Capsule Resocue 20 mg,** instead of innovator brand **Nexium** by Astrazeneca**.**
COA for the **Lot # EMZ046406 of API** used in product development and manufacturing of stability batches.

Proceeding of the case.

During presentation of agenda, the evaluator informed that firm has submitted reply of shortcomings and application is complete as per DRAP guidelines for CTD application.

Decision: Approved.

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

M/s Wezen Pharmaceuticals (DML # 000882)
Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.

Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 granted DML # 000882 (formulation) with following sections.

1. Tablet Section (General)

		2. Capsule Section (General) 3. Sachet Section (General) 4. Ointment / Cream / Gel Section (General)
1073.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 6374 (dated: 06-03-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 0185877999)
	The proposed proprietary name / brand name	**Tablet Parozen 20 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paroxetine HCl equivalent to Paroxetine …… 20 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	SSRI's
	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 and MHRA* approved formulation
	For generic drugs (me-too status)	**Panox®** by M/s Regal
	GMP status of the Finished product manufacturer	Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 granted DML # 000882 (formulation) with following sections. 5. Tablet Section (General) 6. Capsule Section (General) 7. Sachet Section (General) 8. Ointment / Cream / Gel Section (General)
	Name and address of API manufacturer.	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
	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 / 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 Paraxyl tablets** by CCL Pharma performing quality tests (appearance, identification, average weight, content uniformity, Assay, Dissolution).
	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	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**		
API Lot No.	Not given		
Description of Pack (Container closure system)	1 x 10 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**T-04**	**T-05**	**T-06**
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	27/05/2022	27/05/2022	27/05/2022
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).	
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:

3.P.1 In the master formulation of reference product **(Paraxyl by GSK)**, ingredients used in film Coating are Opadry ® while in the applied formulation contains **methanol** along with HPMC E5, Talcum, Tio2. How will you justify the use of methanol in film coating? As methanol is not the part of film coating of innovator / reference product therefore, please submit compatibility studies of methanol as an excipient in the applied formulation.

3.2.P.8.1 The test result submitted for dissolution are performed on UV spectrophotometry while the dissolution performance test in USP specification is to be performed on Chromatography system on LC mode with UV detector at 295 nm. Please follow method of USP pharmacopeia for dissolution performance test and submit results accordingly.

Please provide Lot # of API used in Product development and manufacturing of stability batches along with COA and documents for its clearance / approval from DRAP in case of import.

Decision:

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

1074.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 6375 (dated: 06-03-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 79184249)
	The proposed proprietary name / brand	**Tablet Parozen CR 12.5 mg**

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated film coated controlled release tablet contains: Paroxetine HCl equivalent to Paroxetine …… 12.5 mg
	Pharmaceutical form of applied drug	enteric coated film coated controlled release tablet
	Pharmacotherapeutic Group of (API)	SSRI's
	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 and MHRA* approved formulation
	For generic drugs (me-too status)	**Panox CR 12.5mg®** by M/s Regal
	GMP status of the Finished product manufacturer	Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 granted DML # 000882 (formulation) with following sections. 9. Tablet Section (General) 10. Capsule Section (General) 11. Sachet Section (General) 12. Ointment / Cream / Gel Section (General)
	Name and address of API manufacturer.	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
	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 / 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. Paraxyl CR 12.5mg tablets** by CCL Pharma performing quality tests (appearance, identification, average weight, content uniformity, Assay,

		Dissolution).
	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	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**		
API Lot No.	5821012003		
Description of Pack (Container closure system)	1 x 10 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: 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	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	27/05/2022	27/05/2022	27/05/2022
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).	
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:

3.P.1 In the master formulation of reference product **(Paraxyl CR by GSK)**, ingredients used to form hydrophilic

matrix of tablet *(sustained release)* are **Glyceryl Behenate & HPMC** and for enteric coating layer Eudragit L 100 ® along with other ingredients.
While in the applied formulation of firm, there is nothing mentioned regarding formation of hydrophilic matrix of tablet. In the coating of applied formulation, **methanol** along with Eudragit L 00 ® has been used. Please justify the following points:

- the use of methanol in film coating/ enteric coating?
- As methanol is not the part of film coating / enteric coating of innovator / reference product therefore, please submit compatibility studies of methanol as an excipient in the applied formulation.
- Please also submit details for the ingredients / excipients used to form hydrophilic matrix tablet containing API.

3.2.P.8 In the 3rd month stability batch # **T-01** at **Accelerated conditions**, the results of dissolution of one (01) individual tablets at **2nd hour Buffer Stage** exceeds the limits **(15% - 35%)** of the labelled amount of paroxetine.
In the 3rd month stability batch # **T-02** at **Real time conditions**, the results of dissolution of all 02 tablets at **12th hour Buffer Stage** is below the limits **(NLT 80%)** of the labelled amount of paroxetine.
In the 3rd month stability batch # **T-03** at **Accelerated conditions**, the results of dissolution of all 01 tablet at **12th hour Buffer Stage** is below the limits **(NLT 80%)** of the labelled amount of paroxetine.
In the 6th month stability batch # **T-01** at **Real time conditions**, the results of dissolution of all 02 tablets at **04th hour Buffer Stage** is below the limits **(NLT 80%)** of the labelled amount of paroxetine.
Firm has been advised **to perform Level 2 of Dissolution test as per instructions given in Chapter <711> of USP Pharmacopoeia for *Extended Release Dosage form*** (table given below) and submit the reply along with documents / information / raw data sheets / calculation formulas etc.

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

1075.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 6376 (dated: 06-03-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 22851292)
	The proposed proprietary name / brand name	**Tablet Parozen CR 25 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric film coated controlled release tablet contains: Paroxetine HCl equivalent to Paroxetine …… 25 mg
	Pharmaceutical form of applied drug	enteric coated film coated controlled release tablet
	Pharmacotherapeutic Group of (API)	SSRI's
	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 and MHRA* approved formulation
	For generic drugs (me-too status)	**Panox CR 25mg®** by M/s Regal

	GMP status of the Finished product manufacturer	Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 granted DML # 000882 (formulation) with following sections. 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General) 4. Ointment / Cream / Gel Section (General)
	Name and address of API manufacturer.	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
	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 / 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. Paraxyl CR 12.5mg tablets** by CCL Pharma performing quality tests (appearance, identification, average weight, content uniformity, Assay, Dissolution).
	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	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
API Lot No.	5821012003

Description of Pack (Container closure system)	1 x 10 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**T-07**	**T-08**	**T-09**
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	27/05/2022	27/05/2022	27/05/2022
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).	
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:

3.P.1 In the master formulation of reference product **(Paraxyl CR by GSK)**, ingredients used to form hydrophilic matrix of tablet *(sustained release)* are **Glyceryl Behenate & HPMC** and for enteric coating layer Eudragit L 100 ® along with other ingredients.

While in the applied formulation of firm, there is nothing mentioned regarding formation of hydrophilic matrix of tablet. In the coating of applied formulation, **methanol** along with Eudragit L 100 ® has been used. Please justify the following points:

- the use of methanol in film coating/ enteric coating?
- As methanol is not the part of film coating / enteric coating of innovator / reference product therefore, please submit compatibility studies of methanol as an excipient in the applied formulation.
- Please also submit details for the ingredients / excipients used to form hydrophilic matrix tablet containing API.

3.2.P.8 Please provide Lot # of API used in Product development and manufacturing of stability batches along with COA and documents for its clearance / approval from DRAP in case of import.

- In the 3rd month stability batch # **T-07** at **Accelerated conditions**, the results of dissolution of two (02) individual tablets at **4th hour Buffer Stage** exceeds the limits **(40% - 70%)** of the labelled amount of paroxetine.

4 hour Buffer stage Dissolution test		
Sample #	**Calculation**	**Result**
Sample # 01	Area of Sample → 1215276 Area of Ref. Std → 1270261	**85.25%** *Limits (40% - 70%)*
Sample # 02	Area of Sample → 1218497 Area of Ref. Std → 1270261	**86.33%** *Limits (40% - 70%)*

- In the 3rd month stability batch # **T-07** at **Real time conditions**, the results of dissolution of all 06 tablets at **2nd hour Buffer Stage** exceeds the limits **(10% - 30%)** of the labelled amount of paroxetine.
- In the 3rd month stability batch # **T-08** at **Real time conditions**, the results of dissolution of all 06 tablets at **2nd hour Buffer Stage** exceeds the limits **(10% - 30%)** of the labelled amount of paroxetine.

Firm has been advised **to perform Level 2 of Dissolution test as per instructions given in Chapter <711> of USP Pharmacopoeia for *Extended Release Dosage form*** (table given below) and submit the reply along with documents / information / raw data sheets / calculation formulas etc.

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

1076.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals **(DML # 000882)** Plot # 23 & 24, S-1, RCCI. Industrial Estate, Rawat.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 6376 (dated: 06-03-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-02-2023 (Invoice # 22851292)
	The proposed proprietary name / brand name	**Tablet Parozen CR 37.5 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric film coated controlled release tablet contains: Paroxetine HCl equivalent to Paroxetine …… 37.5 mg
	Pharmaceutical form of applied drug	enteric coated film coated controlled release tablet
	Pharmacotherapeutic Group of (API)	SSRI's
	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 and MHRA* approved formulation
	For generic drugs (me-too status)	**Panox CR 37.5mg®** by M/s Regal
	GMP status of the Finished product manufacturer	Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 granted DML # 000882 (formulation) with following sections.

		5. Tablet Section (General) 6. Capsule Section (General) 7. Sachet Section (General) 8. Ointment / Cream / Gel Section (General)
	Name and address of API manufacturer.	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
	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 / 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. Paraxyl CR 25mg tablets** by CCL Pharma performing quality tests (appearance, identification, average weight, content uniformity, Assay, Dissolution).
	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	**Paroxetine HCl** M/s Zhejiang Haisen Pharmaceutical Co. Ltd. Liushi Street, Dongyang City, Zhejiang Province, China **GMP Certificate valid till 01/01/2025**
API Lot No.	5821012003
Description of Pack (Container closure system)	1 x 10 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: 24 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**T-10**	**T-011**	**T-12**
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	05/2022	05/2022	05/2022
Date of Initiation	27/05/2022	27/05/2022	27/05/2022
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).	
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:

3.P.1 In the master formulation of reference product **(Paraxyl CR by GSK)**, ingredients used to form hydrophilic matrix of tablet *(sustained release)* are **Glyceryl Behenate & HPMC** and for enteric coating layer Eudragit L 100 ® along with other ingredients.

While in the applied formulation of firm, there is nothing mentioned regarding formation of hydrophilic matrix of tablet. In the coating of applied formulation, **methanol** along with Eudragit L 100 ® has been used. Please justify the following points:

- the use of methanol in film coating/ enteric coating?
- As methanol is not the part of film coating / enteric coating of innovator / reference product therefore, please submit compatibility studies of methanol as an excipient in the applied formulation.
- Please also submit details for the ingredients / excipients used to form hydrophilic matrix tablet containing API.

3.2.P.8 Please provide Lot # of API used in Product development and manufacturing of stability batches along with COA and documents for its clearance / approval from DRAP in case of import.

In the stability batch # **T-10**, the results of dissolution of three individual tablets at **Acid stage** of ***Delayed release dosage form*** **(A1)** as sample no 01, sample no. 02 and sample no. 04 are 12.43%, 13.78% & 12.46% while the tolerance level at **acid stage** is **NMT 10%** of the labelled amount of paroxetine.

The drug product exceeds the 10% dissolved limit for individual tablet as per Dissolution USP <711>. Therefore, firm needs to perform analysis on further 06 tablets **(A2)** of stability batch # **T-10** and submit the results of average of the 12 units (*A1 + A2*) is NMT 10% dissolved, and no individual unit is >25% dissolved.

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

1077.	Name and address of manufacturer / Applicant	**M/s Ambrosia Pharmaceuticals** **Plot # 18, Street # 09, National Industrial Zone, Rawat.**
	Brand Name +Dosage Form + Strength	AMBOZIAL-D Syrup
	Composition	Each 5ml contains: Desloratadine ……. 2.5 mg
	Diary No. Date of R& I & fee	Dy.No 16023 dated 07/03/2019 Rs. 20,000/- (Slip # 1900239)
	Pharmacological Group	Anti-histamine
	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 approved formulation
	Me-too status	Jardin-D syrup by M/s High Q
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1078.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet AMBCOX 30 mg
	Composition	Each film coated tablet contains: Etoricoxib ……. 30 mg
	Diary No. Date of R& I & fee	Dy.No 16030 dated 07/03/2019 Rs. 20,000/- (Slip # 1900246) dated 07/03/2019
	Pharmacological Group	NSAID
	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
	Me-too status	not confirmed
	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. • Me too status required.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.	
1079.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet AMBCOX 60 mg
	Composition	Each film coated tablet contains: Etoricoxib ……. 60 mg
	Diary No. Date of R& I & fee	Dy.No 16031 dated 07/03/2019 Rs. 20,000/- (Slip # 1900247) dated 07/03/2019
	Pharmacological Group	NSAID
	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
	Me-too status	Etoxib by M/s Hiranis
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1080.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet AMBCOX 90 mg
	Composition	Each film coated tablet contains: Etoricoxib ……. 90 mg
	Diary No. Date of R& I & fee	Dy.No 16032 dated 07/03/2019 Rs. 20,000/- (Slip # 1900248) dated 07/03/2019
	Pharmacological Group	NSAID
	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
	Me-too status	StarCox by M/s Getz
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1081.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet AMBCOX 120 mg
	Composition	Each film coated tablet contains: Etoricoxib ……. 120 mg
	Diary No. Date of R& I & fee	Dy.No 16033 dated 07/03/2019 Rs. 20,000/- (Slip # 1900249) dated 07/03/2019
	Pharmacological Group	NSAID
	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
	Me-too status	StarCox by M/s Getz
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1082.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Dexflam Suspension
	Composition	Each 5ml contains: Dexibuprofen …… 100 mg

	Diary No. Date of R& I & fee	Dy.No 16022 dated 07/03/2019 Rs. 20,000/- (Slip # 1900238) dated 07/03/2019
	Pharmacological Group	NSAID
	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 confirmed
	Me-too status	Tercica by M/s Sami
	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. • RRA status required.
	Decision: **Registration Board deferred the case for submission of reply to the above cited shortcomings within six months**.	
1083.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet Dexflam 400mg
	Composition	Each film coated tablet contains: Dexibuprofen …… 400 mg
	Diary No. Date of R& I & fee	Dy.No 16024 dated 07/03/2019 Rs. 20,000/- (Slip # 1900240) dated 07/03/2019
	Pharmacological Group	NSAID
	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
	Me-too status	Obsprufen 400mg Tablet by M/s OBS
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1084.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet NABVE 2.5 mg
	Composition	Each uncoated tablet contains: Nebivolol HCL 2.725mg eq. to Nebivolol ……..…. 2.5 mg
	Diary No. Date of R& I & fee	Dy.No 16025 dated 07/03/2019 Rs. 20,000/- (Slip # 1900241) dated 07/03/2019
	Pharmacological Group	Highly cardio selective vasodilator beta 1 receptor blocker
	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.	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too status	Nebil 2.5mg Tablets of M/s Getz Pharma (Reg.#061344)
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1085.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet NABVE 5 mg
	Composition	Each tablet contains: Nebivolol HCL 5.45mg eq. to Nebivolol …….…. 5 mg
	Diary No. Date of R& I & fee	Dy.No 16026 dated 07/03/2019 Rs. 20,000/- (Slip # 1900242) dated 07/03/2019
	Pharmacological Group	Highly cardio selective vasodilator beta 1 receptor blocker
	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.	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too status	Nebil 5mg Tablets of M/s Getz Pharma Pakistan (Reg.#061345)
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1086.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet NABVE 10 mg
	Composition	Each uncoated tablet contains: Nebivolol HCL 10.90 mg eq. to Nebivolol ……..…. 10 mg
	Diary No. Date of R& I & fee	Dy.No 16027 dated 07/03/2019 Rs. 20,000/- (Slip # 1900243) dated 07/03/2019
	Pharmacological Group	Highly cardio selective vasodilator beta 1 receptor blocker
	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.	BYSTOLIC (2.5mg, 5mg, 10mg, 20mg) tablets USFDA Approved
	Me-too status	Bynevol 10mg Tablet by Atco Lab Karachi. Reg No. 81562
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1087.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet ALPRIDE 25 mg

	Composition	Each tablet contains: Levosulpride …….…. 25 mg
	Diary No. Date of R& I & fee	Dy.No 16019 dated 07/03/2019 Rs. 20,000/- (Slip # 1900235) dated 07/03/2019
	Pharmacological Group	Selective antagonist of dopamine D_2 receptor activity
	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.	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	
1088.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Tablet ALPRIDE 50 mg
	Composition	Each tablet contains: Levosulpride …….…. 50 mg
	Diary No. Date of R& I & fee	Dy.No 16020 dated 07/03/2019 Rs. 20,000/- (Slip # 1900236) dated 07/03/2019
	Pharmacological Group	Selective antagonist of dopamine D_2 receptor activity
	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.	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA Italy
	Me-too status	Sapride Tablet 50mg Reg. No. 049950
	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: Approved • **Registration letter shall be issued after submission of valid / fresh GMP certificate OR inspection report conducted within last 03 years confirming the GMP status of the manufacturing facility for the proposed dosage form.**	

Registration-I Section

Case No.1. Request for Change in Registration Status of Pepcidine 20mg Tablets from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi to M/s Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi.

M/s. Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi has requested to change the product registration status of Pepcidine 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.

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 (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.
ii. Copy of DML of M/s OBS Pakistan Pvt Ltd., (DML # 000012) renewed w.e.f. 26-10-2020.

iii. 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
iv. Copy of Approval letter dated 06-07-2022 for change in title of registration holder from M/s OBS Pakistan Pvt Ltd. Karachi to M/s. Searle Pakistan Ltd; Karachi
v. NOC from M/s. Searle Pakistan Ltd; Karachi for transfer of Pepcidine 20mg Tablets in the name of M/s. Aspin Pharma Pvt Ltd., Korangi Industrial Area, Karachi issued on 30-01-2023. Firm has also submitted fresh NOC dated 01-08-2023 (i.e., within 6months)
vi. Request dated 01-06-2023, submitted by M/s. Searle Pakistan Ltd; Karachi for withdrawal of Pepcidine 20mg Tablets
vii. Relevant undertakings & commitments.

Mr. Asadullah (DD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	102826	Pepcidine Tablet 20mg Each film coated tablet contains: Famotidine……20mg (USP Specifications)	Initial Reg. Date: **30-04-2020** Approval from change in registration to new title of the firm: **06-07-2022** Renewal not due yet.
	Name, address of Applicant / Marketing Authorization Holder		**M/s Aspin Pharma (Pvt) Ltd, Karachi. Plot No. 10&25 Korangi Industrial Area, Karachi-Pakistan**
	Name, address of Manufacturing site.		M/s Aspin Pharma (Pvt) Ltd, Karachi. Plot No. 10&25 Korangi Industrial Area, Karachi-Pakistan. **(DML 000045)** ***(Transfer of Registration from M/s OBS Pakistan Pvt. Ltd Karachi,*** ***[NOC attached dated 07-01-2021]***
	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 DML and renewal application, and GMP certificates of manufacturing site mentioning 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. 3055/R&I : 02-02-2023 Dy. No. 10603 : 26-04-2023
	Details of fee submitted		**For transfer of registration:** PKR 30,000/-: DS No. 50247950 deposited on 26-11-2022
	The proposed proprietary name / brand name		**Pepcidine 20 mg Tablet (Reg.102826)**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Famotidine 20mg
	Pharmaceutical form of applied drug	Yellow colour capsule shaped film coated tablet
	Pharmacotherapeutic Group of (API)	H_2 receptor blocker
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1x10x's
	Proposed unit price	-
	The status in reference regulatory authorities	Pepcid 20mg Tablet, Merck Sharp &Dohme (Australia) Pty Ltd.
	For generic drugs (me-too status)	Acicon 20mg Tablets, Barret Hodgson Pakistan Pvt Ltd,. (Reg# 024254)
	Name and address of API manufacturer.	M/s SMS Pharmaceuticals Limited Unit-I, Sy.No. u180/2, Kazipalli (V), Jinnaram (M), Medak District, Telagana, India GMP certificate issued on 07-08-2019 by Drug Control Administration, Government of Telangana, India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	The firm has summarized information related to DS and finished products. The official monograph of DS and FP is available in USP. QOS provides information of general properties including physical form, solubility profiles and polymorphic form (A & B) Form B is being produced by DS manufacturer and related impurities were listed. DS and finish product comply to USP specification. Brief information related to analytical procedures, specification, working standard, container closure system and stability studies of drug substance and drug product has been provided. Manufacturing process and critical process parameters were summarized for FP. The analytical method of USP for FP was verified by FP manufacturer. Batch analysis of 03 FP batches were provided in tabulated format. Stability data sheets of DS and DP were provided at the accelerated and long-term condition as per Zone IVb.
	Module-III Drug Substance:	The Firm has submitted Information for drug substance with related to nomenclature and structure, and provided list of general properties including solubility, polymorphic form. The DS was manufactured at SMS India as Form B of the polymorphic form. The manufacturing process was described along with the studies conducted for structural elucidation. The potential Impurities and residual solvent were studied in 03 batches of DS, which shows detection within limits. USP referenced analytical methods were verified by the DS manufacturer. CoA of DS lot from DS manufacturer and FP manufacturer was provided. CoA of working standards produced by DS manufacturers was submitted. Container closure system and analytical method for packaging material was provided. Degradation studies were also conducted during stability studies.

<table>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data is conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36 months. The famotidine powder was placed in double poly bags and kept in an HDPE drum. The DS remain stable and no significant changes were observed during the stability studies.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data on drug product including its composition, pharmaceutical development, manufacture, manufacturing process, process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. The Specifications and control tests are in compliance to USP. The manufacturing process of DP from mixing to film coating was elaborated and critical parameters were identified with control checks. Manufacturing protocol was also developed. Pharmacopeial grade excipients were used in the formulation and their analytical methods and CoAs were provided. The DP specification were assigned as per USP and accordingly analytical method was verified. Batch analysis of 03 stability batches were provided with their CoAs. Firm claimed that no impurities were detected in the drug product formulation. Working standard provided by the DS manufacturer were used as reference standard. CoA of reference standard was also submitted. BMR of stability batches was also submitted.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>The Pharmaceutical equivalence study was conducted to compare DP against the Nocid 20mg Tab manufactured by GSK Pakistan for Novartis (Batch 034K, Mfg date Mar 2021). The Comparative Dissolution Profile was also studied against the Nocid 20mg tablet in 03 different medium. The summary is tabulated as under:-
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="7">i.</td><td rowspan="7">Acidic buffer (pH 1.2)</td><td>10 min</td><td>68.32%</td><td>60.45 %</td></tr>
<tr><td>15 min</td><td>64.92%</td><td>58.64%</td></tr>
<tr><td>20 min</td><td>60.13%</td><td>54.51 %</td></tr>
<tr><td>30 min</td><td>55.01%</td><td>49.48%</td></tr>
<tr><td>45 min</td><td>49.26%</td><td>43.90%</td></tr>
<tr><td colspan="2">f1 = 11.47
f2= 60.10</td></tr>
<tr><td rowspan="7">ii</td><td rowspan="7">Acetate buffer (pH 4.5)</td><td>10 min</td><td>97.21%</td><td>95.21 %</td></tr>
<tr><td>15 min</td><td>100.20%</td><td>100.02%</td></tr>
<tr><td>20 min</td><td>100.67%</td><td>101.64%</td></tr>
<tr><td>30 min</td><td>100.81%</td><td>101.83%</td></tr>
<tr><td>45 min</td><td>100.99%</td><td>102.08%</td></tr>
<tr><td colspan="2">f1=0.94
f2=91.01</td></tr>
<tr><td rowspan="2">iii</td><td rowspan="2">Phosphate Buffer</td><td>10 min</td><td>88.03 %</td><td>93.11 %</td></tr>
<tr><td>15 min</td><td>95.27 %</td><td>98.29%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td>(pH 6.8)</td><td>20 min</td><td>98.41%</td><td>99.80 %</td></tr>
<tr><td></td><td></td><td>30 min</td><td>101.21%</td><td>100.84%</td></tr>
<tr><td></td><td></td><td>45 min</td><td>102.58%</td><td>101.84%</td></tr>
<tr><td></td><td></td><td colspan="3">f1=2.131
f2=77.231</td></tr>
</table>
f1 and f2 values reflect the similarity of the sample product.
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which a report of verification of analytical method for the drug product has been provided.</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td colspan="3">M/s SMS Pharmaceuticals Limited
Unit-I, Sy.No. u180/2, Kazipalli (V), Jinnaram (M), Medak District, Telagana, India</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">FMT 209 05 22</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="3">Alu/PVC blister in unit carton</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30˚C ± 2˚C / 75% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 6 months
Real time: 06 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9,12 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>295DS01</td><td>295DS02</td><td>295DS03</td></tr>
<tr><td colspan="2">Batch Size</td><td>2500 Tablets</td><td>2500 Tablets</td><td>2500 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>07-2022</td><td>07-2022</td><td>07-2022</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>08-2022</td><td>08-2022</td><td>08-2022</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3"></td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of GMP certificate issued by Drug Control Administration, Government of Telangana, India dated 27-08-2022.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Firm has submitted copy of commercial invoice specifying import of 25Kg of Famotidine USP Batch FMT 209 05 22 dated 31-05-2022, .</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td colspan="3">Firm has submitted that their HPLC system is 21 CFR compliant.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring</td><td colspan="3">Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and</td></tr>
</table>

	of stability chambers (real time and accelerated)	accelerated stability chambers.

Evaluator Queries:

S.NO	Documents	Response
1	Clearance Certificate of DRAP Karachi for API procurement invoice of famotidine.	The commercial invoice for procurement of API with DRAP NOC was provided which shows that famotidine batch No. FMT 209 05 22 was cleared by DRAP Karachi Certificate No. E-1714628152716dated 22-Jun-2022.
2	Whether drug product manufacturers conducted verification or validation of an analytical method for famotidine DS.	The API analytical method (assay) was verified for four parameters suitability, specificity, accuracy, and precision by Ms. Aspin Pharma. Method protocol and report were submitted.
3	Batch Analysis summaries under 2.3.S.4 need to be resubmitted as it shows the data of drug product instead of DS.	The revised batch analysis summary under 2.3.S.4 was provided.
4	Why the API lot used in the manufacturing of stability batches is different from the batch number mentioned on the procurement document?	Firm stated that batch number was mistakenly mentioned and submitted in BMR and same reproduced in the Stability protocol and stability data sheets. Firm submitted corrected protocol and data sheets.
5	Why the identification test is not included in the stability studies of the first 03 months of accelerated and long-term studies?	The firm maintained that identification tests were part of the initial testing and not included in the stability protocol in light of WHO TRS 863.

Conclusive Remarks:

Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.

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.	**102826**	**Pepcidine Tablet 20mg** **Each film coated tablet contains:** **Famotidine……20mg** **(USP 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.

S. No.	Product Name & Composition
i.	**Pepcidine 20 mg Tablet** **Each film coated tablet contains:** **Famotidine……..…20mg** **(USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.02. Request for Change in Registration Status of Mepresor Tablet 100mg from M/s Novartis Pharma Pakistan Limited, 15 West wharf, Karachi to M/s Novartis Pharma (Pakistan) Limited, C-21, S.I.T.E. Area, Karachi.

M/s. Novartis Pharma (Pakistan) Limited C-21, S.I.T.E. Area, Karachi (DML No.000003) has requested to change the registration status of Mepresor Tablet 100mg from M/s Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi (DML#000193) to M/s Novartis Pharma Pakistan Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd,), C-21, S.I.T.E, Area, Karachi (DML#000003). They have also requested for change in manufacturing site from M/s GSK CHC, Petaro Road, Jamshoro (DML No. 000010) (i.e., contract manufacturer) to M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi (i.e., self-manufacturing).

The detail of the case is as follows:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 08-09-2021.
ii. Copy of DML of M/s Novartis Pharma Pakistan Limited (DML # 000003) renewed w.e.f. 18-09-2020.
iii. Copy of Tablet (General) section approval letter dated 28-12-2021 issued by Licensing Division in the name of M/s Novartis Pharma Pakistan Ltd, C-21, S.I.T.E Area Karachi (DML# 000003)
iv. NOC from M/s. Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi (DML#000193) for transfer of Mepresor Tablet 100mg in the name of M/s. Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi, issued on 17-07-2023
v. Request dated 17-07-2023 from M/s Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi (DML#000193) for withdrawal/ cancellation of registration.
vi. Relevant undertakings & commitments.

Detail of submitted documents and remarks of evaluators have been mentioned as under:

Mr. Salateen Waseem Philips (DD-PR)

I	**II**	**III**	**IV**
S/N	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	007823	Mepresor 100mg Tablets Each tablet contains: Metoprolol..... 100mg (USP Specification)	Reg. Date: **22-01-2020** Renewal Granted w.e.f. **22-06-2022 to 21-06-2027** vide letter dated 28-10-2022.
	Change in status of registered product **"MEPRESOR 100 mg TABLET"** of applicant with **DML # 000193** 1. From contract manufacturing at GSK Jamshoro to self-manufacturing at another manufacturing site of applicant at DML # 000003. 2. Transfer of registration from DML # 000193 to DML # 000003		
	Name of the Applicant /Market Authorization Holder		M/s Novartis Pharma (Pakistan) Limited **(DML # 000193)** 15 West Wharf, Dockyard Road, Karachi.
	From		**To**
	Contract manufacturing at **DML # 000010** M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd. Petaro Road, Jamshoro.		Self- manufacturing & registration transfer at **(DML # 000003)** M/s Novartis Pharma (Pakistan) Limited *(formerly M/s Bayer Pakistan (Pvt.) Ltd)* C-21, S.I.T.E. 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. 9565 (dated: 10-04-2023)
	Details of fee submitted	PKR 30,000/-: dated: 20-02-2023 (Invoice # 40237955358)
	The proposed proprietary name / brand name	**Tablet Mepresor 100 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Metoprolol Tartrate ……. 100 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Beta blockers
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per registration letter
	Proposed unit price	As per registration letter
	The status in reference regulatory authorities	*USFDA approved* **Lopressor®** a trademark of Novartis
	For generic drugs (me-too status)	**BetaLoc ZOK 100mg Tablet** by M/s Barrett.
	GMP status of the Finished product manufacturer	GMP valid up to **07th September 2023**
	Name and address of API manufacturer.	Source of API is same for drug product manufacturer at **existing facility as well as proposed facility** M/s Sun Pharmaceutical Industries Limited Sun House, Plot # 201 B/1, Western Express Highway, Goregaon (E) Mumbai, Maharashtra, India. **GMP valid till 08-11-2024**
	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	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. Mepressor Tablets by M/s GSK Jomshoro** by performing quality tests (appearance, identification, average weight, Disintegration, Dissolution, Assay).
	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 *(at new facility)*

M/s Novartis Pharma (Pakistan) Limited **(DML # 000193)** 15 West Wharf, Dockyard Road, Karachi.

Manufacturer of API	M/s Sun Pharmaceutical Industries Limited Sun House, Plot # 201 B/1, Western Express Highway, Goregaon (E) Mumbai, Maharashtra, India.		
API LOT #	ACMTPNF125 & ADMTPNF051		
Description of Pack (Container closure system)	1 folding box unit of Mepressor 100 mg Tablet comprises of 3 Alu-PVC blisters of 10 tablets with 01 folded direction circular.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 0,3,6 months Real time: 0,3,6 months (Data submitted for 06 months)		
Frequency	Accelerated: 0,3,6 months Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)		
Batch No.	**BAC521**	**BAC523**	**BAC527**
Batch Size	100 Packs	100 Packs	100 Packs
Manufacturing Date	08/2022	08/2022	08/2022
Date of Initiation	07/09/2022	07/09/2022	07/09/2022
No. of Batches	03		

Administrative Portion

31.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable	
32.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided	
33.	Documents for the procurement of API with approval from DRAP (in case of import).	**Existing unit**	Invoice # 7000015632 dated 30/06/2018
		New Unit	Invoice # 7000081635 dated 20-06-2022

34.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
35.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
36.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Observations	Reply of the firm
1.3.4(a) Please submit latest GMP certificate for applicant's facility at DML # 000193 which should be valid till date.	Since this is manufacturing site change from GSK Jomshoro DML # 000010 to Novartis Pharma (Pakistan) Ltd, C-21, S.I.T.E. Karachi DML # 000003, we are providing you GMP for both the DMLs. Kindly note that facility of DML # 000193 is neither current nor proposed manufacturer for Mepressor tablet.
1.4.3 No Objection certificate is required from previous contract manufacturer i.e. M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd. Petaro Road, Jamshoro **DML # 000010** for ending / terminating the contract manufacturing and confirming that all legal, financial and codal formalities have been fulfilled and there is nothing pending or in dispute between contract giver (Novartis) and contract acceptor (GSK) as per terms and conditions of contract agreement.	We have requested required NOC from current manufacturing site and will provide you as soon as available with us.
1.6.5 For DML # 000010 (GSK, Jamshoro), Please submit Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin which should be valid till date. For DML # 000003 (Novartis, C-21, S.I.T.E. Karachi), Please submit Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin which should be valid till date.	Kindly note that for DML # 000003 Drug substance manufacture is same. GMP attached .
3.2.S.4.3 For manufacturing facility with DML # 000003, Chromatograms and record required for system suitability confirming that relative retention times for metoprolol and oxprenolol are 0.8 & 1.0, respectively.	Submitted
3.2.S.4.5 COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
3.2.P.1(b) Please submit a comparison in tabulated form of drug product formulation at DML # 000003 (Novartis) and DML # 000010 (GSK) , if there is any change in inactive ingredients then provide justification of change.	Submitted
3.2.P.2 For DML # 000010 (GSK, Jamshoro), please submit details for Pharmaceutical	Submitted

equivalence and comparative dissolution profile established with innovator / comparator product.	
3.2.P.5.4 Please submit a comparison in tabulated form, for batch analysis reports of DML # 000003 and DML # 000193	Submitted
3.2.P.8 Please submit stability data for drug product **separately** for DML # 000003 & DML 000010	Submitted
3.2.P.8 Documents for the procurement of API used in stability batches along with COAs issued by drug substance manufacturer as well drug product manufacturer, with approval from DRAP (in case of import) for both DML # 000003 and DML # 000010.	Submitted

NOVARTIS

Comparison for Formulation of Mepresor 100 mg Tablet

GSK (existing site) vs Novartis (new site)

S. No	Material Description	Composition per Tablet (GSK)	Composition per Tablet (Novartis)	Remarks
1	**Metoprolol tartrate (API)**	100.000	100.000	No Change
2	Aerosil 200	9.000	9.000	No Change
3	Avicel	177.000	177.000	No Change
4	Sodium Carboxy Methyl Starch	40.000	40.000	No Change
5	Magnesium stearate	4.000	4.000	No Change
6	HPM Cellulose	4.714	4.714	No Change
7	Titanium Dioxide	0.881	0.881	No Change
8	Cremophor	0.220	0.220	No Change
9	Talc PH Grade	4.175	4.175	No Change

Batch Analyses comparison

Test	**FPP Specification**	**New Site**			**Existing Site**		
		BAC521	**BAC523**	**BAC527**	**ML5L**	**NJ2W**	**V59Y**
Formulation	Coated Tablet	Complies	Complies	Complies	Complies	Complies	Complies
Form	Round slightly biconvex with beveled edges	Complies	Complies	Complies	Complies	Complies	Complies
Color	White	Complies	Complies	Complies	Compli	Compli	Compl

					es	es	ies
Tablet Marking on one side	"I/P"	Complies	Complies	Complies	Complies	Complies	Complies
Tablet Marking on other side	"CG"	Complies	Complies	Complies	Complies	Complies	Complies
Uniformity of mass 90% (min 18 s.u.)	323 - 357 mg	Complies	Complies	Complies	Complies	Complies	Complies
Uniformity of mass 100% (min 20 s.u.)	306 - 374 mg	Complies	Complies	Complies	Complies	Complies	Complies
Disintegration	Max 30min	Complies	Complies	Complies	-	-	-
Dissolution	Not less than 80% (Q value 75%) of declared content (min-max) Mean	97 – 101% 99% Complies	Min 98 Max 103 Average 101 Complies	Min 98 Max 105 Average 101 Complies	98.2-106.4% 103.14% Complies	101-103% 101.96% Complies	86.9-97.3% 92.36% Complies
Assay	90-110%	98.00%	98.00%	98.00%	99.39%	98.83%	98.09 %
Identification Identification (HPLC)	The retention time of the metoprolol peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies	Complies
Identification by UV	Corresponds to reference	Complies	Complies	Complies	Complies	Complies	Complies
Any individual unspecified degradation product	NMT 0.2%	Not detected Complies	Not detected Complies	Not detected Complies	Not detected Complies	Not detected Complies	<0.1% Complies
Total degradation product	NMT 1%	Not detected Complies	Not detected Complies	Not detected Complies	Not detected Complies	Not detected Complies	0.16% Complies
Uniformity of Dosage units (by Mass variation)	(905) meet the requirements	Complies	Complies	Complies	Complies	Complies	Complies
Microbial Enumeration Tests (MET) - Total aerobic microbial count (TAMC) - Total yeast and moulds count (TYMC) - Specified Microorganisms - Escherichia Coli	Not more than 10^3 CFU/g Not more than 10^2 CFU/g	04 CFU/g Complies 00 CFU/g	03 CFU/g Complies 01 CFU/g Complies	03 CFU/g Complies 01 CFU/g Complies	Not detected Complies	Not detected Complies	20cfu/g Complies

- S. aureas - Ps. Aeruginosa - Salmonella - Bile tolerant Gram -ve bacteria Escherichia Coli	Not detectable/g Not detected Not detected Not detected NA	Complies Note detected Complies Not detected Complies Not detected Complies Not detected Complies NA	Not detected Complies Not detected Complies Not detected Complies Not detected Complies NA	Not detected Complies Not detected Complies Not detected Complies Not detected Complies NA	Not detected Complies Not detected Complies	Not detected Complies Not detected Complies	<10cfu/g Complies Complies

Decision: Registration Board decided as under:

i. Cancelled registration of following product from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition
1.	007823	**Mepresor 100mg Tablets** **Each tablet contains:** **Metoprolol..... 100mg** **(USP Specification)**

ii. Approved registration of following products in the name of M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E Area, Karachi (DML#000003).

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
1.	**Mepresor 100mg Tablets** **Each film coated tablet contains:** **Metoprolol Tartrate..... 100mg** **(USP Specification)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.3. Request for Change in Registration Status of Products from M/s Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi to M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.

M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933) has requested for change in registration status of below mentioned products from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284) to their name.

Detail is as under:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of registration letter and last renewal status.
ii. Copy of DML of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (Manufacturer) issued on 25-05-2021(DML No.000933)
iii. Copy of approval letter dated 27-02-2023 issued by Licensing Division, DRAP for grant of Additional Sections to M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi. The letter confirms approval of "Dry Powder Vial Injection (Cephalosporin)" section.
iv. Copy of GMP certificate of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi based on evaluation conducted on 17-11-2021.
v. NOC dated 26-04-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for transfer of products in the name of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.
vi. Request dated 17-07-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for withdrawal/ cancellation of registration.
vii. Application with Form-5F and required fee as per relevant SRO.
viii. Relevant undertakings & commitments.

Detail of submitted documents/ remarks of evaluators have been mentioned as under:

Evaluator: Mr. Salateen Waseem Philips (DD-PR)

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	024629	Getofin Injection 250mg (IV) Each vial contains: Ceftriaxone (as Sodium)……250mg	Initial Reg. Date: **12-03-2002** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Novamed, Pharmaceuticals (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Transfer of registration for contract manufacturing to self-manufacturing at another manufacturing site of applicant		
	From		**To**
	Contract manufacturing at: M/s Novamed Pharmaceuticals (Pvt.) Ltd, 28km, Ferozpur Road, Lahore.		*Change in Manufacturing site along with transfer of registration at:* M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, 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. 11034 (dated: 03-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 01-02-2023 (Invoice # 405202729)

	The proposed proprietary name / brand name	**Getofin IV Injection 250 mg** *(Reg. no. # 024629)* **Initial Registration:** 12-03-2002 **Last extension in contract manufacturing**: Valid till 30th June 2025
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium) ……. 250 mg
	Pharmaceutical form of applied drug	Powder for solution for injection
	Pharmacotherapeutic Group of (API)	*Cephalosporin*
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per registration letter
	Proposed unit price	As per registration letter
	The status in reference regulatory authorities	*USFDA approved* formulation.
	For generic drugs (me-too status)	**Oxidil 25 0mg Injection** by M/s Sami.
	GMP status of the Finished product manufacturer	Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China **GMP valid till 05/12/2023**
	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	**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. Oxidil 250mg IV injection**

		by **M/s Sami** by performing quality tests (appearance, constituted solution, identification, Average weight of content, uniformity of dosage units by weight variations, pH, water content, Assay).
	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	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China	
API LOT #	3052206016	
Description of Pack (Container closure system)	250mg, White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial + 5 ml sterile water	
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.	**C006DS01**	**C006DS02**
Batch Size	2000 Vials	2000 vials
Manufacturing Date	19/09/2022	19/09/2022
Date of Initiation	08/10/2022	08/10/2022
No. of Batches	02	

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 # K-7643522637624 dated 27-07-2022
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 the Evaluator:

Query Items	Getz Pharma Response
Please provide comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site.	Submitted
Please justify that why Pharmaceutical Equivalence studies have been conducted against **Oxidil IV 250mg Injection** while recommended comparator/innovator is Rocephin.	This is to bring to your kind information that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical Drug products for human use", to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed'*. We have established Pharmaceutical Equivalence of **Getofin IV Injection 250mg** (Manufactured by M/s Getz Pharma Pvt. Ltd) with comparator product **Oxidil IV Injection 250mg** Manufactured by M/s Healthtek Pvt. Ltd as innovator brand is currently not available in Pakistan. Further, this is to inform you that Ceftriaxone for Injection is a pharmacopoeial product available in USP, and all the test parameters of Getofin IV Injection 250mg complies with USP Specification.
Source of API at previous site **(Novamed Pharma)** along with COA.	This is to inform you M/s Zhuhai United Laboratories Co., Ltd., China is the source of API at previous site (M/s Novamed Pharma). Please refer to **Annexure II** for the Certificate of Analysis (COA).

Test	Specification	New Site		Current Site		
		C006DS01	C006DS02	17872	17872	18256
Appearance	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.	Complies	Complies	Complies	Complies	Complies
Constituted Solution (Completeness and Clarity of Solution)	When constituted, the solution should be clear and meets the requirements.	Complies	Complies	Complies	Complies	Complies
Identification Test by IR	The IR spectrum of sample is concordant to that of the reference standard.	Complies	Complies	Complies	Complies	Complies

Identification Test by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Average weight of content	298.00 mg ± 10.0 %	301.15 mg	302.74 mg	304.25 mg	302.96 mg	303.22 mg
Uniformity of Dosage Units by weight variation	Acceptance value L1 should be less than 15 for 10 units.	9.50 %	9.80 %	9.91 %	9.68 %	9.84 %
pH	6.00 – 8.00	6.77	6.83	6.45	6.54	6.59
Water Content	8.00 % – 11.00 %	10.40 %	10.29 %	9.72 %	9.45%	9.31%
Assay of Ceftriaxone	95.00 % – 110.00 %	100.13 %	99.75%	101.55%	99.18%	100.54%
Related Substance						
Deacetylcefotaxime lactone	Not more than 0.50 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone triazine analog	Not more than 1.0 %	0.27%	0.23%	0.32%	0.25%	0.28%
Ceftriaxone benzothiazolyloxime	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Deacyl ceftriaxone	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone 3-ene isomer	Not more than 0.30 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone E-Isomer	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Any individual unspecified impurities	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Total Impurities	Not more than 5.0 %	0.27 %	0.23%	0.32%	0.25%	0.28%
Bacterial endotoxin test	NMT 0.20 USP Endotoxin Unit/mg of ceftriaxone	Complies	Complies	Complies	Complies	Complies
Sterility test	Meets the requirements	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 10 µm	6000 particles per container	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 25 µm	600 particles per container	Complies	Complies	Complies	Complies	Complies

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**

2.	024628	Getofin Injection 250mg (IM) Each vial contains: Ceftriaxone (as Sodium)……250mg	Initial Reg. Date: **12-03-2002** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Novamed, Pharmaceuticals (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Transfer of registration for contract manufacturing to self-manufacturing at another manufacturing site of applicant		
	From		**To**
	Contract manufacturing at: M/s Novamed Pharmaceuticals (Pvt.) Ltd, 28km, Ferozpur Road, Lahore.		*Change in Manufacturing site along with transfer of registration at:* M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, 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. 11033 (dated: 03-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 30-01-2023 (Invoice # 0576789752)
	The proposed proprietary name / brand name		**Getofin IM Injection 250 mg** *(Reg. no. # 024628)* **Initial Registration:** 12-03-2002 **Last extension in contract manufacturing**: Valid till 30th June 2025
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each vial contains: Ceftriaxone (as sodium) ……. 250 mg
	Pharmaceutical form of applied drug		Powder for solution for injection
	Pharmacotherapeutic Group of (API)		*Cephalosporin*
	Reference to Finished product specifications		USP Specification
	Proposed Pack size		As per registration letter
	Proposed unit price		As per registration letter
	The status in reference regulatory authorities		*USFDA approved* formulation.
	For generic drugs (me-too status)		**Oxidil 250mg Injection** by M/s Sami.
	GMP status of the Finished product manufacturer		Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.		**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China **GMP valid till 05/12/2023**

	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	**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. Oxidil 250mg IM injection** by **M/s Sami** by performing quality tests (appearance, constituted solution, identification, Average weight of content, uniformity of dosage units by weight variations, pH, water content, Assay).
	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	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China
API LOT #	3052206016
Description of Pack (Container closure system)	250mg, White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial + Lidocaine 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: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months)

		Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)	
Batch No.		**C006DS01**	**C006DS02**
Batch Size		2000 Vials	2000 vials
Manufacturing Date		19/09/2022	19/09/2022
Date of Initiation		08/10/2022	08/10/2022
No. of Batches		02	
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 # K-7643522637624 dated 27-07-2022	
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 the Evaluator:			

Query Items	Getz Pharma Response
Please provide comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site.	Submitted
Please justify that why Pharmaceutical Equivalence studies have been conducted against **Oxidil IV 250mg Injection** while recommended comparator/innovator is Rocephin.	This is to bring to your kind information that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical Drug products for human use", to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed'*. We have established Pharmaceutical Equivalence of **Getofin IV Injection 250mg** (Manufactured by M/s Getz Pharma Pvt. Ltd) with comparator product **Oxidil IV Injection 250mg** Manufactured by M/s Healthtek Pvt. Ltd as innovator brand is currently not available in Pakistan. Further, this is to inform you that Ceftriaxone for Injection is a pharmacopoeial product available in USP, and all the test parameters of Getofin IV Injection 250mg complies with USP Specification.
Source of API at previous site **(Novamed Pharma)** along with COA.	This is to inform you M/s Zhuhai United Laboratories Co., Ltd., China is the source of API at previous site (M/s Novamed Pharma). Please refer to **Annexure II** for the Certificate of Analysis (COA).

Test	Specification	New Site		Current Site		
		C006DS01	C006DS02	17872	17872	18256
Appearance	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.	Complies	Complies	Complies	Complies	Complies
Constituted Solution (Completeness and Clarity of Solution)	When constituted, the solution should be clear and meets the requirements.	Complies	Complies	Complies	Complies	Complies
Identification Test by IR	The IR spectrum of sample is concordant to that of the reference standard.	Complies	Complies	Complies	Complies	Complies

Identification Test by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Average weight of content	298.00 mg ± 10.0 %	301.15 mg	302.74 mg	304.25 mg	302.96 mg	303.22 mg
Uniformity of Dosage Units by weight variation	Acceptance value L1 should be less than 15 for 10 units.	9.50 %	9.80 %	9.91 %	9.68 %	9.84 %
pH	6.00 – 8.00	6.77	6.83	6.45	6.54	6.59
Water Content	8.00 % – 11.00 %	10.40 %	10.29 %	9.72 %	9.45%	9.31%
Assay of Ceftriaxone	95.00 % – 110.00 %	100.13 %	99.75%	101.55%	99.18%	100.54%
Related Substance						
Deacetylcefotaxime lactone	Not more than 0.50 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone triazine analog	Not more than 1.0 %	0.27%	0.23%	0.32%	0.25%	0.28%
Ceftriaxone benzothiazolyloxime	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Deacyl ceftriaxone	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone 3-ene isomer	Not more than 0.30 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone E-Isomer	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Any individual unspecified impurities	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Total Impurities	Not more than 5.0 %	0.27 %	0.23%	0.32%	0.25%	0.28%
Bacterial endotoxin test	NMT 0.20 USP Endotoxin Unit/mg of ceftriaxone	Complies	Complies	Complies	Complies	Complies
Sterility test	Meets the requirements	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 10 µm	6000 particles per container	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 25 µm	600 particles per container	Complies	Complies	Complies	Complies	Complies

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**

3.	019875	Getofin Injection 500mg (IV) Each vial contains: Ceftriaxone (as Sodium)……500mg	Initial Reg. Date: **04-09-1996** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Novamed, Pharmaceuticals (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Transfer of registration for contract manufacturing to self-manufacturing at another manufacturing site of applicant		
	From		**To**
	Contract manufacturing at: M/s Novamed Pharmaceuticals (Pvt.) Ltd, 28km, Ferozpur Road, Lahore.		*Change in Manufacturing site along with transfer of registration at:* M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, 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. 11036 (dated: 03-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 01-02-2023 (Invoice # 5790820783)
	The proposed proprietary name / brand name		**Getofin IV Injection 500 mg** *(Reg. no. # 019875)* **Initial Registration:** 04-09-1996 **Last extension in contract manufacturing**: Valid till 30th June 2025
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each vial contains: Ceftriaxone (as sodium) ……. 500 mg
	Pharmaceutical form of applied drug		Powder for solution for injection
	Pharmacotherapeutic Group of (API)		*Cephalosporin*
	Reference to Finished product specifications		USP Specification
	Proposed Pack size		As per registration letter
	Proposed unit price		As per registration letter
	The status in reference regulatory authorities		*USFDA approved* formulation.
	For generic drugs (me-too status)		**Oxidil 500mg Injection** by M/s Sami.
	GMP status of the Finished product manufacturer		Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.		**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China **GMP valid till 05/12/2023**

	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	**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. Oxidil 500mg IV injection** by **M/s Sami** by performing quality tests (appearance, constituted solution, identification, Average weight of content, uniformity of dosage units by weight variations, pH, water content, Assay).
	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	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China
API LOT #	3052206016
Description of Pack (Container closure system)	500mg, White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial + 5 ml sterile water
Stability Storage	Real time: 30°C ± 2°C / 65% ± 5%RH

Condition		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.		**C007DS01**	**C007DS02**
Batch Size		2000 Vials	2000 vials
Manufacturing Date		19/09/2022	19/09/2022
Date of Initiation		08/10/2022	08/10/2022
No. of Batches		02	
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 # K-7643522637624 dated 27-07-2022	
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 the Evaluator:			

Query Items	Getz Pharma Response
Please provide comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site.	Submitted
Please justify that why Pharmaceutical Equivalence studies have been conducted against **Oxidil IV 500mg Injection** while recommended comparator/innovator is Rocephin.	This is to bring to your kind information that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical Drug products for human use", to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed'*. We have established Pharmaceutical Equivalence of **Getofin IV Injection 500mg** (Manufactured by M/s Getz Pharma Pvt. Ltd) with comparator product **Oxidil IV Injection 500mg** Manufactured by M/s Healthtek Pvt. Ltd as innovator brand is currently not available in Pakistan. Further, this is to inform you that Ceftriaxone for Injection is a pharmacopoeial product available in USP, and all the test parameters of Getofin IV Injection 250mg complies with USP Specification.
Source of API at previous site **(Novamed Pharma)** along with COA.	This is to inform you M/s Zhuhai United Laboratories Co., Ltd., China is the source of API at previous site (M/s Novamed Pharma). Please refer to **Annexure II** for the Certificate of Analysis (COA).

Test	Specification	New Site		Current Site		
		C007DS01	C007DS02	18176	18287	18271
Appearance	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.	Complies	Complies	Complies	Complies	Complies
Constituted Solution (Completeness and Clarity of Solution)	When constituted, the solution should be clear and meets the requirements.	Complies	Complies	Complies	Complies	Complies
Identification Test by IR	The IR spectrum of sample is concordant to that of the reference standard.	Complies	Complies	Complies	Complies	Complies

Identification Test by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Average weight of content	596.00 mg ± 7.5 %	604.42 mg	601.37 mg	606.62 mg	604.19 mg	603.40 mg
Uniformity of Dosage Units by weight variation	Acceptance value L1 should be less than 15 for 10 units.	2.40 %	3.50 %	3.45 %	3.39 %	2.96 %
pH	6.00 – 8.00	6.71	6.79	6.64	6.82	6.89
Water Content	8.00 % – 11.00 %	10.16 %	10.23%	9.54%	9.71%	9.83%
Assay of Ceftriaxone	95.00 % – 110.00 %	100.18 %	100.53%	103.68%	101.45%	102.49%
Related Substance						
Deacetylcefotaxime lactone	Not more than 0.50 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone triazine analog	Not more than 1.0 %	0.30%	0.31%	0.24%	0.33%	0.34%
Ceftriaxone benzothiazolyloxime	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Deacyl ceftriaxone	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone 3-ene isomer	Not more than 0.30 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone E-Isomer	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Any individual unspecified impurities	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Total Impurities	Not more than 5.0 %	0.30%	0.31%	0.24%	0.33%	0.34%
Bacterial endotoxin test	NMT 0.20 USP Endotoxin Unit/mg of ceftriaxone	Complies	Complies	Complies	Complies	Complies
Sterility test	Meets the requirements	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 10 µm	6000 particles per container	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 25 µm	600 particles per container	Complies	Complies	Complies	Complies	Complies

I	II	III	IV

S.No.	Reg. No.	Existing Product Name & Composition	Registration Trail
4.	024627	Getofin Injection 500mg (IM) Each vial contains: Ceftriaxone (as Sodium)……500mg	Initial Reg. Date: **12-03-2002** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Novamed, Pharmaceuticals (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Transfer of registration for contract manufacturing to self-manufacturing at another manufacturing site of applicant		
	From		**To**
	Contract manufacturing at: M/s Novamed Pharmaceuticals (Pvt.) Ltd, 28km, Ferozpur Road, Lahore.		*Change in Manufacturing site along with transfer of registration at:* M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, 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. 11035 (dated: 03-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 01-02-2023 (Invoice # 329261490880)
	The proposed proprietary name / brand name		**Getofin IM Injection 500 mg** *(Reg. no. # 024627)* **Initial Registration:** 12-03-2002 **Last extension in contract manufacturing**: Valid till 30th June 2025
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each vial contains: Ceftriaxone (as sodium) ……. 500 mg
	Pharmaceutical form of applied drug		Powder for solution for injection
	Pharmacotherapeutic Group of (API)		*Cephalosporin*
	Reference to Finished product specifications		USP Specification
	Proposed Pack size		As per registration letter
	Proposed unit price		As per registration letter
	The status in reference regulatory authorities		*USFDA approved* formulation.
	For generic drugs (me-too status)		**Oxidil 500mg Injection** by M/s Sami.
	GMP status of the Finished product manufacturer		Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.		**Ceftriaxone Sodium**

		M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China **GMP valid till 05/12/2023**
	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	**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. Oxidil 500mg IM injection** by **M/s Sami** by performing quality tests (appearance, constituted solution, identification, Average weight of content, uniformity of dosage units by weight variations, pH, water content, Assay).
	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	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China
API LOT #	3052206016
Description of Pack (Container closure system)	500mg, White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial + Lidocaine 1% 2ml
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.	**C007DS01**	**C007DS02**
Batch Size	2000 Vials	2000 vials
Manufacturing Date	19/09/2022	19/09/2022
Date of Initiation	08/10/2022	08/10/2022
No. of Batches	02	

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 # K-7643522637624 dated 27-07-2022
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 the Evaluator:		

Query Items	Getz Pharma Response
Please provide comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site.	Submitted
Please justify that why Pharmaceutical Equivalence studies have been conducted against **Oxidil IM 500mg Injection** while recommended comparator/innovator is Rocephin.	This is to bring to your kind information that as per DRAP guidelines "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical Drug products for human use", to perform Pharmaceutical Equivalence *'The comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests shall be submitted and discussed'*. We have established Pharmaceutical Equivalence of **Getofin IM Injection 500mg** (Manufactured by M/s Getz Pharma Pvt. Ltd) with comparator product **Oxidil IM Injection 500mg** Manufactured by M/s Healthtek Pvt. Ltd as innovator brand is currently not available in Pakistan. Further, this is to inform you that Ceftriaxone for Injection is a pharmacopoeial product available in USP, and all the test parameters of Getofin IV Injection 250mg complies with USP Specification.
Source of API at previous site **(Novamed Pharma)** along with COA.	This is to inform you M/s Zhuhai United Laboratories Co., Ltd., China is the source of API at previous site (M/s Novamed Pharma). Please refer to **Annexure II** for the Certificate of Analysis (COA).

COMPARATIVE ANALYSIS OF BATCHES AT EXISITING & NEW SITES

Test	Specification	New Site		Current Site		
		C007DS01	C007DS02	18265	18272	18058
Appearance	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.	Complies	Complies	Complies	Complies	Complies
Constituted Solution (Completeness and Clarity of Solution)	When constituted, the solution should be clear and meets the requirements.	Complies	Complies	Complies	Complies	Complies
Identification Test by IR	The IR spectrum of sample is concordant to that of the reference standard.	Complies	Complies	Complies	Complies	Complies

Identification Test by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Average weight of content	596.00 mg ± 7.5 %	604.42 mg	601.37 mg	608.22 mg	605.26 mg	601.02 mg
Uniformity of Dosage Units by weight variation	Acceptance value L1 should be less than 15 for 10 units.	2.40 %	3.50 %	3.46 %	3.87 %	3.21 %
pH	6.00 – 8.00	6.71	6.79	6.79	6.86	6.67
Water Content	8.00 % – 11.00 %	10.16 %	10.23%	9.83%	9.71%	9.41%
Assay of Ceftriaxone	95.00 % – 110.00 %	100.18 %	100.53%	101.27%	100.02%	102.76%
Related Substance						
Deacetylcefotaxime lactone	Not more than 0.50 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone triazine analog	Not more than 1.0 %	0.30%	0.31%	0.29%	0.31%	0.33%
Ceftriaxone benzothiazolyloxime	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Deacyl ceftriaxone	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone 3-ene isomer	Not more than 0.30 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone E-Isomer	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Any individual unspecified impurities	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Total Impurities	Not more than 5.0 %	0.30%	0.31%	0.29%	0.31%	0.33%
Bacterial endotoxin test	NMT 0.20 USP Endotoxin Unit/mg of ceftriaxone	Complies	Complies	Complies	Complies	Complies
Sterility test	Meets the requirements	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 10 µm	6000 particles per container	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 25 µm	600 particles per container	Complies	Complies	Complies	Complies	Complies

I	II	III	IV

S.No.	Reg. No.	Existing Product Name & Composition	Registration Trail
5.	019876	Getofin Injection 1gm (IV) Each vial contains: Ceftriaxone (as Sodium)……1000mg	Initial Reg. Date: **04-09-1996** Extension in contract till **30-06-2025** (issued vide letter dated 12-08-2020) Contract manufacturer: M/s Novamed, Pharmaceuticals (Pvt.) Ltd., 28-km, Ferozepur Road, Lahore.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000284)** Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi
	Transfer of registration for contract manufacturing to self-manufacturing at another manufacturing site of applicant		
	From		**To**
	Contract manufacturing at: M/s Novamed Pharmaceuticals (Pvt.) Ltd, 28km, Ferozpur Road, Lahore.		*Change in Manufacturing site along with transfer of registration at:* M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, 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. 11037 (dated: 03-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 01-02-2023 (Invoice # 637940899)
	The proposed proprietary name / brand name		**Getofin 1 G Injection IV** *(Reg. no. # 019876)* **Initial Registration:** 04-09-1996 **Last extension in contract manufacturing**: Valid till 30th June 2025
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each vial contains: Ceftriaxone (as sodium) ……. 1 G
	Pharmaceutical form of applied drug		Powder for solution for injection
	Pharmacotherapeutic Group of (API)		*Cephalosporin*
	Reference to Finished product specifications		USP Specification
	Proposed Pack size		As per registration letter
	Proposed unit price		As per registration letter
	The status in reference regulatory authorities		*USFDA approved* formulation.
	For generic drugs (me-too status)		**Oxidil 1 G Injection** by M/s Sami.
	GMP status of the Finished product manufacturer		Dry Powder injection (cephalosporin) Section granted in 289th meeting of Central Licensing Board held on 23-02-2023.
	Name and address of API manufacturer.		**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd.

		No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China **GMP valid till 05/12/2023**
	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	**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. Oxidil 1 G IV injection** by **M/s Sami** by performing quality tests (appearance, constituted solution, identification, Average weight of content, uniformity of dosage units by weight variations, pH, water content, Assay).
	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	**Ceftriaxone Sodium** M/s Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, Guangdong, China

API LOT #	3052206016	
Description of Pack (Container closure system)	1000mg, White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial + WFI 10ml	
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.	**C008DS01**	**C008DS02**
Batch Size	2000 Vials	2000 vials
Manufacturing Date	20/09/2022	20/09/2022
Date of Initiation	08/10/2022	08/10/2022
No. of Batches	02	

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 # K-7643522637624 dated 27-07-2022
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 the Evaluator:

Query Items	Getz Pharma Response
Please provide comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site.	Please refer to **Annexure I** for comparative data of batch analysis of two production batches at new site vs the last three batches from the previous site
Source of API at previous site **(Novamed Pharma)** along with COA.	This is to inform you M/s Zhuhai United Laboratories Co., Ltd., China is the source of API at previous site (M/s Novamed Pharma). Please refer to **Annexure II** for the Certificate of Analysis (COA).

COMPARATIVE ANALYSIS OF BATCHES AT EXISITING & NEW SITES

Test	Specification	New Site		Current Site		
		C008DS01	C008DS02	18253	18254	18283
Appearance	White to yellowish-orange crystalline powder, filled in a clear glass USP type II vial.	Complies	Complies	Complies	Complies	Complies
Constituted Solution (Completeness and Clarity of Solution)	When constituted, the solution should be clear and meets the requirements.	Complies	Complies	Complies	Complies	Complies
Identification Test by IR	The IR spectrum of sample is concordant to that of the reference standard.	Complies	Complies	Complies	Complies	Complies
Identification Test by HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Average weight of content	1193.00 mg ± 7.5 %	1200.09 mg	1198.74mg	1202.96mg	1199.19mg	1201.47mg
Uniformity of Dosage Units by weight variation	Acceptance value L1 should be less than 15 for 10 units.	1.10 %	1.50%	1.25%	1.16%	1.44%
pH	6.00 – 8.00	6.74	6.69	6.28	6.21	6.30
Water Content	8.00 % – 11.00 %	9.73 %	9.86 %	9.26%	9.31%	9.41%
Assay of Ceftriaxone	95.00 % – 110.00 %	99.97 %	100.34%	99.24%	101.84%	102.85%
Related Substance						
Deacetylcefotaxime lactone	Not more than 0.50 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone triazine analog	Not more than 1.0 %	0.00%	0.29%	0.26%	0.31%	0.27%
Ceftriaxone benzothiazolyloxime	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%

Deacyl ceftriaxone	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone 3-ene isomer	Not more than 0.30 %	0.00%	0.00%	0.00%	0.00%	0.00%
Ceftriaxone E-Isomer	Not more than 1.0 %	0.00%	0.00%	0.00%	0.00%	0.00%
Any individual unspecified impurities	Not more than 0.20 %	0.00%	0.00%	0.00%	0.00%	0.00%
Total Impurities	Not more than 5.0 %	0.00%	0.29%	0.26%	0.31%	0.27%
Bacterial endotoxin test	NMT 0.20 USP Endotoxin Unit/mg of ceftriaxone	Complies	Complies	Complies	Complies	Complies
Sterility test	Meets the requirements	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 10 µm	6000 particles per container	Complies	Complies	Complies	Complies	Complies
Particulate Matter at ≥ 25 µm	600 particles per container	Complies	Complies	Complies	Complies	Complies

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Getz Pharma Pvt. Ltd. Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284):

S. No.	Reg. No.	Product Name & Composition
1.	**024629**	**Getofin Injection 250mg (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……250mg**
2.	**024628**	**Getofin Injection 250mg (IM)** **Each vial contains:** **Ceftriaxone (as Sodium)……250mg**
3.	**019875**	**Getofin Injection 500mg (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……500mg**
4.	**024627**	**Getofin Injection 500mg (IM)** **Each vial contains:** **Ceftriaxone (as Sodium)……500mg**
5.	**019876**	**Getofin Injection 1gm (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……1000mg**

ii. Approved registration of following products in the name of M/s Getz Pharma Pvt. Ltd. Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933).

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

1.	**Getofin Injection 250mg (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……250mg** **(USP Specification)**
2.	**Getofin Injection 250mg (IM)** **Each vial contains:** **Ceftriaxone (as Sodium)……250mg** **(USP Specifications)**
3.	**Getofin Injection 500mg (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……500mg** **(USP Specifications)**
4.	**Getofin Injection 500mg (IM)** **Each vial contains:** **Ceftriaxone (as Sodium)……500mg** **(USP Specifications)**
5.	**Getofin Injection 1gm (IV)** **Each vial contains:** **Ceftriaxone (as Sodium)……1g** **(USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.4. Request of M/s Getz Pharma Pvt. Ltd., Karachi for Cancellation of Registration of Cefaloget Range

M/s Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284) has requested for cancellation of registration of following products which are registered by way of contract manufacturing at M/s Novamed Pharmaceuticals (Pvt.) Ltd., 28-KM, Ferozpur Road, Lahore. Detail is given as under:

S/N	Reg. No.	Brand name and composition	Justification	Date of Reg.
I	**II**	**III**	**IV**	**VI**
1.	090844	Cefaloget 250mg Capsule Each Capsule contains: Cefaclor monohydrate eq. to Cefaclor….....250mg (USP Specification)	This is to inform you that we have established new Cephalosporin manufacturing facility Getz Pharma (Pvt) Limited situated at Plot No. 01, Sector 25, Korangi Industrial Area Karachi and we already have submitted Initial product registration applications of aforementioned products to PE& R Division of DRAP. Therefore, we intend to cancel the registration of said contract manufactured products.	30-07-2018
2.	090845	Cefaloget 500mg Capsule Each Capsule contains: Cefaclor monohydrate eq. to Cefaclor.....….500mg (USP Specification)		30-07-2018
3.	090846	Cefaloget Drops 50mg/ml Each ml contains: Cefaclor monohydrate eq. to Cefaclor.....….50mg (USP Specification)		30-07-2018
4.	090847	Cefaloget Suspension 125/5ml Each 5ml contains: Cefaclor monohydrate eq. to Cefaclor.....125mg (USP Specification)		30-07-2018
5.	090848	Cefaloget Suspension 250mg/5ml Each 5ml contains: Cefaclor monohydrate eq. to Cefaclor.....250mg (USP Specification)		30-07-2018

Documents submitted by the firm in the light of SOP approved vide 283rd meeting of Registration Board	a. Copy of Registration Letter. b. List of alternate brands available in the country. c. Justification. d. An Undertaking that: i. No case is pending at any forum/ court of law regarding above mentioned products. ii. Provided information/ documents are true/ correct.

Decision: **Keeping in view the justification submitted by the applicant, Registration Board acceded to the request of M/s Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284) for cancellation of registration of following products:**

S/N	Reg. No.	Brand Name and Composition
I	II	III
1.	**090844**	**Cefaloget 250mg Capsule** **Each Capsule contains:** **Cefaclor monohydrate eq. to Cefaclor….....250mg** **(USP Specification)**
2.	**090845**	**Cefaloget 500mg Capsule** **Each Capsule contains:** **Cefaclor monohydrate eq. to Cefaclor.....….500mg** **(USP Specification)**
3.	**090846**	**Cefaloget Drops 50mg/ml** **Each ml contains:** **Cefaclor monohydrate eq. to Cefaclor.....….50mg** **(USP Specification)**
4.	**090847**	**Cefaloget Suspension 125/5ml** **Each 5ml contains:** **Cefaclor monohydrate eq. to Cefaclor.....125mg** **(USP Specification)**
5.	**090848**	**Cefaloget Suspension 250mg/5ml** **Each 5ml contains:** **Cefaclor monohydrate eq. to Cefaclor.....250mg** **(USP Specification)**

Case No.5. Request of M/s E-Pharm Laboratories, Karachi for Revision/ Change in Formulation of Epsaline Nasal Drops 0.9%w/v

Registration Board in its 285th meeting held on 03rd-04th October, 2018 approved application M/s E-Pharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi for registration of Epsaline Nasal Drops 0.9% w/v. Detail is as under:

Table-I	
Name and address of manufacturer / Applicant	E- Pharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi.
Brand Name +Dosage Form + Strength	Epsaline Nasal Drops 0.9% w/v
Composition	Each ml contains: Sodium Chloride ……..0.09g (0.9% w/v)
Diary No. Date of R& I & fee	Dy. No. 19713 ; 01-11-2017; Rs.20,000/- (31-10-2017)
Pharmacological Group	Sodium salt for nasal congestion
Type of Form	Form- 5
Finished product Specification	Manufacturers
Pack size & Demanded Price	1 x 30 ml & as per SRO
Approval status of product in Reference Regulatory Authorities.	Saline nasal drops of Sandoz (Health Canada)
Me-too status	Norsaline-P Nasal 9mg/ ml Drops of M/s Atco (Reg. # 053354)
GMP status	Last GMP inspection was conducted on 01-03-2018 and the report concludes satisfactory level of GMP compliance.

Remarks of the Evaluator	• The official monograph of the applied formulation is not available in USP and BP.
Decision of M-285: Approved with innovator's specifications.	

The firm has now requested for revision of formulation/ strength of above-mentioned product from Sodium Chloride 0.9%w/v to Sodium Chloride 0.65%w/v stating that Sodium Chloride 0.9%w/v has been discontinued from RRA (Health Canada). While, Sodium Chloride 0.65%w/v has been approved by USFDA. Detail of revised application is as under:

Table-II	
Name and address of manufacturer / Applicant	E- Pharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi.
Brand Name +Dosage Form + Strength	Epsaline Nasal Drops 0.65% w/v
Composition	Each ml contains: Sodium Chloride ……..6.5mg (0.65% w/v)
Diary No. Date of R& I & fee	Dy. No. 14804 ; 12-06-2023; Rs.30,000/- (DS#54186431299)
Pharmacological Group	Sodium salt for nasal congestion
Type of Form	Form- 5
Finished product Specification	Manufacturers
Pack size & Demanded Price	1 x 30 ml & as per SRO
Approval status of product in Reference Regulatory Authorities.	Saline Nasal-Sodium Chloride 0.65% Spray of M/s Lee Pharmaceuticals verified from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5a23325e-0521-4006-be73-586cb045df02 accessed on 17-07-2023
Me-too status	Xynosine Nasal spray 0.65% of M/s Zafa Pharma (R#082163)
GMP status	Copy of GMP certificate dated 20-06-2022 based on evaluation conducted on 30-12-2021.
Remarks of the Evaluator	• The official monograph of the applied formulation is not available in USP and BP.

Decision: **Registration Board approved the request of M/s E-Pharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi for revision/ change in formulation of 'Epsaline Nasal Drops'. Revised composition is as under:**

"Epsaline Nasal Drops 0.65% w/v
Each ml contains:
Sodium Chloride ……..6.5mg (0.65% w/v)"

Case No.6. **Request for Change in Registration Status of Mezeron 30mg Tablet from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi to M/s Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi.**

M/s. Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area Karachi has requested to change the product registration status of Mezeron 30mg Tablet from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi, to their name.

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 (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.
ii. Copy of DML of M/s OBS Pakistan Pvt Ltd., (DML # 000012) renewed w.e.f. 26-10-2020.
iii. 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

iv.	Copy of Approval letter dated 25-04-2022 for change in title of registration holder from M/s OBS Pakistan Pvt Ltd. Karachi to M/s. Searle Pakistan Ltd; Karachi
v.	NOC from M/s. Searle Pakistan Ltd; Karachi for transfer of Mezeron 30mg Tablet in the name of M/s. Aspin Pharma Pvt Ltd., Korangi Industrial Area, Karachi issued on 01-06-2023
vi.	Request (dated 18-07-2023) for withdrawal of Mezeron 30mg Tablet submitted by M/s. Searle Pakistan Ltd; Karachi
vii.	Relevant undertakings & commitments.

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	026397	Mezeron 30mg Tablet Each tablet contains: Mirtazapine …….30mg (USP Specification)	Initial date of Reg. in the name of **M/s Organon, Karachi. DATED:** 25-09-2001 **Renewal of Registration DATED:** 28-04-2006 **Transfer of Registration to** MSD of Pakistan, Karachi **DATED:** 13-12-2008 Transfer of Registration to **M/s OBS Pakistan Pvt. Ltd** C-14 Mangopir Road SITE Karachi. **DATED:** 09-07-2009 Transfer of plant & Registration to **M/s Searle Pakistan Limited (DML # 000012)** C-14 Mangopir Road SITE Karachi. **Dated: 25-04-2022** **Change of Brand Name DATED:** 26-08-2014 & Last Renewal **DATED:** 26-03-2019

History of the case:

Vide Dy.No. 357/DDC(Reg-I) dated 18-04-2019, Firm submitted application on Form 5F(CTD) for change in manufacturing site along with transfer of registration **from** M/s OBS Pakistan Pvt. Ltd C-14 Mangopir Road SITE Karachi, **To** M/s Aspin Pharma (Pvt) Ltd, Karachi. **(DML # 000012)** Plot No. 10&25 Korangi Industrial Area, Karachi-Pakistan. **(DML 000045)**.

The case was evaluated and accordingly presented in 307th meeting of Registration board wherein Board decided as under:

"Deferred for submission of stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Board in its 290th meeting under *"Requirement of The Storage Conditions for The API Stability and FPP Stability".*

The firm vide letter no. ASP/RAL/04/03 dated April 05, 2022 has now submitted that:-

"This is with reference to the subject stated above. We Aspin Pharma (Pvt.) Ltd. would like to bring into your knowledge that the stability data of API i.e. Mirtazapine used in one of our products. Mezeron Tablet 30mg is according to zone II as provided by the API manufacturer.

We do understand that the requirement of submission of API long term stability data is 30ºC±2C/ 65%RH±5%RH. However, API is stored in our warehouse under controlled conditions till it is processed into finished product.

Besides that, API manufacturer has performed accelerated stability at 40'C±2"C/ 75%RH±5%RH for a total of six consecutive batches and tested for up to 6 months. the results of which are unchanged from the initial testing which shows the stable nature of API and its controlled manufacturing process

As WHO and ICH recommended the stability study storage condition for FPP to be determined according to climate zone and on that basis. Pakistan falls under zone IVA On the other hand. we are performing stability study on more stringent conditions i.e. 30ºC±2C/ 75%RH±5%RH and the results of accelerated and long term data shows that the product is stable. Please further note that the product is tested according to USP monograph and the results of assay is indicating the potency of API w1th1n the defined limit in Pharmacopoeia.

Therefore. we request the honorable DRAP to accept the stability study provided for API for climate condition 25ºC±2 C/ 60%RH±5%RH along with its six months accelerated stability at 40ºC±2ºC/ 75%RHx5%RH and the FPP stability on the recommended storage condition in the country of origin as an evidence that product is stable and in compliance with the specification and have no impact on product's quality parameters

We have already completed our stability studies for finished product for 21\ months at 30ºC±2'C/ 75%RH±5%RH as well as six months accelerated stability study at 40ºC±2ºC and 75%RH±5%RH. The results of which are satisfactory.

We commit & assure that we will follow the required storage condition of API throughout its transportation till its use in the finished product for all the future shipments.

In the view of above-mentioned justification. we do hope acceptance of the stability data of API and our Finished Product further for registration process."

As per the decision of the Registration Board aforementioned, the firm was required to submit followings information in accordance to the decision of the 290th meeting of the Registration Board: -

I. Data logger for the storage condition through the transportation of the API of Mezeron 30mg tablets imported in August, 2018 from M/s Zhejiang Liaoyuan Pharmaceutical Co. Ltd, Linhai City, China
II. Real time stability studies of the Mezeron 30mg Tab performed by the M/s Aspin Pharma, Karachi along with the degradation studies.

The firm has submitted stability data sheets for the real time stability studies performed for two years at 30ºC±2ºC, 75%RH±5% as well as accelerated stability of 6 months performed at 40ºC±2ºC and 75%RH±5%RH. However, the degradation studies data is not provided.

Decision of RB in its 317th meeting:

Registration Board deferred the case for submission of stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of following information/ documents as already decided by the Board in its 290th meeting under "Requirement of The Storage Conditions for The API Stability and FPP Stability":

i. Record of the data logger for the storage condition throughout the transportation of the API of Mezeron 30mg tablets imported in August, 2018 from M/s Zhejiang Liaoyuan Pharmaceutical Co. Ltd, Linhai City, China
ii. Real time stability studies of the Mezeron 30mg Tablet performed for at least 01 year along with the degradation studies by M/s Aspin Pharma, Karachi.

Current status of Application:

On 07th June 2023, Applicant has submitted revised application on Form 5F **with new source of API** along with prescribed fee of PKR 30,000/- dated 22-05-2023**.** This revision is in response to the decision of 317th DRB meeting which required the active Pharmaceutical stability data as per Zone IV-A for **Mezeron Tablet 30mg.** The reason for this change is the unavailability of stability data of the existing source of API as per Zone IV-A.

The details of previous and new source are given below

Previous API source	New API source
M/s Zhejiang Liaoyuan Pharmaceutical Co. Ltd. Zhejiang Provincial Chemical and Medical	**M/s Maithri Drugs Private Limited** Sy. No. 205,222 to 226, IDA Bonthapally (Village) Gummadidala (Mandal) Sangareddy

Raw Material Base Linhai Zone Duqiao Town, Linhai City, Zhejiang Province.	District Telgana, India.

Accordingly, application has been evaluated as under:-

Name, address of Applicant / Marketing Authorization Holder	M/s Aspin Pharma (Pvt) Ltd, **(DML 000045)**. Plot No. 10 & 25 Korangi Industrial Area, Karachi.
Name, address of Manufacturing site.	**Transfer of Registration:** **From** M/s Searle Pakistan Limited **(DML # 000012)** *Formerly (M/s OBS Pakistan Pvt. Ltd)* C-14 Mangopir Road S.I.T.E Karachi. *(NOC attached dated 1st June,2023)* **To** M/s Aspin Pharma (Pvt) Ltd, Karachi. **(DML 000045)**. Plot No. 10 & 25 Korangi Industrial Area, Karachi.
Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	Inspection report dated **13-06-2022** GMP compliance level **"A"**
Evidence of approval of manufacturing facility	Renewal of DML # 000045 dated 16th June 2021 with following sections i. Tablet (General) ii. Capsule (General) iii. Cream/Ointment/Gel (General) iv. Liquid Syrup (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. 14289 dated 07-06-2023
Details of fee submitted	PKR 30,000/-: 22-05-2023 **(Slip # 695206250750)**
The proposed proprietary name / brand name	**Mezeron 30mg Tablets** *(Reg.No. 026397)*
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Mirtazapine ……. 30 mg
Pharmaceutical form of applied drug	Tan colored, oval shape, film coated tablets, upper side plain & score line on lower side.
Pharmacotherapeutic Group of (API)	Antidepressants
Reference to Finished product specifications	USP Specification
Proposed Pack size	As per registration letter
Proposed unit price	As per registration letter
The status in reference regulatory authorities	USFDA approved **Remeron®** 30mg Tablet, by Organon
For generic drugs (me-too status)	**Mirtazep®** by M/s Zafa
Name and address of API manufacturer.	**M/s Maithri Drugs Private Limited** Sy. No. 205,222 to 226, IDA Bonthapally (Village) Gummadidala (Mandal) Sangareddy District Telgana, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. & submitted summarized information related to general properties, physical form, specification, impurities & degradation products, specification, analytical procedures, batch analysis, working standards, container closure system and stability studies of drug substance & drug products.
	Module-III Drug Substance:	The firm has submitted data of drug substance related details of manufacturers, nomenclature, structure. general properties description of manufacturing process and controls, impurities, specifications, analytical procedure, CoAs , batch analysis and justification of specification, reference standards or materials , container closure system.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 batches (54.1 kg each) of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40oC ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 25oC ± 2oC / 60% ± 5% RH for 60 months. The Mirtazapine is packed in double-layer of polyethylene bags, tied with a nylon ribbon. Then the bags are put in fibre drum and labelled
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, formulation development, manufacture, product, specifications, analytical procedures, verification of analytical procedures. However, following comments are submitted for consideration: Firm has not provided manufacturing process, in-process controls, and process validation protocol. Firm has not provided DS & excipients compatibility studies. Significant difference for the manufacturing process used for primary stability batch and process for commercial batches were not identified. Instead of pharmacopeia reference standards, firm used to work standards provided by DS manufacturer. Firm has not conducted Container Closure System suitability studies,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profiles for **Mezeron 30mg Tablets against Remeron 30mg Tablets (Italy)** were generated in different dissolution media i.e. HCl (pH 1.2), Phosphate buffer (pH 6.8), and Acetate buffer (pH 4.5). More than 85% of the labelled amount of the API released within 10 minutes from both products in pH 1.2 HCl buffer and phosphate buffer pH 6.8. F1 and f2 Factors were calculated and results were compliant. Following tests are mentioned in Pharmaceutical equivalence report of **Mezeron 30mg Tablets against Remeron 30mg Tablets (Italy)** i. Appearance ii. Identification iii. Weight variation iv. Disintegration test v. Assay vi. Dissolution vii. Organic impurities
	Analytical method validation/verification of product	Firm has USP specification and verification of analytical method for the drug product has been provided.

STABILITY STUDY DATA			
Manufacturer of API	**M/s Maithri Drugs Private Limited** Sy. No. 205,222 to 226, IDA Bonthapally (Village) Gummadidala (Mandal) Sangareddy District Telgana, India. **GMP certificate valid up to 21-07/2023**		
API Lot No.	MZ0120522		
Description of Pack (Container closure system)	Mezeron 30mg Tablet is available in blister (ALU-PVDC) Pack of 10's (1x10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**195DS04**	**195DS05**	**195DS06**
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09/2022	09/2022	09/2022
Date of Initiation	19-10-2022	19-10-2022	19-10-2022
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.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	K-896628153687 dated 29-08-2022 Invoice # 6500225060 dated 16-08-2022
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 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 provided a certificate for HPLC system as 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 Remarks:

- The formulation of the drug product at new site, is same as in the previous site.
- Applicant submitted CDP & pharmaceutical equivalence studies against **Remeron®** by Organon.
- Source of API submitted stability data for both Zone II as well Zone IV-A.
- Firm submitted in tabulated form the results of quality tests for Mezeron 30mg tablet manufactured at new site vs previous site.

Test	**Specifications**	**Previous Site**			**New Site**	
		Batch # CEE001	**Batch # CED002**	**Batch # CED001**	**Batch # 195DS04**	**Batch # 195DS05**

Appearance	Tan colored, oval shaped film coated tablet.	Complies	Complies	Complies	Complies	Complies
Identification	The retention time of the major peak of Standard solution, corresponds to that of sample solution	Complies	Complies	Complies	Complies	Complies
Weight variation	309mg/tablet ±7.5% Min: 285.82 mg/tablet Max: 332.17 mg/tablet	308.2mg/tab	308.3mg/tab	310.4mg/ Tab	303.32 g/tablet	307.54 mg/tablet
Disintegration Time	Not more than 30 minutes	6min	5min	5min	2 minutes	2 minutes
Assay (By HPLC) Mirtazapine	28.5 to 33.0 mg/tablet NLT 95.0% and NMT 110.0% of the label claim	30.38 mg/Tab 101.27%	30.14mg/ Tab 100.47%	30.37mg/ Tab 101.26%	30.78 mg/tab 102.60%	31.27 mg/tab 104.24 %
Dissolution (By UV)	Not less than 85% (Q+5) in 15 minutes	96 .2 %	102.6%	99.8%	102 %	105 %
Content Uniformity	85%-115% (Searle)	98.0%	102.3%	103.6%	-	-
	NMT 15 (Aspin)	-	-	-	5.98	6.12
	Mirtazapine N-oxide NMT 0.2 %	0.00 %	0.00 %	0.00 %	Not detected	Not detected
	1-Ketomirtazapine NMT 0.2 %	0.00 %	0.00 %	0.00 %		

	10-Ketomirtazapine NMT 0.2 %	0.00 %	0.00 %	0.00 %		
	Any individual unspecified degradation product NMT 0.2 %	-	-	-		
	Total impurity NMT 2 %	0.00 %	0.00 %	0.00 %		

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.	026397	Mezeron 30mg Tablet Each tablet contains: Mirtazapine …….30mg (USP Specification)

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.

S. No.	Product Name & Composition
1.	Mezeron 30mg Tablet Each film coated tablet contains: Mirtazapine ……. 30mg (USP Specifications)

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.7: Request of M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan for Manufacturing of Ketlar Injection 500mg/ml (Reg.No. 014966) to Consume the Available API

Registration Board in its 323rd meeting held on 06th – 08th December, 2022 considered application of M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan for permission to consume the imported quantity of Ketamine Hydrochloride (i.e., 50kg) for production of Ketlar Injection 500mg/ml (Reg. No. 014966) (by way of contract manufacturing at M/s. Neutro Pharma (Pvt) Ltd.9.5 KM, Sheikhupura Road, Lahore). Detail is as under:

Proceedings of M-323:

M/s Akhai Pharmaceuticals (Pvt) Ltd., A-248 & A-256 to A-259, Hub Industrial Trading Estate Lasbella Balochistan has informed that they have contract manufacturing permission (valid till 30th June, 2025) of Ketlar Injection (Reg. No.014966) by M/s. Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupra Road, Lahore.

The firm has further informed that the contract manufacturer i.e. M/s Neutro Pharma had imported 50kg of Ketamine HCl on their behalf and for the exclusive manufacturing of their above stated product. Primary and secondary packaging materials are also available with them. However, Ketamine has recently been classified under controlled substances. Now there is acute shortage in the market and patient is suffering due to non-availability of this essential drug. Accordingly, the firm has requested for permission to consume the available quantity of Ketamine HCl in the best interest of patient.

In this context, it is submitted that Ketamine and its salts has been declared as "Psychotropic substances" vide SRO Number 1350(I)/2021 dated 15th October, 2021. Furthermore, as the existing contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021, Rule 20 A 2(c):

"Contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;"

However, the above referred product was granted registration for contract manufacturing well before classification of Ketamine under controlled substances.

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.

Decision of M-323:

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, above-mentioned decision of Registration Board has been communicated to QA& LT Division for deciding fate of imported API "Ketamine'. Furthermore, M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan has been issued show-cause along-with personal hearing notice to appear before the Registration Board on 25th July, 2023 at 2.00 P.M.

Decision of 330th Meeting:

Registration Board decided that the firm shall be provided one final opportunity of personal hearing in the next meeting.

Registration-II Section

Case No. 01: Decision of USFDA to Withdraw Approval of Makena (Hydroxyprogesterone Caproate Injection) and its Generics.

On April, 06, 2023, U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

2. In 2011, FDA approved Makena to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. This accelerated approval was based

on a trial that showed the drug reduced deliveries before 37 weeks of pregnancy, an intermediate clinical endpoint that FDA determined was reasonably likely to predict clinical benefit to the newborn.

3. As a condition of Makena's accelerated approval, the sponsor was required to conduct a confirmatory clinical trial to verify and describe the predicted clinical benefit to newborns. This trial, which was nearly four times larger than the trial that supported Makena's approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Nor have Makena and its generics been shown to be effective for any subgroup of this population, including in women at high risk of preterm birth. In addition, there are known risks associated with Makena. Accordingly, these drugs do not have benefits that outweigh their risks to patients.

4. Registration Board while considering the approval of Hydroxyprogesterone Injection in USFDA registered following drug products.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore	Renewal is not yet due
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is not yet due
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	M/s. Zafa Pharmaceutical, Karachi.	Renewal is valid
4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Not Submitted
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate....……250mg	Haji Medicines, Rawalpindi	Renewal Not Submitted
8.	003833	HYDROXYPROGESTRONE Each ml contains: Hydroxyprogesterone caproate....……250mg		Renewal Not Submitted

5. Following combination drug products containing Hydroxyprogesterone were also registered by the Registration Board.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	103324	Kevi Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Hansel Pharmaceuticals (Pvt) Ltd., Plot No 2 Pharma City 30-Km Multan Road Lahore. , Lahore	Renewal is not yet due
2.	084375	Contrex Injection Each ml contains:	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid

		Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg		
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	VIO-DEPOT INJ HYDROXYPROGESTERONE CARPOATE 250MG QUESTRADIOL VALERATE 5MG SESAME OIL 693MG	Wilson's Pharmaceuticals	Renewal Not Submitted
5.	000798	GRAVIBINON INJECTION HYDROXY PROGESTERONE CAPROATE 250MG, , OESTRADIOL VALERATE IN OILY SOLUTION	Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore	Last renewal was submitted dated 02-10-2018

6. Sub-rule 10 (a) of Rule 30 of Drugs (L, R & A) Rules, 1976 narrates as under:

"(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;"

7. Decision of 327th Meeting:

Registration Board decided to issue show-cause notice to all registration holders having valid registration of Hydroxyprogesterone containing drug products under section 7(11) (d) read with section 42 of Drug Act 1976 that why the registration of their products may not be cancelled in the public interest. For products having in-valid registration, RRR-Section is advised to proceed for cancellation of registration.

8. **(Hydroxyprogesterone Caproate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Proluton Depot Injection (Hydroxyprogesterone Caproate) in response of withdrawal of Makena by USFDA. Request of the firm is as under:

i. *Proluton Depot is Bayer's innovator product, registered in Pakistan since 1988. However, Makena was first approved by USFDA in 2012 under the accelerated approval pathway.*
ii. *It is important to note that approval of Makena was Withdrawn by USFDA due to lack of efficacy in approved indication i.e. To reduce the risk of preterm birth which is entirely different from approved indication of Proluton Depot i.e., Habitual and imminent abortion, infertility due to corpus luteum insufficiency, primary and secondary amenorrhea but not due to quality or safety reasons.*
iii. *Bayer is the manufacturer of Drug Substance i.e., Hydroryprogesterone caproate) used for the manufacturing of Proluton Depot.*
iv. *Proluton Depot is available in many countries across the World including Austria (SRA), Bahrain, Malaysia, Afghanistan, lran, Turkey, Qatar, Yemen, Lebanon, Oman, Thailand Argentina and Singapore.*
v. *Firm has also submitted snapshot of Austria's Official Health Authority Website confirming the approval of Proluton Depot indication which are reproduced as under:*
"After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation

of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.
lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.
Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.
Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency."

9. Firm has further submitted a justification provided by Bayer AG, Germany, their ultimate parent company which outlines the differences between the products further and clearly sets out that the USFDA's Makena decision does not have any implication for Proluton Depot. Thus recall is not applicable.

10. **(Hydroxyprogesterone caproate + Estradiol valerate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has also submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Gravibinan Injection (Estradiol Valerate + Hydroxyprogesterone Caproate) in response of withdrawal of Makena (Hydroryprogesterone caproate) and its generics by USFDA stating that Gravibinan, a combination product comprising Estradiol valerate and Hydroxyprogesterone caproate, should not be encompassed in the recent proceedings of the Drug Registration Board meeting regarding the decision of the USFDA to withdraw the approval of Makena (Hydroryprogesterone Caproate) and its generics due to lack of efficacy, i.e. Makena's, approved indication is to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

11. They have further submitted that Gravibinan should be excluded from the scope of this decision, and presented following points:

i. *Regarding Therapeutic Indication of Gravibinan Injection firm has submitted that Gravibinan is not only a distinct product as it is a combination of Estradiol valerate and Hydroxyprogesterone caproate but is also indicated for the prophylaxis of abortion and threatened abortion. Hence, its therapeutic use differs significantly from that of Makena. Furthermore, they have also enclosed a justification provided by Bayer AG, their parent company based in Germany, which outlines the differences between the products and stablishes that the USFDA's decision regarding Makena does not impact Gravibinan.*
ii. *Regarding need for Gravibinan Injection in Pakistan firm has submitted as under:*
    a. *Currantly there are no alternative options available in injectable form for the prophylaxis of abortion and threatened abortion.*
    b. *The prevalence of prophylaxis of abortion and threatened abortion is considerably high within our country.*
    c. *Gravibinan alone serves an annual patient turnover of 630,417.*

12. They have requested to reconsider the decision of 327th meeting of the Board regarding Hydroxyprogesterone caproate and Estradiol valerate + Hydroxyprogesterone caproate.

13. In USFDA, an NDA product DELALUTIN (Hydroxyprogesterone caproate) is discontinued with remarks that "***Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons***". Furthermore, one generic approval of Hydroxyprogesterone caproate Injection 250mg/ml is available as a status of prescription [Abbreviated New Drug Application (ANDA): 200271] with following indication and usage:

> **Hydroxyprogesterone Caproate Injection USP is indicated in non-pregnant women: for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); in the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as sub mucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.**

14. Moreover, approved indications of Makena (Hydroxyprogesterone Caproate) are as under:

> **Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.**

15. Indication approved by Austria as claimed by M/s. Bayer are as under:

After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.
lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.
Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.
Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency.

Decision: **Registration Board decided that M/s Bayer shall be provided an opportunity of personal hearing in the next meeting to present their stance and brief the Board regarding approval status of their products in reference regulatory authorities.**

Case No. 02: Standardization/Correction of Label Claim as Per Reference / Innovator Product.

i. M/s Biogen Pharma 8-KM Rawat Chak Beli Road Rawat Rawalpindi.

Registration Board in its 295th approved following product of M/s Biogen Pharma 8-KM Rawat Chak Beli Road Rawat Rawalpindi. Firm has submitted request for standardization of label claim as per reference product Ketosteril Tablets approved in Germany. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Drug(s) & Composition	Label claim as per RRA (Germany)
1.	Keto Tablet Each film-coated tablet contains: (L-Isoleucine……67mg L-Leucine……. 101mg L-Phenylalanine… 68mg L-Valine ……86mg L-Methionine ……59mg Lysine Acetate ….105mg L-Threonine ……...53mg L-Tryptophan ……23mg L-Histidine ……38mg L-Tyrosine ……..30mg	**Each film-coated tablet contains:** **α-keto analogue of isoleucine, calcium salt…67mg** **α-keto analogue of leucine, calcium salt … 101mg** **α-keto analogue of phenylalanine, calcium salt…68mg** **α-keto analogue of valine, calcium salt …….. 86mg** **α-Hydroxy analogue of methionine, calcium salt…59mg** **Lysine acetate 105mg corresponding to lysine.…… 75mg** **Threonin …… 53mg** **Tryptophan …… 23mg** **Histidin ……... 38mg** **Tyrosin ……...…. 30mg** **Total nitrogen / tablet……...…36mg** **Calcium / tablet…1,25mmol = 50mg**

Decision of 323rd Meeting:

Registration Board decided to defer the case for evidence of availability of testing facility for drug product along with analytical procedure.

As per above decision of the Board, firm has submitted that testing method of Keto Tablet is on HPLC and they have facility of HPLC in their quality control laboratory. Firm has also submitted analytical procedure of Keto Tablet and drug substances.

Submitted for consideration of the Board.

Decision: **Registration Board acceded to the request of M/s Biogen Pharma, 8-KM Rawat, Chak Beli Road Rawat, Rawalpindi for standardization/ correction in label claim of 'Keto Tablet'. Correct label claim is as under:**

"Each film-coated tablet contains:
α-keto analogue of isoleucine, calcium salt…67mg
α-keto analogue of leucine, calcium salt … 101mg
α-keto analogue of phenylalanine, calcium salt…68mg
α-keto analogue of valine, calcium salt …….. 86mg
α-Hydroxy analogue of methionine, calcium salt…59mg
Lysine acetate 105mg corresponding to lysine.…… 75mg
Threonin …… 53mg
Tryptophan …… 23mg
Histidin ……... 38mg

Tyrosin ……..…. 30mg
Total nitrogen / tablet……..…36mg
Calcium / tablet…1,25mmol = 50mg"

ii. M/s Care Pharmaceuticals, 8Km, Thokor Raiwind Road, Lahore.

Registration Board in its 249th approved following product of M/s Care Pharmaceuticals, 8Km, Thokor Raiwind Road, Lahore. Firm has submitted request for correction of label claim as per reference regulatory authority as USFDA and MHRA approved strength is 0.25mg instead of 2.5mg. Firm has also submitted fee of Rs.30,000/- vide challan No. 97701652, verified from website. Detail is as under:

Sr. No.	Name of Drug(s) & Composition	Label claim as per RRA (USFDA)
1.	Sinocare Cream Each gm contains: Fluocinolone acetonide……...2.5mg (USP Specifications)	Sinocare Cream Each gm contains: Fluocinolone acetonide……0.25mg (0.025%) (USP Specifications)

Furthermore, Registration Board in 249th meeting has also decided as under:

Firm shall submit undertaking that they will arrange segregated dispensing booths, and will conduct cleaning validation and control studies for processes and adequate system to minimize the potential risk of cross contamination and authorized Chairman for issuance of registration letter.

As per above mentioned decision of the Board firm has submitted following:

i. GMP Inspection report confirms availability of separate dispensing booth for steroidal products.
ii. Undertaking regarding cleaning validation and control studies for processes and adequate system to minimize the potential risk of cross contamination.

Decision: Registration Board acceded to the request of M/s Care Pharmaceuticals, 8Km, Thokor Raiwind Road, Lahore for correction in label claim of 'Sinocare Cream'. Correct label claim is as under:

"Sinocare Cream
Each gm contains:
Fluocinolone acetonide……0.25mg (0.025%)
(USP Specifications)"

Case No.03: Registration of Drug M/s. Medisave Pharmaceuticals Plot No.578-579 Sundar Industrial Estate Lahore.

Registration Board in its 235th meeting approved following product of M/s. Medisave Pharmaceuticals Plot No.578-579 Sundar Industrial Estate Lahore. Registration letter was not issued and firm has requested for issuance of registration letter. Detail is as under;

Sr. No.	Name of Drug(s)	Demanded Pack Size/Price	Decision of M-235	Remarks
1.	Tisan Tablets Each tablet contains: Levosulpride……...25mg (As per Innovator's Specifications)	2x10's As per SRO	Approved subject to the satisfactory last GMP Inspection report.	Approved in Italy.

Firm has submitted following documents;

i. Form 5
ii. Evidence of submission of fee of Rs. 8,000/- and Rs. 12000/- (Photocopies). Firm has also deposited fresh submission of Rs.30000/- vide challan No. 996504344375, verified from website, in lieu of verification of fee challan.
iii. Firm has submitted GMP Certificate issued based upon evaluation conducted on 18-09-2021.

Decision: Registration Board acceded to the request of Medisave Pharmaceuticals, Plot No.578-579 Sundar Industrial Estate Lahore for registration of "Tisan (Levosulpiride) Tablet 25mg" as per following detail:

"Tisan Tablets
Each tablet contains:
Levosulpride……...25mg
(As per Innovator's Specifications)"

Case No. 04: Correction in Minutes of registration Board.

i. M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore.

Registration Board in its 321st meeting approved following registration application of M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore. Detail is under:

Name and address of manufacturer / Applicant	M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore
Brand Name +Dosage Form + Strength	Vastamer 40mg Tablet
Composition	Each Tablet Contains: Atorvastatin as calcium ……..…40mg
Diary No. Date of R& I & fee	Dy. No. 12801 dated 06.03.2019 Rs. 20,000/- dated 06.03.2019
Pharmacological Group	HMG CoA reductase inhibitors
Type of Form	Form 5
Finished Product Specification	The firm has claimed USP specifications.
Pack size & Demanded Price	10's; As per SRO
Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
Me-too status	Fatilor 40mg Tablet by Lisko Pakistan Ltd. Reg No. 58163 (does not depict film-coating)
GMP status	The firm was inspected on 09.12.2019 and 26.01.2020, wherein renewal of DML was recommended,
Remarks of the Evaluator.	• The firm's title is Ameer Pharma (Pvt) Limited in fee challan and GMP inspection report. • Had already adjusted the weight of API as per salt factor. The reference product in Health Canada contains Atorvastatin as calcium trihydrate. Revised the label claim from Atorvastatin as calcium to Atorvastatin as calcium trihydrate, and Atorvastatin calcium to Atorvastatin calcium trihydrate in the master formula. • Submitted Rs. 7500 (challan- 10165654)
Decision: Registration Board discussed the matter of the incomplete title of the firm declared in Form 5 and while acknowledging the fact that covering letter of firm's application declared full title of firm i.e., M/s Ameer Pharma (Pvt.), 23 KM-Sheikhupura Road, Lahore and also each page of Form 5 has been stamped with the title as "M/s Ameer Pharma Pvt. Ltd." decided to approve the product as per following label claim: **"Each film coated tablet Contains:** **Atorvastatin as calcium ……10mg"** **Firm shall submit revised label claim along with master formulation for film coated tablet along with fee of Rs. 7,500/- for correction/pre-approval change/ in product label claim from uncoated to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

While processing registration letter it was transpired that applied strength of the product is 40mg while in decision of the Board it was mentioned as 10mg. Hence, correction ids required in decision of the Board. Firm has also submitted Firm has submitted revised label claim along with master formulation and fee of Rs.30,000/-", [Rs.7500/-, vide challan No. 666070574000 and Rs.22500/- vide challan No. 58992619140, verified from website. Accordingly, correct formulation is as under:

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…40mg"

Decision of 326th meeting:

Registration Board decided to approve the correction in above product with following details.

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…40mg"

In decision of 326th meeting, name of drug substance was mentioned as Rosuvastatin (as calcium) instead of Atorvastatin as Calcium trihydrate. Registration letter has been issued with correct formulation as

"Each film coated tablet Contains:
Atorvastatin as calcium trihydrate……40mg"

Submitted for information of the Board.

ii. M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.

a. Zanaflex 4mg Tablet

Name and address of manufacturer / Applicant	M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.
Brand Name + Dosage Form + Strength	Zanaflex 4mg Tablet
Composition	Each Film Coated Tablet Contains: Tizanidine Hydrochloride…4mg
Diary No. Date of R& I & fee	Dy.No 16037 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
Pharmacological Group	Centrally acting agent; muscle relaxant
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	1 x 10's; As per the brand leader
Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
Me-too status (with strength and dosage form)	SN Skelax 4 mg Tablets by M/s SNB Pharma (Pvt) Ltd. (Reg#078413)
GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring label claim in terms of Tizanidine, and dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 1604826473. "Each Tablet Contains: Tizanidine as HCl…..…125mg"	
Decision: Approved as per following label claim: **"Each Tablet Contains:** **Tizanidine as HCl…..…125mg"**	

While processing registration letter it was observed that in decision of the Board, strength was mentioned as 125mg instead of 4mg. With reference to fee challan No. 1604826473, verified from website [eDRAP - Portal] submitted for correction in label claim, firm has mentioned correct label claim with correct strength. While it is typo error in decision of the Board. Hence, registration letter has been issued with correct label claim as:

Each Tablet Contains:
Tizanidine as HCl…..…4mg

Submitted for information of the Board.

b. Zanaflex 2mg Tablet

Name and address of manufacturer / Applicant	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
Brand Name + Dosage Form + Strength	Zanaflex 2mg Tablet
Composition	Each Film Coated Tablet Contains: Tizanidine Hydrochloride…2mg

Diary No. Date of R& I & fee	Dy.No 16037 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
Pharmacological Group	Centrally acting agent; muscle relaxant
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
Me-too status (with strength and dosage form)	SN Skelax 4 mg Tablets by M/s SNB Pharma (Pvt) Ltd.
GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22

Remarks of the Evaluator [II]:

- Submit revised label claim as per innovator product declaring label claim in terms of Tizanidine, and dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.
- Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 27845250049.

"Each Tablet Contains:
Tizanidine as HCl…..…125mg"

Decision: Approved as per following label claim:
"Each Tablet Contains:
Tizanidine as HCl…..…125mg"

While processing registration letter it was observed that in decision of the Board, strength was mentioned as 125mg instead of 2mg. With reference to fee challan No. 1604826473, verified from website [eDRAP - Portal] submitted for correction in label claim, firm has mentioned correct label claim with correct strength. While it is typo error in decision of the Board. Hence, registration letter has been issued with correct label claim as:

Each Tablet Contains:
Tizanidine as HCl…..…2mg

Submitted for information of the Board.

iii. M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore.

	Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32816 dated 15-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**MAGNIX 2gm IV/IM injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperzone sodium eq. to Cefoperazone …… 1000mg Sulbactam sodium eq. to Sulbactam …….

		1000mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	JP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cebac 2G injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd., USFDA Approved. Reg. No.073420
	For generic drugs (me-too status)	Sulperazone 2g injection by M/s Pfizer
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR 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 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 Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of 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 have been established against t Cebac 2Gm injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
API Lot No.	1093EJ81NE

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.	TCR001	TCR002	TCR003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	09-04-22	10-04-22	11-04-22
No. of Batches	03		

Name, address of Applicant / Marketing Authorization Holder	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore**
Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
Dy. No. and date of submission	Dy.No 32815 dated 15-11-2022
Details of fee submitted	PKR 30,000/-: dated 29/10/2022
The proposed proprietary name / brand name	**MAGNIX 1gm IV/IM injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperzone sodium eq. to Cefoperazone … 500mg Sulbactam sodium eq. to Sulbactam ……..500mg Sulbactam
Pharmaceutical form of applied drug	Dry powder injection
Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
Reference to Finished product specifications	In-house
Proposed Pack size	1’s
Proposed unit price	As per SRO
The status in reference regulatory authorities	Cebac 1G injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd., USFDA Approved. Reg. No.073420
For generic drugs (me-too status)	Sulperazone 1g injection by M/s Pfizer
GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
Name and address of API manufacturer.	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR 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 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 Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of 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 have been submitted against the Cebac 1Gm injection IM/IV by M/s Bosch pharmaceutical.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.	1093EJ81NE		
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.	TCS001	TCS002	TCS003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	05-04-22	06-04-22	07-04-22
No. of Batches	03		

Administrative Portion		
37.	Reference of previous approval of applications	N/A

	with stability study data of the firm (if any)	
38.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
39.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Cefoperazone sodium/Sulbactam sodium dated 18-03-2022. • Copy of commercial Invoice # JTRF210908-MQ in name of M/s Medisave Phamraceuticals, attested by AD I&E Lahore dated 01-10-2021 for import of 100 KG Cefoperazone sodium + Sulbactam sodium.
40.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr.#	Observations	Firm's response
1.5.6	The said section mentions the drug product specifications as "In-house" whereas section 3.2.P.5.1 declares the drug product specifications as per JP monograph. Clarification shall be submitted in this regard.	Firm has submitted revised section 1.5.6 declaring drug product specifications as per JP for both strengths.
1.6.5	Valid copy of GMP certificate/DML of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate no. SD20180660 issued by CFDA valid till 008-02-2023
3.2.P.1	Details of accompanying reconstitution diluent shall be submitted.	Firm has referred to WFI as reconstitution diluent.
3.2.P.2.2.1	Justification shall be submitted for not performing test of pH and water Content in Pharmaceutical equivalence studies.	Firm has submitted performance of test of pH and water content in Pharmaceutical equivalence studies.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Compatibility studies with WFI has been submitted for both strengths.
3.2.P.5.2	The submitted analytical procedure does not mention use of internal standard solution in Assay test as recommended by JP monograph. Clarification shall be submitted in this regard.	It is submitted that the system suitability test has been performed during analytical method verification studies as per JP monograph wherein internal standard solution was used along with standard and sample solutions. Firm has also submitted revised analytical procedure.
3.2.P.6	COA of reference/working standard of "Sulbactam" shall be submitted.	Submitted.
3.2.P.8	Justification shall be submitted for manufacturing of trial batches sin April 2022, whereas section approval	Inspection was conducted on 21st March 2022 and sections were approved as per inspection report.

	was granted on 07-06-2022.	

Decision: Registration Board approved the applications of MAGNIX 2gm IV/IM injection & MAGNIX 1gm IV/IM injection. Registration letter will be issued after verification of the loan letter by M/s Medisave Pharmaceuticals and submission of fee of Rs. 75,000/- for each strength for correction/pre-approval change in stability data 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.**

As mentioned in remarks of evaluator, firm has submitted revised section 1.5.6 declaring drug product specifications as per JP for both strengths. Hence, it is a typo error in minutes of meeting that firm has submitted revised stability. Firm had submitted fee of Rs.7500/- for change of specification to "JP Specifications", vide challan No. 82736284, verified from website and registration letter was issued.

Decision: Registration Board noted the following information:

i. **Correction in minutes of 326th meeting of Registration Board with respect to "Vastamer 40mg Tablet" of M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore. Correct composition/ label claim is as under:**

"Each film coated tablet contains:
Atorvastatin as Calcium Trihydrate……40mg"

ii. **Correction in minutes of 323rd meeting of Registration Board with respect to "Zanaflex Tablet 4mg and 2mg" of M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore. Correct composition/ label claim of both products is as under:**

"Zanaflex Tablet 4mg
Each Tablet Contains:
Tizanidine as HCl…..…4mg

Zanaflex Tablet 2mg
Each Tablet Contains:
Tizanidine as HCl…..…2mg"

iii. **Correction in minutes of 323rd meeting of Registration Board with respect to "Magnix 2gm IV/IM Injection" and "Magnix 1gm IV/IM Injection" of M/s Wimits Pharmaceuticals (Pvt) Ltd., Plot #129 Sundar Industrial Estate, Raiwind road, Lahore. Correct decision is as under:**

Registration Board approved the applications of MAGNIX 2gm IV/IM injection & MAGNIX 1gm IV/IM injection. Registration letter will be issued after verification of the loan letter by M/s Medisave Pharmaceuticals and submission of fee of Rs.7,500/- for each strength for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

Case No. 05: Stability Data of Linagliptin + Metformin Tablet of M/s. CCL Pharmaceuticals (Pvt) Ltd. 62 Industrial Estate Kot Lakhpat Lahore.

Registration Board in its 243rd meeting approved following products in the name of M/s. CCL Pharmaceuticals (Pvt) Ltd. 62 Industrial Estate Kot Lakhpat Lahore. Detail of products is as under:

Sr. No.	Name of Drug	Demanded Pack Size / Price	Decision of 243rd DRB
1.	Lina-Met 2.5/500 Tablet Linagliptin …. 2.5mg Metformin HCl …. 500mg	14's As per brand leader	**The Board approved registration of above products.**
2.	Lina-Met 2.5/850 Tablet Linagliptin …. 2.5mg Metformin HCl …. 850mg	14's As per brand leader	
3.	Lina-Met 2.5/1000 Tablet Linagliptin …. 2.5mg Metformin HCl …. 1000mg	14's As per brand leader	

Being new molecule firm has submitted 6 Month accelerated and 24 Month real time stability studies data. Detail is as under:

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
1.	M/s CCL Pharmaceuticals Pvt Ltd 6, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	Lina-Met 2.5/ 500 mg Tablet Each tablet contains: Linagliptin …… 2.5 mg Metformin HCL ….. 500 mg	Dy. No. 1100/R&I 12-01-2023 Rs. 30,000/- (Slip # 996179471)	

Remarks of Evaluator:

- The firm has submitted stability study data along with required documents as per checklist approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	**Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017
API Lot No.	Metformin HCl: MT20411221 Linagliptin: L-L9-20210905-D02-L09-04
Description of Pack (Container closure system)	Alu-Alu in bleach board with leaflet
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.		T2-22	T3-22	T4-22
Batch Size		1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date		04-2022	05-2022	05-2022
Date of Initiation		05-2022	05-2022	05-2022
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 ErtuSita 15/100 mg, for which the inspection was conducted on 16-06-2021		
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 at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.		
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy **Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017		
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-12-2021 specifying 06 Kgs of Linagliptin. The invoice is cleared by AD (I&E) DRAP. Firm has submitted copy of commercial invoice cleared dated 21-01-2022 specifying 10,000 Kgs of Metformin HCl. 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	Firm has provided Batch Manufacturing Record for		

	stability batches.	all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Jentadueto 2.5/500 mg Tablets in 3 dissolution medias.
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
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 both stability chambers for accelerated as well as real time stability studies.

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
2.	M/s CCL Pharmaceuticals Pvt Ltd 6, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	Lina-Met 2.5/ 850 mg Tablet Each tablet contains: Linagliptin …… 2.5 mg Metformin HCL ….. 850 mg	Dy. No. 1101/R&I 12-01-2023	

Remarks of Evaluator:

- The firm has submitted stability study data along with required documents as per checklist approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	**Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017		
API Lot No.	Metformin HCl: MT20411221 Linagliptin: L-L9-20210905-D02-L09-04		
Description of Pack (Container closure system)	Alu-Alu in bleach board with leaflet		
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.	T2-22	T3-22	T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	04-2022	05-2022	05-2022
Date of Initiation	05-2022	05-2022	05-2022

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 ErtuSita 15/100 mg, for which the inspection was conducted on 16-06-2021
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 at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy **Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-12-2021 specifying 06 Kgs of Linagliptin. The invoice is cleared by AD (I&E) DRAP. Firm has submitted copy of commercial invoice cleared dated 21-01-2022 specifying 10,000 Kgs of Metformin HCl. 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 Jentadueto 2.5/500 mg Tablets in 3 dissolution medias.
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 &	Firm has submitted certificate of 21 CFR

	audit trail reports on product testing.	compliance for the HPLC system
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 both stability chambers for accelerated as well as real time stability studies.

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
3.	M/s CCL Pharmaceuticals Pvt Ltd 6, Quaid-e- Azam Industrial Estate, Kot Lakhpat, Lahore	Lina-Met 2.5/ 1000 mg Tablet Each tablet contains: Linagliptin …… 2.5 mg Metformin HCL ….. 1000 mg	Dy. No. 1102/R&I 12-01-2023	

Remarks of Evaluator:

- The firm has submitted stability study data along with required documents as per checklist approved in 293rd meeting of Registration Board.

STABILITY STUDY DATA

Manufacturer of API	**Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017		
API Lot No.	Metformin HCl: MT20411221 Linagliptin: L-L9-20210905-D02-L09-04		
Description of Pack (Container closure system)	Alu-Alu in bleach board with leaflet		
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.	T2-22	T3-22	T4-22
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	04-2022	05-2022	05-2022
Date of Initiation	05-2022	05-2022	05-2022
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 ErtuSita 15/100 mg, for which the inspection was conducted on 16-06-2021
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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
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5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy **Metformin HCL**: M/s Wanbury Limited situated at Doctors Organic Chemicals Division, Iragavaram (M), K. illindalaparuu-534217, West Godavari Distric, Andhra Pardesh, India bearing License 107/WG/AP/95/B/R dated 19-05-1995, retained from 29-07-2018 to 28-07-2023 issued by DCA Govt of Andhra Pardesh, India **Linagliptin:** Fuxin Long Rui Pharmaceutical Co., Ltd, Flouride Industrial park, Fuxin city, Liaoning Province-123000 China issued by Food and Drug Administration of Liaoning Province valid until December 20,2022, issued date 21/2017
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-12-2021 specifying 06 Kgs of Linagliptin. The invoice is cleared by AD (I&E) DRAP. Firm has submitted copy of commercial invoice cleared dated 21-01-2022 specifying 10,000 Kgs of Metformin HCl. 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 Jentadueto 2.5/500 mg Tablets in 3 dissolution medias.
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
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 both stability chambers for accelerated as well as real time stability studies.

Decision: **Registration Board deferred the case for submission of following information/ documents by the applicant:**

i. **Evidence for inclusion of Arginine in the drug product formulation.**
ii. **Analysis of Arginine content in the drug product.**
iii. **Analysis of Enantiomeric purity of Linagliptin.**

iv. Valid GMP Certificates of API manufacturer and stability data of API as per conditions of Zone-IV-A.

Case No. 06: Recommendation to Registration Board in Light of Decision of Meetings of Pharmacovigilance Risk Assessment Expert Committee.

Pharmacovigilance Risk Assessment Expert Committee (PAEC) of Pharmacy Services Division of DRAP has forwarded following recommendations to Registration Board.

A. RECOMMENDATIONS OF 1ST MEETING OF PAEC.

1. DOMESTIC SIGNALS

1.1 Anaphylactic Reaction with Diclofenac Sodium.

Decision of PRAEC:

i. The PRAEC after detailed deliberation and discussion decided to update the warning, precaution & contraindication sections of the prescribing information/ safety specification/ label of Diclofenac Sodium injection about the occurrence of anaphylactic reaction/ anaphylactic shock and its contraindication in a patient with a history of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.

ii. Furthermore, the PRAEC in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022 decided to recommend the Registration Board to update the safety specification/ label of Diclofenac Sodium Injection.

1.2 Infusion-related hypersensitivity reactions with Remdesivir

Decision of PRAEC

The PRAEC after detailed deliberation & discussion and in light of recommendations of the National Pharmacovigilance Centre decided as under:

i. To update the prescribing information/ safety specification/ label of Remdesivir with the inclusion of information related to infusion-related hypersensitivity reactions and its monitoring in the warning and precaution sections and onward recommendation to the Registration Board in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022. Furthermore, all the registration holders should also introduce educational training for healthcare professionals on proper preparation, administration and flow rate of Remdesivir, and monitoring of patients;

ii. To advise the Registration Board to review the grant of Emergency Use Authorization for the product Viso-Rem Solution for infusion in light of the investigation carried out by the panel of QA and LT Division of the DRAP; and

iii. Furthermore, to advise the QA and LT Division of the DRAP in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022 to strengthen its surveillance mechanism of registration holders of Remdesivir.

2. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

2.1. Clozapine: Risk of serious bowel complications

Decision of PRAEC

i. The PRAEC after detailed deliberation and discussion decided to update and strengthen the warning section of Clozapine with gastrointestinal side effects, including constipation and severe bowel problem in light of Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022.

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.2 Iodinated contrast media (ICM) injections: Risk of Hypothyroidism in babies and young children.

Decision of PRAEC

i. The PRAEC after detailed deliberation and discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the warning and precaution section of the

prescribing information of the entire class of iodinated contrast media (ICM) that are used for radiological purposes to include risks of an underactive thyroid or a temporary decrease in thyroid hormone levels in children 3 years or younger i.e newborns, particularly those born premature, and children in their first 3 years with underlying conditions such as heart issues etc

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.3 Remdesivir: Risk of sinus bradycardia

Decision of PRAEC

i. The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the prescribing information (warning & adverse drug reactions sections) of Remdesivir to include the potential risk of sinus bradycardia.

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.4 Atezolizumab: Risk of severe cutaneous adverse reactions (SCARs)

Decision of PRAEC

i. The PRAEC after deliberation decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update prescribing information of Atezolizumab (Tecentriq®) to include the risk of severe cutaneous adverse reactions (SCAR) including Stevens-Johnsons Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN).

ii. Furthermore, it was decided that registration holders should issue direct healthcare professional communication in this regard.

iii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.5 Metformin and reduced vitamin B12 levels

Decision of PRAEC

i. The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update prescribing information of Metformin and other medicines containing Metformin to state that vitamin B12 deficiency is an adverse drug reaction with Metformin use and the risk of this adverse reaction occurrence increases with increasing metformin dose and treatment duration and in patients with risk factors known to cause vitamin B12 deficiency.

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.6 Pregabalin: Risk of Major Congenital Malformations

Decision of PRAEC

i. The PRAEC after detailed deliberation and discussion decided as per Rule 10 (1) (h) (iv) and (vi) of Pharmacovigilance Rules, 2022 to update prescribing information of Pregabalin to include information from a new study that pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy and include advise on effective contraception during treatment in pregnancy.

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter

2.7 Interaction between hydroxychloroquine or chloroquine, and macrolide antibiotics: increased risk of cardiovascular events with co-administration.

Decision of PRAEC

i. The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) and (vi) of Pharmacovigilance Rules, 2022 to update prescribing information (warning and interaction sections) of hydroxychloroquine, chloroquine and macrolide antibiotics (azithromycin, erythromycin or clarithromycin excluding topical macrolides) about the potential interaction of increased risk of cardiovascular events and cardiovascular mortality if hydroxychloroquine or chloroquine is taken with a macrolide-antibiotic.

ii. It was decided to onward recommend/inform the Registration Board for necessary action in the matter.

2.8 Hydroxyethyl-starch solutions for infusion: risk of kidney injury and death

Decision of PRAEC

The PRAEC after detailed deliberation and discussion and as per Rule 10 (1) (h) (v) of Pharmacovigilance Rules, 2022 decided to recommend to the Registration Board to suspend the registration of Hydroxyethyl-Starch (HES) solutions in Pakistan subject to the availability of alternative treatment options.

B. RECOMMENDATIONS OF 2ND MEETING OF PAEC.

1. DOMESTIC SIGNALS

1.1 Hypersensitivity Reactions with Pegaspargase (Peg L Asparaginase).

Decision:

A. The PRAEC after detailed deliberation and discussion decided to recommend to the Registration Board of the DRAP as per Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022 as follows:

1. To direct registration holders to change/update the prescribing information/safety specification of Pegaspargase by including the following information:

a. Information related to hypersensitivity reactions and its monitoring in the warning and precaution sections; and

b. Information on treatment modification as per the grade of hypersensitivity reactions in dosage and administration sections.

2. To direct registration holders to introduce an educational training programme for healthcare professionals on proper preparation, administration and monitoring of Pegaspargase and to ensure that resuscitation equipment and other appropriate means for the treatment of anaphylaxis/hypersensitivity reactions such as epinephrine, oxygen, intravenous steroids, etc. are available at the administrative sites.

3. The importer should establish an active pharmacovigilance system by appointing a Qualified Person for Pharmacovigilance (QPPV) within 15 days and regularly submit the data of collected ADRs to the National Pharmacovigilance Centre as per Pharmacovigilance Rules, 2022.

B. The PRAEC also decided to recommend to National Pharmacovigilance Centre (NPC), DRAP as per Rule 10 (1) (b) to issue an advisory to all hospitals where Pegaspargas is distributed in Pakistan to strictly follow standard chemotherapy protocol for preparation, administration and monitoring of Pegaspargas.

2. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

2.1. Buprenorphine: Risk of dental problems

Decision:

- *The PRAEC decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the prescribing information/safety specification of buprenorphine medicines that are dissolved in the mouth by including information related to the risk of dental issues, pre-prescribing assessment of patients and guidelines of taking extra steps after use in the warning and precaution section.*
- *To recommend Registration Board to update the prescribing information of buprenorphine-containing medicines that are orally dissolved in light of the PRAEC decision and as per the US-FDA label.*

2.2 **Benzodiazepines: Potential Risk of Abuse, Dependence and Withdrawal.**

Decision:

A. The PRAEC decided as per Rule 10 (1) (h) (iv) & (vi) of Pharmacovigilance Rules, 2022 as follows:

I. Registration holders of all benzodiazepines should update the prescribing information/safety specification by including information related to abuse, misuse, addiction and withdrawal in the warning and precaution section;

II. *Registration holders should create the boxed warning in the prescribing information/safety specification as per the below format;*

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS.
• Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.
• The use of benzodiazepines, including **Drug X** exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing **Drug X** and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

III. *Registration holders should also include information related to abuse, misuse, addiction and withdrawal of benzodiazepine in their educational training and promotional material for healthcare professionals.*

B. *To recommend Registration Board to update the prescribing information of all benzodiazepine-containing medicines as per the decision of PRAEC and as per US-FDA and MedSafe, Newzealand label/prescribing information.*

C. *Keeping in view the sale of benzodiazepine without a prescription (if any) at medical stores/pharmacies across Pakistan, that may further enhance the patient's risk of abuse, misuse and addiction and illicit use. The PRAEC decided to request the QA/LT Division of the DRAP to further coordinate with provincial drug control administrations including the drug control administration of Azad Jammu and Kashmir, Gilgit Baltistan and Islamabad to ensure strict control on the over-the-counter sale of benzodiazepine by medical stores/pharmacies and maintenance of sale records of all benzodiazepine sold through prescription.*

2.3 Janus Kinase (JAK) Inhibitors: Risk of serious heart-related events, blood clots, cancer and death.

Decision:

- *The PRAEC decided as per Rule 10 (1) (h) (iv) and (vi) of Pharmacovigilance Rules that registration holders should update prescribing information/safety specification of Xeljanz ® (tofacitinib) with the inclusion of information related to heart attack or stroke, cancer, blood clots, and death in the warning and precaution section and to create a Boxed warning as per below format:*

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), AND THROMBOSIS
• Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with XELJANZ/XELJANZ XR/XELJANZ Oral Solution if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.
• Higher rate of all-cause mortality, including sudden cardiovascular death with XELJANZ vs. TNF blockers in rheumatoid arthritis (RA) patients.
• Malignancies have occurred in patients treated with XELJANZ. Higher rate of lymphomas and lung cancers with XELJANZ vs. TNF blockers in RA patients.
• Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with XELJANZ vs. TNF blockers in RA patients.
• Thrombosis has occurred in patients treated with XELJANZ. Increased incidence of pulmonary embolism, venous and arterial thrombosis with XELJANZ vs. TNF blockers

in RA patients.

- *To recommend Registration Board to update the prescribing information of Xeljanz ® (tofacitinib) in light of the decision of PRAEC and as per the label/prescribing information of Health Canada, MHRA-UK, US-FDA and PMDA Japan.*

3.4 **Insomnia medicines: Risk of complex sleep behaviours.**

Decision:

- *The PRAEC decided as per Rule 10 (1) (h) (ii), (iv) and (vi) of Pharmacovigilance Rules, 2022 that registration holders should update the prescribing information/safety specification of zolpidem-containing drugs by including information related to complex sleep behaviour in the warning and precaution sections, information related to contraindications in patients who have experienced complex sleep behaviours after taking these drugs in the past, and to create a boxed warning as per the following format:*

WARNING: COMPLEX SLEEP BEHAVIORS
Complex sleep behaviors including sleep-walking, sleep-driving, and engaging in other activities while not fully awake may occur following use of ***zolpidem***. Some of these events may result in serious injuries, including death. Discontinue ***zolpidem*** immediately if a patient experiences a complex sleep behavior

- *To recommend Registration Board to update the prescribing of zolpidem-containing medicines in light of the decision of PRAEC and as per the label/prescribing information of US-FDA and PMDA Japan.*

3.5 Finasteride: Potential risk of suicidal ideation/thoughts & self-injury.

Decision:

- *The PRAEC decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders should update prescribing information/safety specification of Finasteride containing drugs by strengthening the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors before starting treatment.*
- *To recommend Registration Board to update the prescribing information of Finasteride-containing medicines in light of the decision of PRAEC and as per the product monograph/prescribing information of Health Canada.*

3.6 Pholcodine: Potential risk of developing anaphylactic reactions to neuromuscular blocking agents (NMBA):

Decision:

The PRAEC deliberated the case in detail and considered that at present there is a lack of possibility to identify effective measures to minimize the risk of anaphylactic reactions to neuromuscular blocking agents (NMBAs) in patients with a previous history of Pholcodine use and also considered the free availability of alternative treatment options for the treatment of cough and flu/cold in the market of Pakistan. Accordingly, the PRAEC decided to recommend to the Registration Board as per Rule 10(1)(h)(v) of Pharmacovigilance Rules, 2022 to suspend the registrations of "Pholcodine" containing products till the final outcome or decision by the European Commission, following which the case will be reconsidered

Proceedings of 330th Meeting:

Registration Board was apprised that for all cases (including Domestic signals or Reliance on international safety decisions), recommendations of PRAEC to update the prescribing information/ safety specifications are based on updated SmPC of innovator's/ reference drug products. In this context, following links have also been shared by Pharmacy Services Division:

A. RECOMMENDATIONS OF 1ST MEETING OF PAEC.

1. DOMESTIC SIGNALS

1.1 Anaphylactic Reaction with Diclofenac Sodium.
Section 4.3, 4.4 and 4.8 of SmPC EMC-UK.
https://www.medicines.org.uk/emc/product/9399/smpc
Contraindication and adverse drug reaction section of FDA label.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022396lbl.pdf

1.2 Infusion-related hypersensitivity reactions with Remdesivir
US-FDA Label:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214787s019lbl.pdf
Section 4.4 and 4.8 of SmpC of UK
https://www.medicines.org.uk/emc/product/11597

2. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

2.1. Clozapine: Risk of serious bowel complications
Warning and Precaution sections of US-FDA Label Clozapine
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019758

2.2 Iodinated contrast media (ICM) injections: Risk of Hypothyroidism in babies and young children.
Warning and Precaution sections of US-FDA Label of Omnipaque, Ultravist, Visipaque
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018956s116,020608s049lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020220Orig1s055;021425Orig1s037lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020351s057,020808s035lbl.pdf

2.3 Remdesivir: Risk of sinus bradycardia
Section 4.8 of the product monograph of Canada:
https://pdf.hres.ca/dpd_pm/00071267.PDF
section of 4. 8 of EMC of MHRA UK
https://www.medicines.org.uk/emc/product/11597

2.4 Atezolizumab: Risk of severe cutaneous adverse reactions (SCARs)
Section 4.8 of EMC of UK
https://www.medicines.org.uk/emc/product/8442/smpc

2.5 Metformin and reduced vitamin B12 levels
Sections 4.4 and 4.8 of EMC of UK
https://www.medicines.org.uk/emc/product/987/smpc

2.6 Pregabalin: Risk of Major Congenital Malformations
Sections 4.4 and 4.6 of EMC of UK
https://www.medicines.org.uk/emc/product/10303/smpc

2.7 Interaction between hydroxychloroquine or chloroquine, and macrolide antibiotics: increased risk of cardiovascular events with co-administration.
Section 4.5 of Azithromycin and chloroquine
https://www.medicines.org.uk/emc/product/1073/smpc
https://www.medicines.org.uk/emc/product/5490/smpc

B. RECOMMENDATIONS OF 2ND MEETING OF PAEC.

1. DOMESTIC SIGNALS

1.1 Hypersensitivity Reactions with Pegaspargase (Peg L Asparaginase).
Warning and precaution sections and dosage and administration sections of the FDA label of Pegaspargase.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103411s5205lbl.pdf
EMC SmPC of UK.
https://www.medicines.org.uk/emc#gref.

2. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

2.1. Buprenorphine: Risk of dental problems
5.12 section of FDA label buccal tablets of Buprenorphine
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207932s019s020lbl.pdf

3.2 Benzodiazepines: Potential Risk of Abuse, Dependence and Withdrawal.
A boxed warning, warning and precaution section and dosage and administration sections of FDA label of diazepam, lorazepam and alprazolam etc and all BZD
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/013263Orig1s098lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018276s059lbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/017794s049lbl.pdf

3.3 Janus Kinase (JAK) Inhibitors: Risk of serious heart-related events, blood clots, cancer and death.
Warning and Precautions section and Boxed warning of Xeljanz FDA label:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203214s028,208246s013,213082s003lbl.pdf
Section 4.4 and 4.8 of SmPC of Xeljanz of EMC-UK
https://www.medicines.org.uk/emc/product/9410/smpc

3.4 Insomnia medicines: Risk of complex sleep behaviours.
A boxed warning, warning and precaution section (5.1) and contraindication sections of the FDA label of zolpidem.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/019908s40s044s047lbl.pdf

3.5 Finasteride: Potential risk of suicidal ideation/thoughts & self-injury.
Post-Market Adverse Drug Reactions (Psychiatric Disorders) of Product Monograph of Canada.
https://pdf.hres.ca/dpd_pm/00060780.PDF
https://pdf.hres.ca/dpd_pm/00060786.PDF

While, following two cases are based on reliance on the decisions taken by reference regulatory authorities:

Hydroxyethyl-starch solutions for infusion: risk of kidney injury and death
European Commission update:
https://www.ema.europa.eu/en/news/hydroxyethyl-starch-solutions-infusion-recommended-suspension-market#:~:text=Hydroxyethyl%2Dstarch%20solutions%20for%20infusion%20recommended%20for%20suspension%20from%20the%20market,-Share&text=Update%20as%20of%2026%20July,of%20HES%20solutions%20for%20infusion.
PRAEC recommendation:
https://www.ema.europa.eu/en/news/prac-recommends-suspending-hydroxyethyl-starch-solutions-infusion-market-0

Pholcodine: Potential risk of developing anaphylactic reactions to neuromuscular blocking agents (NMBA):
TGA suspension:
https://www.tga.gov.au/safety/information-about-specific-safety-alerts-and-recalls/about-pholcodine-cough-medicines-cancelled-tga-and-recalled-pharmacies-safety-reasons
PRAC, CMdH of EMA withdrawal:
https://www.ema.europa.eu/en/medicines/human/referrals/pholcodine-containing-medicinal-products
MHRA:
https://www.gov.uk/government/news/safety-withdrawal-of-pholcodine-containing-cough-and-cold-medicines
WHO Alerts:
https://cdn.who.int/media/docs/default-source/medicines/pharmacovigilance/pholcodine-safety-alert.pdf?sfvrsn=887d8597_3

Decision:
Registration Board decided as under:

i. **Keeping in view the recommendations forwarded by PRAEC and updated SmPC of the innovator's/ reference drug products, all relevant registration holders/ manufacturers shall update the label/ prescribing information/ safety specification/ warning/ adverse drug reaction/ interaction/ precaution/ contraindication sections (whichever is applicable) of their**

registered products. For this purpose, a general advisory shall be issued to all registration/ marketing authorization holders for regular update/ revision in label/ prescribing information/ safety specifications of their registered products in line with SmPc of the innovator's/reference drug products. Furthermore, the advisory shall also include, introduction of educational training programs (where ever applicable) for Health care professionals.

ii. **Keeping in view the international practices with respect to emergency use authorizations of Remdesivir, relevant manufacturers shall be directed to apply for grant of registration/ full marketing authorization along-with submission of data/ studies as required for registration on Form-5F.**

iii. **QA & LT Division shall be advised to strengthen its surveillance mechanism with respect to registration/ emergency use authorization holders of Remdesivir.**

iv. **Following cases shall be further deliberated in the next meeting. For this purpose, the Board advised to present complete record and updated decisions taken by the reference regulatory authorities with respect to these cases:**

   a. **Review of grant of Emergency Use Authorization for the product "Viso-Rem Solution for infusion (of M/s Vision Pharmaceuticals, Islamabad)" in light of the investigation carried out by the panel of QA and LT Division of the DRAP**
   b. **Risk of kidney injury and death associated with Hydroxyethyl-starch solutions for infusion and recommendation of PRAEC to suspend the registration of Hydroxyethyl-Starch (HES) solutions in Pakistan subject to the availability of alternative treatment options.**
   c. **Potential risk of developing anaphylactic reactions to neuromuscular blocking agents (NMBA) in patients with a previous history of Pholcodine use and recommendations of PRAEC to suspend the registrations of "Pholcodine" containing products till the final outcome or decision by the European Commission, following which the case will be reconsidered.**

Post Registration-I Section

Case 1: Applications of M/s AGP Limited, Karachi for transfer of manufacturing of drug products from import to local manufacturing

M/s AGP Limited, Karachi had applied for transfer of manufacturing of their two (02) products form import to local manufacturing.

2. The dossier of the product was submitted on Form-5F (CTD).

6.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited. B-23-C, S.I.T.E, Karachi
	Transfer of registrationof brand**"CLOZARIL"**from ***Import to Local Manufacturing***	
	From	**To**
	Product License Holder: M/s Mylan Pharma GmbH Turnmstrasse 24 6312 Steinhausen Switzerland. **Manufacturer** M/s Madaus GmbH LutticherStraBe, Troisdorf, Germany **MAH for import in Pakistan by:** M/s AGP Limited. B-23-C, S.I.T.E, Karachi	**Marketing Authorization Holder** **&** **Local manufacturing proposed at:** M/s AGP Limited.**(DML # 000348)** B-23-C, S.I.T.E, Karachi **Intellectual Property Rights** *transferred to: (Product ownership)***:** OBS (Pakistan) Private Limited *(a subsidiary of AGP)* Floor 2B, B-23-C, S.I.T.E. Karachi. *(West Sindh 75700)*
	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. 11878 (dated: 15-05-2023)
	Details of fee submitted	PKR 30000 Dated: 05-05-2023 (Invoice # 76769224654)
	The proposed proprietary name / brand name	**Clozaril 25 mg Tablet** *(Reg. no. # 097361)* **Initial Registration:** 23-08-2019 **Renewal Status:** not yet due
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Clozapine …….. 25 mg
	Pharmaceutical form of applied drug	Immediate release Tablet
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	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* **Clozaril®***by*Novartis
	For generic drugs (me-too status)	**Zopin** by M/s Hilton.
	GMP status of the Finished product manufacturer	cGMP Certificate valid till **02-06-2023**
	Name and address of API manufacturer.	M/sAlmon HealthCare Pvt. Ltd. 408/409/410, Baleswar city, Block # A, near Hathijan ring road circle, vatva, Ahmedabad India. GMP valid till **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	**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
	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. Clozaril by M/s Mylan** by performing quality tests (appearance, identification, uniformity of dosage unit, Disintegration time, Assay, Dissolution).
	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	M/sAlmon HealthCare Pvt. Ltd. 408/409/410, Baleswar city, Block # A, near Hathijan ring road circle, vatva, Ahmedabad India.		
API LOT #	**LF/CLOZ/042022/002**		
Description of Pack (Container closure system)	Off white to light yellow colored round flat compressed scored tablet plain on other side blistered with ALU/PVC and packed in printed 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: 24months*(Data submitted of 06 months)*		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18& 24(Months)		
Batch No.	**001DS01**	**001DS02**	**001DS03**
Batch Size	5000 Tablets	5000 Tablets	5000 Tablets
Manufacturing Date	10/2022	10/2022	10/2022
Date of Initiation	18/10/2022	18/10/2022	18/10/2022
No. of Batches	03		

Administrative Portion		
43.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
44.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
45.	Documents for the procurement of API with approval from DRAP (in case of import).	K-632264687816 dated 23-06-2022
46.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
47.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Initial Shortcomings in applications and reply of the firm:

Observations	Reply of firm
1.4.3 Please submit following information related to Asset purchase agreement (APA) made between OBS &Viatris.	
i. Description of assets to be sold, including tangible and intangible assets, real estates, intellectual property and contracts	Only brands with their complete drug product dossiers have been acquired along with their intellectual property rights and Marketing Authorization [MA]. List of acquired brands is **enclosed as Annex-I**
ii. Closing conditions of the agreement.	Approval from Competition Commission of Pakistan and State Bank of Pakistan, which have been duly obtained. OBS Pakistan shall initiate the process to deliver funds or cause to be delivered to Viatris.
iii. Indemnification conditions regarding who is responsible for any liabilities arising from the sold assets.	The company who has sold the product and issued the warranty will be responsible until its shelf life. Similarly, OBS Pakistan will be responsible for those batches which will be supplied by it after the closing /MA transfer of these products.
iv. Details of transfer of Intellectual property including patents, trademarks, copyrights etc.	We have acquired the trademarks of products.
1.4.4 Please submit the following	
legalized copy of No Objection Certificate issued by Viatris for allowing OBS to use brand name "Clozaril".	The No objection Certificate [NOC] is under legalization process, and we will submit the legalized NOC before issuance of the transfer letter.
1.6.5 Please submit details of the following:	
i. Are API supplier and Excipient suppliers of Viatris for the proposed drug product, part of Asset purchase agreement?	Yes, Viatris has transferred complete and up-to-date drug product dossiers concerning the **"Clozaril Tablet"** to the OBS. It is a documentation based **"Product Knowledge transfer"**. The details of drug substance and excipients & packing included in the technical dossier submitted in DRAP for approval of local manufacturing in Pakistan, has been finalized after comparing with drug product dossier provided by Viatris for Clozaril Tablets. The specifications and relevant functional characteristics of the starting materials (APIs and excipients) to be used at AGP are consistent with materials used at the Viatris. The formulation of the drug product for local manufacturing is same as compared with formulation of Clozaril manufactured by Viatris.
ii. Drug Substance manufacturer and excipients manufacturer for the drug product **"Clozaril "** used by Viatris.	Currently, Clozaril is manufactured in Germany. Therefore, they are using the drug substance complied with Eur. Phr. The monograph of Eur. Phr. Is enclosed as **Annex-II**
iii. Please justify that API supplier chosen by OBS has same impurity profile of API and	We have selected the drug substance that complies with USP because of the following factors: -

bioequivalence to the API supplier of Viatris.	• The specifications and relevant functional characteristics of the starting materials (APIs and excipients) to be used in local manufacturing in Pakistan are consistent with materials used at the Viatris. • Technology transferhas been made with documented evidence that OBS can manufacture the Clozaril, with same processesand methodsas per set of specifications as agreed with the Viatris. • The limits of impurities are same in USP and Eur. Phr. While USP also required to perform test for residual solvents as well as the particle size of our API is D (90) less than 10 microns which will also enhance the dissolution & improve the bioavailability, **enclosed in Annex-II.** • The finished product is currently registered with USP specs. The manufacturing process and excipients recommended in the dossier are same used in our Drug Product formulation **(Annex-IV)**. • We have done the pharmaceutical equivalence study and comparative dissolution test with Clozaril and submitted with the dossier.
iv. Submit COA of API supplier of Viatris.	The COA of API supplier of Viatris submitted.

Formulation & Process Equivalence Summary

S#	Components	Clozaril by Madaus GmbH	Clozaril by AGP
1.	Composition	Clozapine, Lactose, Starch Maize, Talc, PVP, Colloidal silicon Dioxide, Magnesium Sterate.	Clozapine, Lactose monohydrate, Starch Maize, Talc, PVP, Colloidal silicon Dioxide, Magnesium Sterate.
2.	Process Flow Chart	Dry mixing → wet granulation → drying → crushing → blending → lubrication → compression	Dry mixing → wet granulation → drying → crushing → blending → lubrication → compression
3.	Physical Parameters	25 mg Tablets ---- round flat shape 100 mg Tablets --- round biconvex shape	25 mg Tablets ---- round flat shape 100 mg Tablets --- round biconvex shape

Pharmaceutical Equivalence Summary

S#	Components	Reference Product	Clozaril by AGP
1.	Active Moeity	Clozapine	Clozapine
2.	Salt/Ester	N/A	N/A
3.	Product Dosage form	Immediate Release Tablet	Immediate Release Tablet
4.	Route of Administration	Oral	Oral
5.	Amount of Drug	25 mg / Tablet	2 mg / Tablet
6.	Identification	By HPLC Retention Time	By HPLC Retention Time
7.	Disintegration time	2 min, 48 sec	1 min, 50 sec
8.	Uniformity of Dosage form	AV_{10}=3.26	AV_{10}=3.95
9.	Assay of the product	99.11% of the labeled amount	99.60% of the labeled amount
10.	Dissolution Rate	97% of the labeled amount	96% of the labeled amount
11.	Organic impurities	Below reporting limit	Below reporting limit

Decision:

The Registration Board approved request of the firm for change in registration status of

Clozaril 25 mg Tablet *(Reg. no. # 097361)* from finished import to local manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML # 000348) (contract manufacturing) subject to submission of differential fee of Rs.45000/-

7.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited. B-23-C, S.I.T.E, Karachi
	Transfer of registration from import to local manufacturing	
	From	**To**
	<u>Product License Holder:</u> M/s Mylan Pharma GmbH Turnmstrasse 24 6312 Steinhausen Switzerland. **<u>Manufacturer</u>** M/s Madaus GmbH LutticherStraBe, Troisdorf, Germany **MAH for import in Pakistan by:** M/s AGP Limited. B-23-C, S.I.T.E, Karachi	**Marketing Authorization Holder** **&** **Local manufacturing proposed at:** M/s AGP Limited.**(DML # 000348)** B-23-C, S.I.T.E, Karachi **Intellectual Property Rights** *transferred to: (Product ownership)***:** OBS (Pakistan) Private Limited *(a subsidiary of AGP)* Floor 2B, B-23-C, S.I.T.E. Karachi. *(West Sindh 75700)*
	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. 11879 (dated: 15-05-2023)
	Details of fee submitted	PKR 30000 Dated: 05-05-2023 (Invoice # 963077776)
	The proposed proprietary name / brand name	**Clozaril 100 mg Tablet** *(Reg. no. # 097362)* **Initial Registration:** 23-08-2019 **Renewal Status:** not yet due
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Clozapine ……...100 mg
	Pharmaceutical form of applied drug	Immediate release Tablet
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	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* **Clozaril®***by*Novartis
	For generic drugs (me-too status)	**Zopin** by M/s Hilton.
	GMP status of the Finished product manufacturer	cGMP Certificate valid till**02-06-2023**
	Name and address of API manufacturer.	M/sAlmon HealthCare Pvt. Ltd. 408/409/410, Baleswar city, Block # A, near Hathijan

		ring road circle, vatva, Ahmedabad India. GMP valid till **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	**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
	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. Clozaril by M/s Mylan** by performing quality tests (appearance, identification, uniformity of dosage unit, Disintegration time, Assay, Dissolution).
	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	M/sAlmon HealthCare Pvt. Ltd. 408/409/410, Baleswar city, Block # A, near Hathijan ring road circle, vatva, Ahmedabad India.
API LOT #	**LF/CLOZ/042022/002**
Description of Pack (Container closure system)	Off white to light yellow colored round biconvex compressed tablet plain on both side blistered with ALU/PVC and packed in printed 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: 24months*(Data submitted of 06 months)*		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18& 24(Months)		
Batch No.	**002DS01**	**002DS02**	**002DS03**
Batch Size	1834 Tablets	1834 Tablets	1834 Tablets
Manufacturing Date	10/2022	10/2022	10/2022
Date of Initiation	18/10/2022	18/10/2022	18/10/2022
No. of Batches	03		

Administrative Portion

49.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
50.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
51.	Documents for the procurement of API with approval from DRAP (in case of import).	K-632264687816 dated 23-06-2022
52.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
53.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
54.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Initial Shortcomings in applications and reply of the firm:

Observations	Reply of firm
1.4.3 Please submit following information related to Asset purchase agreement (APA) made between OBS &Viatris.	
v. Description of assets to be sold, including tangible and intangible assets, real estates, intellectual property and contracts	Only brands with their complete drug product dossiers have been acquired along with their intellectual property rights and Marketing Authorization [MA]. List of acquired brands is **enclosed as Annex-I**
vi. Closing conditions of the agreement.	Approval from Competition Commission of Pakistan and State Bank of Pakistan, which have been duly obtained. OBS Pakistan shall initiate the process to deliver funds or cause to be delivered to Viatris.
vii. Indemnification conditions regarding who is responsible for any liabilities arising from the sold assets.	The company who has sold the product and issued the warranty will be responsible until its shelf life. Similarly, OBS Pakistan will be responsible for those batches which will be supplied by it after the closing /MA transfer of these products.
iii. Details of transfer of Intellectual property including patents, trademarks, copyrights etc.	We have acquired the trademarks of products.

1.4.4 Please submit the following	
legalized copy of No Objection Certificate issued by Viatris for allowing OBS to use brand name "Clozaril".	The No objection Certificate [NOC] is under legalization process, and we will submit the legalized NOC before issuance of the transfer letter.
1.6.5 Please submit details of the following:	
v. Are API supplier and Excipient suppliers of Viatris for the proposed drug product, part of Asset purchase agreement?	Yes, Viatris has transferred complete and up-to-date drug product dossiers concerning the **"Clozaril Tablet"** to the OBS. It is a documentation based **"Product Knowledge transfer"**. The details of drug substance and excipients & packing included in the technical dossier submitted in DRAP for approval of local manufacturing in Pakistan, has been finalized after comparing with drug product dossier provided by Viatris for Clozaril Tablets. The specifications and relevant functional characteristics of the starting materials (APIs and excipients) to be used at AGP are consistent with materials used at the Viatris. The formulation of the drug product for local manufacturing is same as compared with formulation of Clozaril manufactured by Viatris.
vi. Drug Substance manufacturer and excipients manufacturer for the drug product **"Clozaril "** used by Viatris.	Currently, Clozaril is manufactured in Germany. Therefore, they are using the drug substance complied with Eur. Phr. The monograph of Eur. Phr. Is enclosed as **Annex-II**
vii. Please justify that API supplier chosen by OBS has same impurity profile of API and bioequivalence to the API supplier of Viatris.	We have selected the drug substance that complies with USP because of the following factors: - • The specifications and relevant functional characteristics of the starting materials (APIs and excipients) to be used in local manufacturing in Pakistan are consistent with materials used at the Viatris. • Technology transferhas been made with documented evidence that OBS can manufacture the Clozaril, with same processesand methodsas per set of specifications as agreed with the Viatris. • The limits of impurities are same in USP and Eur. Phr. While USP also required to perform test for residual solvents as well as the particle size of our API is D (90) less than 10 microns which will also enhance the dissolution & improve the bioavailability, **enclosed in Annex-II.** • The finished product is currently registered with USP specs. The manufacturing process and excipients recommended in the dossier are same used in our Drug Product formulation **(Annex-IV)**. • We have done the pharmaceutical equivalence study and comparative dissolution test with Clozaril and submitted with the dossier.
iii. Submit COA of API supplier of Viatris.	The COA of API supplier of Viatris submitted.

<u>Formulation & Process Equivalence Summary</u>

S#	Components	Clozaril by Madaus GmbH	Clozaril by AGP

4.	Composition	Clozapine, Lactose, Starch Maize, Talc, PVP, Colloidal silicon Dioxide, Magnesium Sterate.	Clozapine, Lactose monohydrate, Starch Maize, Talc, PVP, Colloidal silicon Dioxide, Magnesium Sterate.
5.	Process Flow Chart	Dry mixing → wet granulation → drying → crushing → blending → lubrication → compression	Dry mixing → wet granulation → drying → crushing → blending → lubrication → compression
6.	Physical Parameters	25 mg Tablets ---- round flat shape 100 mg Tablets --- round biconvex shape	25 mg Tablets ---- round flat shape 100 mg Tablets --- round biconvex shape

Pharmaceutical Equivalence Summary

S#	Components	Reference Product	Clozaril by AGP
12.	Active Moeity	Clozapine	Clozapine
13.	Salt/Ester	N/A	N/A
14.	Product Dosage form	Immediate Release Tablet	Immediate Release Tablet
15.	Route of Administration	Oral	Oral
16.	Amount of Drug	25 mg / Tablet	2 mg / Tablet
17.	Identification	By HPLC Retention Time	By HPLC Retention Time
18.	Disintegration time	2 min, 48 sec	1 min, 50 sec
19.	Uniformity of Dosage form	AV_{10}=3.26	AV_{10}=3.95
20.	Assay of the product	99.11% of the labeled amount	99.60% of the labeled amount
21.	Dissolution Rate	97% of the labeled amount	96% of the labeled amount
22.	Organic impurities	Below reporting limit	Below reporting limit

Decision:

The Registration Board approved request of the firm for change in registration status of Clozaril 100 mg Tablet *(Reg. no. # 097362)* from finished import to local manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML # 000348) (contract manufacturing) subject to submission of differential fee of Rs.45000/-

<table>
<tr><td colspan="2">Case No. 2</td><td colspan="4">M/s. SAMI Pharmaceuticals (Pvt.) Ltd., F-95, off Hub River Road, S.I.T.E, Karachi</td></tr>
<tr><td>1.</td><td>076759</td><td>Lagita Advance Suspension
Each 10ml of suspension contains:
Sodium Alginate BP...1gm
Potassium Bicarbonate BP....200mg
(Manufacturer's Specifications)</td><td>Lagita Advance Suspension
Each 10ml of suspension contains:
Sodium Alginate BP...1gm
Potassium Bicarbonate BP....200mg
(BP Specifications)</td><td>24-03-2015 Registration Board granted the renewal w.e.f. 24-03-2020 to 23-03-2025</td><td>Fee Rs.10,000/- deposited on 15-01-2020 Dy.No1059 - PR-I dated 18.08.2022</td></tr>
<tr><td colspan="2">Decision of 84th PRVC</td><td colspan="4">The committee considered the case and defer the request for confirmation of availability of applied formulation in BP.</td></tr>
<tr><td colspan="2">Reply of firm</td><td colspan="4">The firm submitted that their product complies to BP monograph of Alginate Antacid oral suspension compound. Moreover, the brand leader Gaviscon is also using term Alginate compound.</td></tr>
<tr><td colspan="2">Decision of 94th PRV</td><td colspan="4">The Chairman Registration Board on the recommendation of the Committee defer the case for confirmation of Innovator's formulation along with clarification as BP monograph mentions Alginate while instant formulation has 02 APIs.</td></tr>
<tr><td colspan="2">Fresh Reply</td><td colspan="4">Reg.: LAGITA ADVANCE Suspension Regn. No. 076759
Ref.: Your Letter No. F.94-PRVC/2023 (PR-I) dated 13th January, 2023

In response to your above referred letter, we are respectfully submitting hereunder point wise reply to each query

1. <u>Using 02 APIs:</u>

• Product title as per British Pharmacopoeia 2023 is "Compound Alginate Antacid Oral Suspension" and product description is as under
"Compound Alginate Antacid Oral Suspension is a suspension containing an alginate in a suitable flavored vehicle.<u>The suspension has an acid neutralizing capacity</u>." (Annex I)

• As per Handbook of Excipients "Salts of alginate do not have pH neutralizing capacity"
(Annex II)
• Potassium Bicarbonate is used in medicines as an antacid. It has been registered by FDA under the section of "suitable, safe and effective ingredients for OTC antacids."(Annex III)
• Alginate-based formulations either contain alginate as the principle active agent or combine the alginate with antacid (a type of medicine that is alkaline in nature and works by neutralizing excess acid)
• Secondly it is also evident, according to the definition and testing requirement of BP, that the product should contain more than one API:
"Content of aluminum, Al; calcium; Cal magnesium, Mg; potassium, K; sodium, Na, as appropriate 84.0 to 116.0% of requisite amount, this being calculated from the stated amounts of the relevant constituents"
(Annex I)
• Sodium Alginate itself does not contain any of the above constituent except Sodium

2. <u>Confirmation of Innovator formulation:</u>

• As per Public Assessment Report of GAVISCON ADVANCE SUSPENSION:</td></tr>
</table>

	▪ *Gaviscon Advance contains the ingredients sodium alginate and potassium bicarbonate, and belongs to a group of medicines known as "reflux suppressants".* ▪ *Reflux is a process in which the acid stomach juices flow back up into the food pipe.* ▪ *Unlike the stomach, the food pipe is not resistant to acid so that when reflux occurs, it causes pain and discomfort commonly known as heartburn.* ▪ *Gaviscon Advance forms a protective layer that floats on top of the stomach contents and keeps the stomach contents away from the lining of the food pipe to relieve the symptoms of heartburn and acid indigestion* **(Annex IV)** . • *As per a* ***Review article****:* ***Alginate-raft formulations in the treatment of heartburn and acid reflux*** ▪ *"Alginate-based formulations also contain antacid components, which can provide significant* ***acid neutralization capacity****, the efficacy of these formulations to reduce heartburn symptoms does not appear to be totally dependent on the neutralization of bulk gastric contents."* ▪ *"Alginate-based raft-forming formulations usually contain sodium or potassium bicarbonate"* **(Annex V)** **Conclusion:** Based on above-stated references, it is evident that: • BP monograph is for the more than one API and not for Sodium Alginate only • Our product does comply with BP and Innovator Specs both
Decision of 102 PR-I	*The Chairman Registration Board on recommendation of committee decided to refer the complete case to Registration Board.*
Remarks	
Decision	**Registration Board considered the data submitted by firm and acceded to request of firm for change in finished product specifications from "Manufacturer's Specifications" to "BP Specifications".**

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s NabiQasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, for export purposes only.

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

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 2-20/85-Lic dated 27-04-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 27-05-2022
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.	Irpo Syrup Each 5ml contains: Iron (III) hydroxide polymaltose complex equivalent to Elemental Iron.....125mg	Purchase order from Kenya	Dy. No. 533(02.06.2023) Rs.75,000/- (23.02.2023) Registration status of formulation in country of import is required.

Decision:

Registration Board deliberated that although the aforementioned formulation is neither a 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 Kenya. Hence, to increase the export revenue of the country, Registration Board approved above product exclusively for export purpose only.

Case No.02: Registration of Drug (s) of M/s Glitz Pharma, Plot No. 265, Industrial Triangle, Kahuta Road Islamabad, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-35/2003-Lic dated 22-09-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 17-06-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Ferilitz Plus Syrup Each 5ml contains: Ferric ammonium citrate.....45mg Folic acid BP.....0.5mg Vitamin B1 BP.....1mg Vitamin B6 BP.....2mg Vitamin B12 BP.....18mcg Nicotinamide.....10mg	Purchase order from Burundi	Dy. No. 499(31.06.2023) Rs.75,000/- (23.02.2023) Registration status of formulation in country of import is required.

Decision: Registration Board deliberated that although the aforementioned formulation is neither a me-too formulation nor available in any RRA. However, based on purchase order from Burundi & to increase the export revenue of the country, Registration Board approved above product exclusively for export purpose only.

Case No.03: Registration of Drug (s) of M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area 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 2-11/2005-Lic dated 15-06-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of

	DML dated 12-02-2020
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

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.	Infacolic Drops Each ml contains: Simethicone.....40mg Dill Oil.....0.005ml Fennel oil.....0.0007ml	Purchase order from Yaman	Dy. No. 545(06.06.2023) Rs.30,000/- (29.06.2023) Rs.45,000/- (29.06.2023) Registration status of formulation in country of import is required.
2.	Fero B Syrup Each 5ml contains: Green iron (ferric ammonium citrate) BPc.....200mg Thiamine HCl BP.....2mg Riboflavin BP.....0.5mg Cyanocobalamin BP.....2.5mcg Nicotinamide BP.....5mg	Ero B Syrup by M/s Eros	Dy. No. 546(06.06.2023) Rs.30,000/- (13.05.2023) Registration status of formulation in country of import is required. Differential fee of Rs. 45000/- is required.

Decision:

Registration Board deliberated that although the aforementioned formulations are neither me-too formulations nor available in any RRA. However, the said formulations are simple formulations which do not require special manufacturing conditions and the firm has purchase order from Yaman. Therefore, to increase the export revenue of the country, Registration Board decided as follows:

- **Approved the product at Sr. No. 1 exclusively for export purpose only.**
- **Approved the product at Sr. No. 2 exclusively for export purpose only subject to submission of differential fee of Rs. 45000/-.**

Case No.04: Registration of Drug (s) of M/s Winlet Pharmaceuticals (Pvt.) Ltd, 30-Km, Lahore Sargodha Road, Sargodha, 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 cGMP Certificate dated 25-11-2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 25-11-2022
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.	Kofrelax-D EXP Syrup Each 5ml Syrup contains:	Purchase order from Senegal	Dy. No. 563(08.06.2023) Rs.30,000/- (11.05.2023)

	Guaiphenesin.....50mg Phenylephrine HCl.....5mg Chlorpheniramine Maleate.....2mg Ammonium Chloride.....100mg		Rs.45,000/- (02.06.2023) Registration status of formulation in country of import is required.
2.	Maxiglobin FA Syrup Each 5ml syrup contains: Iron-III-Hydroxide polymatose complex eq to Elemental Iron.....125mg Folic acid.....0.35mg	Purchase order from Senegal	Dy. No. 564(08.06.2023) Rs.30,000/- (11.05.2023) Rs.45,000/- (02.06.2023) Registration status of formulation in country of import is required.

Decision:

Registration Board deliberated that although the aforementioned formulations are neither me-too formulations nor available in any RRA. However, the said formulations are simple formulations which do not require special manufacturing conditions and the firm has purchase order from Senegal. Therefore, to increase the export revenue of the country, Registration Board approved above products exclusively for export purpose only.

Case No.05: Registration of Drug (s) of M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-22/95-Lic dated 20-11-2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 02-02-2022
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.	Macofen Plus Suspension Each 5ml contains: Paracetamol.....162.5mg Ibuprofen.....100mg	Purchase order from Sudan	Dy. No. 580(09.06.2023) Rs.75,000/- (25.05.2023) Registration status of formulation in country of import is required.

Decision:

Registration Board deliberated that although the aforementioned formulation is neither me-too formulation nor available in any RRA. However, the said formulation is simple formulation which does not require special manufacturing conditions and the firm has purchase order from Sudan. Therefore, to increase the export revenue of the country, Registration Board approved above product exclusively for export purpose only.

<u>Deferred case 94-PRVC</u>

Case No. 1: Registration of Drug (s) of M/s Shrooq Pharmaceuticals (Pvt.) Ltd, 21-Km, Ferozepur Road, Lahore, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 488-444/C)

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 (Page-500/C). Approval of relevant section verified from letter No. F 1-29/2001-Lic (Vol-II) dated 05-01-2022 (Page 501/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 25-10-2022 (Page 502-503/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 504-545/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.	Oxomin Injection Each 1ml ampoule contains: Hydroxocobalamine Acetate eq to Hydroxocobalamine……..1mg/ml	Neutrofer by M/s Neutro	Dy. No. 8696/22 (27.12.2022) Rs.30,000/- (21.12.2022) **Correct Me-too status**

Decision of 94th PRVC:

"The Chairman Registration Board on the recommendation of the Committee considered the cases and deferred the request of the firm for product at sr. no. 4 for evidence of availability of formulation in Pakistan & RRAs."

Updated Status

The firm has submitted RRA status of above formulation in HPRA Ireland and has deposited differential fee of Rs 45000/-.

Decision:

Registration Board approved Oxomin Injection for export purpose only.

Deferred case 323-PRVC

Case No. 2: Registration of Drug(s) of M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road, Lahore Exclusively for Export Purpose.

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

Requirements as Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form-5; (Page No.1218–1226/C).
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 (P.No.1227/C). Approval of concerned Sections confirmed from issuance of DML dated 23-January-2019 (P.No.1228/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP Status/ application submitted by firm for issuance dated 16-November-2021 (P.No.1229/C)
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (P.No.1231-1232/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(R&I)/Fee with date
I	II	III	IV
1.	Ferroplex 40mg Injections Each ml contains: Activated Vitamin B12 (injectable raw liver, N.F. 2mcg/ml) Equivalent to Cyanocobalamin……...…….0.20mcg Vitamin C……...……5.00mg Vitamin B12 (Cyanocobalamin)……500.00mcg	Mexico Approved Formulation	Dy. No.7578/22 (07.04.2022) Rs.75,000/- (11.03.2022)

	Ferrous Citrate…….....….0.02g Panthenol (B5)……...…….3.00mg Thiamine HCl (B1)……..……..50.00mg Riboflavin (B2)……...……0.60mg Pyridoxine HCl (B6)……..……3.00mg Niacinamide (B3)…….…….45.00mg Choline Chlorhydrate…….……6.00mg Inositol…….……..6.00mg		

Decision of 323rd RB:

"*The Registration Board approved the request of the firm for registration of product for Export Purpose Only."*

At the time of issuance of registration letter, it was observed that Injectable raw liver is mentioned along with activated Vitamin B12, so it was decided to ask the firm for clarification of said formulation for which the firm has submitted the following response:

"It is stated that Activated Vitamin B12 are vitamins in their most active form, meaning that they are more bioavailable for immediate absorption into your system.

When given via the parenteral route, it reaches the blood immediately, In the blood, it attaches itself to plasma proteins. Tissues absorb vitamin B12 by specific B12 binding proteins, transcobalamin 1 and, II, allowing it to enter the cells. Most of the vitamin is stored in the liver. Vitamin B12 is essential for DNA synthesis and energy production. VitaminB12 is necessary for the growth and reproduction of many cells, which is especially critical for DNA repair and fetal development, Other useful function include maintaining the nervous system and aiding sheep in the production of wool."

Remarks:

The firm has not submitted any clarification of injectable raw liver mentioned in the composition of product.

Decision:

Registration Board deferred the case for clarification regarding using injectable raw liver in formulation.

Import & Vet-I Section

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Report of Manufacturer Abroad.

Following imported product approved in 321st 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. Medi Mark Pharmaceuticals, Liaqat Chowk, Sahiwal./ M/s. Shanghai Starry Pharmaceutical Co., Ltd., No. 500, Maoye Road, Jinshan Industrial Zone, Shanghai, China	Hexol Injection 100ml Each 100ml contain:- 75.5gm of Iohexol equivalent to 35gm of Iodine (350mg Iodine/ml)	(i) Mr. Abdullah Abro, Deputy Director (CD), Drug Regulatory Authority of Pakistan, Islamabad. (ii) Syed Zia Husnain, Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Islamabad.

Accordingly, inspection was carried out by inspection panel dated 21st & 22nd 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 there are certain observations regarding GMP as mentioned above in the report. Moreover, the firm finished product specifications were as per Chinese pharmacopeia instead of BP or USP. Initially firm was reluctant to show the retained sample room, however same was shown after about one hour. Firstly, firm also claimed that their product is also registered in other countries, however during verification it was revealed the product is only registered in China with Chinese Pharmacopeia Specifications. Stability data for Pakistan market is also required.

Under the explained circumstances panel is of the view that re-verification requires to be done after developing of process validations of product under reference as the USP, stability testing with proper documentation as well as submission of CAPA by the manufacturer on observations mentioned above in the report.

Panel also strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm with one year of re-verification as virtual inspection can never replace physical/in-person inspection. Moreover, detailed and systematic evaluation of mechanical operations of production and QC equipment, documents, SOPs, Log book etc. and respective cross discussion with the technical and operational staff can only be done through on-site inspection.

Decision: -

Registration Board 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.

Case No. 02: 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 Projects Pvt. 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.

Decision: -

Registration Board 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.

Case No. 03: Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 324th meeting approved following drugs as per policy of inspection of manufacturer abroad of below mentioned products in the name of /s. Better Traders International, 23-Z, Saifullah Shaheed Road, Madina Town, Faisalabad subject to submission of full fee of registration for correction/pre-approval change in DSL address as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 before issuance of registration letter.

M/s. Better Traders International, 23-Z/E, Saifullah Shaheed Road, Madina Town, Faisalabad./ **Manufacturer & marketing authorization holder** M/s. Kepro B.V. Maagdenburgstraat 17, 7421 ZA Deventer, Holland.	Doxyvet 200 Water Soluble Powder Each gam contains:- Doxycycline Hyclate…200mg
	Oxy 200 Water Soluble Powder Each gram contains:- Oxytetracycline HCl…….200mg
	Vit AD3E 300 Injection Each ml contains:- Vitamin A……...300,000 IU Vitamin D3……..…100,000 IU Vitamin E……..…...50mg
	Vitaflash Injection Each ml Contains: Vitamin A……..…50,000 IU Vitamin D3……...25,000 IU Vitamin E……..….4mg Vitamin B1 HCl……..……2.5mg Vitamin B2 Phosphate Sodium….2mg Vitamin B3……...….12.5mg Vitamin B6 HCl……1.25mg Vitamin B12……...…..30µg Vitamin C……...……2mg D-Panthenol……...……3mg

As per SRO No.F.7-11/2012B&A/DRAP dated 07-05-2021 correction/pre-approval change in DSL address full fee is not mentioned and as per practice such cases consider with fee Rs.7500/- if fall under pre-registration and Rs.10,000/- in case of post registration variation.

Decision:-

Registration Board deliberated the matter and decided to process the case as per No.F.7-11/2012B&A/DRAP and the policy of inspection of manufacturer abroad

Case No. 04:- 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:-

. 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:-	(Manufactured by M/s. Industrial	Market Authorization Holder &	100g 1 Kg 5 Kg	22-05-2014 13-03-2019

		Lincomycin (as HCL)……..150mg	Veterinaria, S.A.-Invesa Esmeralda, 19, E-08950 Esplugues De Llobregat (Barcelona) Spain).	Manufacturer:- M/s. Industrial Veterinaria, S.A. Esmeralda, 19 08950 Esplugues De Llobregat (Barcelona) Spain). 03 years		

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.

Decision:-

Registration Board 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.

Case No. 05: Registration of Drugs under the Drugs Act, 1976.

M/s Biorific Pharma, Islamabad submitted a request for consideration of their product referred to expert working group in 324th meeting as similar formulation of M/s Decent Pharma, Islamabad approved in the same meeting. The details are as under:

Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
Brand Name +Dosage Form + Strength	Pneumodox Oral Powder
Composition	Each 1000gm contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…500 MIU Bromhexine HCl…5gm Streptomycin Sulphate…20gm
Diary No. Date of R& I & fee	Dy.No 17326 dated 12-09-2019 Rs.20,000 dated 12-09-2019
Pharmacological Group	Antibiotic/ Expectorant
Type of Form	Form 5
Finished product Specification	Innovator's specifications
Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: Decontrolled
Me-too status	Respi Dox Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Islamabad. (Reg. No. 072684)
GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
Remarks of the Evaluator [X]	• **Oral Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • Provided conversion of Colistin Sulphate from IU to miligrams. (19000IU of Colistin Sulphate = 1mg)

Decision 324: Referred to Ministry of Food Security to review therapeutic requirement keeping in view safety, efficacy and quality parameters.

Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
Brand Name +Dosage Form + Strength	ST-Dox Oral Powder
Composition	Each Kg contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…450 MIU Bromhexine HCl…5gm Streptomycin Sulphate…36gm
Diary No. Date of R& I & fee	Dy.No 18065 dated 19-09-2019 Rs.20,000 dated 19-09-2019
Pharmacological Group	Antibacterial/ bronchodilator
Type of Form	Form 5
Finished product Specification	Manufacturer's specifications
Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg, 25Kg: Decontrolled
Me-too status	Pulmodox-S Powder of M/s Attabak Pharmaceutical Islamabad. (Reg. No. 071069)
GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
Remarks of the Evaluator [X]	• **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. • Provided conversion of Colistin Sulphate from MIU to grams. (19000IU = 1mg)
Decision 324: Approved.	

Decision:-
Registration Board deliberated the matter and decided to refer the case to Ministry of Food Security to review therapeutic requirement keeping in view safety, efficacy and quality parameters.

Case No. 6: Registration of Drugs under the Drugs Act, 1976

Registration Board in its 287th meeting approved the following imported veterinary products of M/s. Vet Line International, Flat No.55/5, First Floor, Main Shadman Market, Lahore as per following details:

S. No./	Name of Importer/ Manufacturer	Name of Drug(s) & Composition	Approved Packs Size/ Shelf Life	Decision
1.	M/s. Vet Line International, Lahore (Godown: Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-I, Lahore. / Manufacturer & Marketing Authorization Holder:- M/s. Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia.	Moxi 50% Oral Powder Each gm contains:- Amoxicillin (as Trihydrate)…500mg	1gm 500gm 1Kg 36 months	Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.
2.		Lincofeed 4.4% Powder Each Kg contains:- Lincomycin as Hydrochloride……44g	10 Kg 25 Kg 3 years	Approved as per policy of inspection of manufacturer abroad.
3.		Doxsure 50% Powder	100g	Approved as

		Each gm contains:- Doxycycline as Hydrochloride…500mg	500g 1000g 3 years	per policy of inspection of manufacturer abroad.

(i) The firm has submitted application with a fee of Rs.7500/- for each product for exemption of inspection abroad in the light of Circular No.F.3-2/2005-Reg-I (Vol-II) dated 10th September 2021 on the basis of CoPP issued by **PIC/S** participating authority i.e. Malaysia.

(ii) Firm has submitted email/documents which shows that manufacturer have no dedicated section for penicillin containing products and follow campaign basis manufacturing followed by decontamination and cleaning procedures.

As per DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976 SCHEDULE-B
5.2 Dedicated Facilities for Production
Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials **(e.g., penicillin)** or Biological preparation…. cytotoxic substances or radiopharmaceuticals or veterinary immunological preparation….

Firm reply against query:
Penicillin containing products should be manufactured on a campaign basis and should be followed by appropriate validated decontamination and cleaning procedures.
Attached documents:

1. **European Union:**

Official website of the European Union shows that
EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines
Manufacture of Veterinary Medicinal Products Other Than Immunological Veterinary Medicinal Products
Manufacture of veterinary medicinal products containing penicillins
7. The use of penicillins in veterinary medicine does not present the same risks of hypersensitivity in animals as in humans. Although incidents of hypersensitivity have been recorded in horses and dogs, there are other materials which are toxic to certain species, e.g. the ionophore antibiotics in horses. Although desirable, the requirements that such products be manufactured in dedicated, self-contained facilities (point 3.6) may be dispensed with in the case of facilities dedicated to the manufacture of veterinary medicinal products only. However, all necessary measures should be taken to avoid cross contamination and any risk to operator safety in accordance with the guide. In such circumstances, penicillin-containing products should be manufactured on a campaign basis and should be followed by appropriate, validated decontamination and cleaning procedures.

2. **Australian:**

Australian code of GMP practice for veterinary chemical products:
Products containing penicillins and other highly sensitising antibiotics The use of penicillins and other highly sensitising antibiotics in veterinary medicines does not present the same risks of hypersensitivity in animals as in humans. Nevertheless, when veterinary products containing penicillins and other highly sensitising antibiotics are not manufactured in dedicated facilities all necessary measures should be taken to avoid cross-contamination and any risk to operator safety

3. **Canada**

Good Manufacturing Practices Guidelines – Veterinary Drugs, Canada
Premises C.02.004 11.1 Campaign production can be accepted on a product by product basis where proper justification is provided, validation is conducted, and validated controls and monitoring are in place to minimize any risk of cross-contamination. In the case of facilities producing other veterinary drugs, campaign production of veterinary drugs containing penicillin is considered acceptable provided that the following conditions are met: • non-penicillin drug products for human use are not fabricated, packaged/labelled or stored in the same facility; and • validated decontamination and cleaning procedures are in place to minimize any risk of crosscontamination.

4. **PIC/S Guide**

i. PIC/S Guide to GMP for medicinal products 2021:

THE MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS CONTAINING PENICILLINS 7. The use of penicillins in veterinary medicine does not present the same risks of hypersensitivity in animals as in humans. Although incidents of hypersensitivity have been recorded in horses and dogs, there are other

materials which are toxic to certain species, e.g. the ionophore antibiotics in horses. Although desirable, the requirements that such products be manufactured in dedicated, self-contained facilities (point 3.6) may be dispensed with in the case of facilities dedicated to the manufacture of veterinary medicinal products only. However, all necessary measures should be taken to avoid cross contamination and any risk to operator safety in accordance with the guide. In such circumstances, penicillin-containing products should be manufactured on a campaign basis and should be followed by appropriate, validated decontamination and cleaning procedures.

Decision: -

Registration Board deliberated the matter and decided to refer the case to Authority for guidance in the matter.

Case No. 07:- Registration of Drugs under the Drugs Act, 1976/Issuance of Registration Letter.

Registration Board in its 324th meeting approved following imported veterinary drug of M/s Ghazi Brothers, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi as per decision mentioned alongside.

S. No.	Name of Importer/ Manufacturer	Name of Drug(s) & Composition	Approved Packs Size/ Shelf Life	Decision
1.	M/s. Ghazi Brothers, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi./ Manufacturer & Marketing Authorization Holder:- M/s. Richter Pharma AG, Feldgasse 19 4600 Wels, Austria.	Butomidor 10mg/ml Solution for Injection Each ml contains:- Butorphanol Tartrate.....14.58mg eq.to Butorphanol..10mg	Not mentioned As per Form-5A the pack size mentioned 10ml 5x10ml 10x10ml 50ml 3 years	Approved as per policy of inspection of manufacturer abroad.

During process for issuance of registration letter the manufacturer and market authorization holder mentioned in minutes are same but as per CoPP both are different. The details are as under:-

S. No.	Name of Importer/ Manufacturer mentioned in Minutes	Product License Holder & Manufacturer as per CoPP
	M/s. Ghazi Brothers, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi./ Manufacturer & Marketing Authorization Holder:- M/s. Richter Pharma AG, Feldgasse 19 4600 Wels, Austria.	**Product License Holder** M/s. Richter Pharma AG, Feldgasse 19 4600 Wels, Austria. **Manufacturer:** M/s. Richter Pharma AG., DurisolstraBe 14, 4600 Wels, Austria.

Accordingly, registration letter issued to M/s. Ghazi Brothers, Karachi as per CoPP.

Decision: -

Registration Board noted the information.

Case No. 08:- Registration of Drugs under the Drugs Act, 1976/Issuance of Registration Letter.

Registration Board in its 287th & 312th meetings approved the below mentioned products as per policy of inspection of manufacturer abroad as per decision mentioned alongside. Details are as under:-

S. No	Name of Applicant/ Manufacturer	Name of Drugs & Composition	Shelf Life and Pack Sizes
1.	M/s. Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, District Sargodha./ Manufacturer & Marketing Authorization Holder:- M/s. Vietnam Sakan Technology Development & Investment Joint Stock Company. Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District BacNinh Province, Veitnam.	Genmox LA Injection Each 100ml contains:- Amoxicillin (as trihydrate)…..….15gm Gentamicin(as sulphate)……..……..4g Solvent (Propylene glycol dicaprylocaprate)….q.s **(M-287)**	20ml 50ml 100ml 24 months
2.		Amox LA Injection Each 100ml contains: Amoxicillin (as trihydrate)…15gm **(M-287)**	20ml 50ml 100ml 24 months
3.		Cef 5.0 Injection Each 100ml contains:- Ceftiofur (as hydrochloride)…5gm **(M-287)**	20ml 50ml 100ml 24 months
4.		Doxy 50% Gold Oral Water Soluble Powder Each 100g contains:- Doxycycline HCl…50g Bromhexine HCl……250mg **(M-312)**	20g 50g 100g 2 years
Approved with Innovator' specifications as per policy of inspection of manufacturer abroad.			

Virtual inspection of the manufacturer abroad M/s. Vietnam Sakan Technology Development & Investment Joint Stock Company. Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District BacNinh Province, Veitnam was carried out by the nominated panel comprising Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), Drug Regulatory Authority of Pakistan, Islamabad & Mr. Ayaz Ahmad, Deputy Director (HOTC), Drug Regulatory Authority of Pakistan, Islamabad on 28th February, 3023 and **the panel rated the manufacturing facility as "good" and recommended for betalactams and non- betalactams oral powder.**

Accordingly, registration letter issued to M/s. Atzan Pharmaceuticals, Sargodha for product at Sr.No.4. Remaining product at Sr.No.1-3 of above mentioned products are not recommended by the panel of inspector's.

Decision: -

Registration Board deliberated the matter and decided to remand back the case, limited to the products at sr. no. 1-3, to inspecting panel for clear and candid recommendation regarding the grant of registrations of the said remaining products.

Import & Vet-II Section

Case No. 1 REGISTRATION OF DRUGS UNDER DRUG ACT, 1976.

M/s Martin Dow Limited Submitted a request with reference to the decision of 324th meeting of registration board held on 24th to 26th January 2023 regarding registration of Alvosuni Capsule 50mg (Sunitinib)

imported in Finished Pharmaceutical Product from Lotus Pharmaceutical Co., Ltd., Taiwan.
Decision of M-324;

Approved as per policy of inspection of manufacturer abroad and according to Authority's (DRAP) decision regarding Import of finished drug product from Taiwan.

• Firm shall submit full fee of registration as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter since firm had initially applied fee from the head of DML instead of DSL.

Firm request is reproduced as under:

We M/s Martin Dow Limited, License No 000267 would like to inform your good self that we have submitted our application on DSL License No # 565 issued for the premises situated at Plot No. 37 Sec 19 Korangi Industrial Area Karachi, as per the CTD guidance document PE&R/GL/AF/004 dated 1st October 2020 Section 1.3.4. Only the challan generated as per the Online Challan & Fee Submission procedure via portal is on DML. Therefore, DML number is mentioned on deposit slip while the application for product registration was applied on DSL and rest of the details are same as mentioned above.

Meanwhile, the same case was addressed in 307th. Drug Registration Board meeting held on 8-10th June 2021. via short coming on M/s Pfizer Pakistan Limited, where the applicant also clarified that the application was filed on DSL and only the fee challan was on DML while maintaining that both licenses belong to the same factory. This response considered to be justified by the board in 313th Meeting of DRB held on 16- 18 November 2021 and subsequent approval was granted to the applicant.
With reference to the above justification and the provided documents, we would like to request you to please consider our case on the same ground and issue us the registration letter with the following details and proposed brand name as per COPP to avoid any delay in this life-saving drug (chemotherapeutic agent) used for the treatment of renal cell carcinoma (RCC) and imatinib-resistant gastrointestinal stromal tumor (GIST) to be marketed in Pakistan.

Decision: -

Registration Board deliberated the matter and decided to refer the case to Authority for decision/guidance.

Case No.02: REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.

M/s GlaxoSmithKline Pakistan Limited, 35 West Wharf, Dockyard Road, Karachi has submitted request for cancellation of registration of imported drugs as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	009975	Zovirax IV for Infusion Each vial contains: - Acyclovir 250mg sterile freeze dried acyclovir as the sodium salt.	Suitable therapeutic alternatives and advance therapies are available in the market. Better / new molecules to cater the same portfolio are also available in the market. Virtually there is no demand of this product in local market	Aclova of M/s Akhai Aclovir of M/s Genix Acylex of M/s Ferozsons Clovirex of M/s Brookes Hypovir of M/s Nabiqasim
2.	010333	Zovirax Cream Contains: - Acyclovir 5% w/w		-do-
3.	086486	Incruse Ellipta Dry Powder Inhaler Each pre-dispensed dose contains. Umeclidinium (equivalent to 74.2 mcg of umecidinium bromide).....62.5mcg		Breavent of M/s Highnoon Combivair of M/s Highnoon Formiet M/s Getz
4.	010058	Imuran Tablets Each tablet contains: - Azathioprine BP 50mg		Amorin of M/s Mass Pharma Pharmazorine of M/s Pharmedic Azafrine M/s Al-Habib

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision: -

Registration Board deliberated the matter and decided to refer the case to Authority for guidance.

Case No.03: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for cancellation of registration of imported drugs as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products

1.	001581	Syntocinon Injection 2IU	Products have been divested to M/s Mylan Pharma GmbH, globally. Manf. & License holder of these products have already de-registered and discontinued production globally.	Oxytocin of M/s Dosaco Labs. Oxytocin of M/s Shifa Labas. Tocinox of M/s Geofman Pharmaceuticals.
2.	001582	Syntocinon Injection 5IU		-do-
3.	080132	Syntocinon Injection 5IU Each ampoule contains: Synthetic oxytocin ..5IU (USP Specification)		-do-

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision: -

Registration Board deliberated the matter and decided to refer the case to Authority for guidance.

Case No.03: SANDOSTATIN (OCTREOTIDE) 0.1MG, 0.2MG, 0.5MG & 0.05MG INJECTION REGISTRED IN NAME OF M/S NOVARTIS PHARMA KARACHI

M/s Novartis Pharma Pakistan Limited Karachi holds the registrations of octreotide containing products used for symptomatic control and reduction of growth hormone (GH) and IGF-1 plasma levels in patients with acromegaly who are inadequately controlled by surgery or radiotherapy.
The firm has applied for change of manufacturing site on **10.03.2022** of product at Sr. No 1 & 2 from M/s Novartis Pharma AG Basle, Switzerland to M/s Delpharm Dijon 6 boulevard de l'Europe 21800 Quetigny France.:

Sr. No.	**Product Name and Reg. Number**	**Date of Reg**	**Manufacturer**
1.	Sandostatin 0.1mg 013472	19-01-1993	M/s Sandoz Pharma Switzerland.
2.	Sandostatin 0.05mg 013473	19-01-1993	**-do-**
3.	Sandostatin 0.2mg 086485	12-02-2018	M/s Novartis Pharma Stein AG, Schaffhausertasse, 4332 Stein Switzerland

During scrutiny of the documents it was observed that firm does not possess the approval of change of title from M/s Sandoz Pharma AG Basle, Switzerland to M/s Novartis Pharma AG Basle, Switzerland and then change of manufacturing site to M/s Novartis Pharma Stein AG, Schaffhausertasse, 4332 Stein Switzerland for the products mentioned in sr. no. 1 &2.

However, the firm submitted following document in the past.

i. The firm submitted a letter, for information and record, dated 25.04.1997 for change of name of parent company from M/s Sandoz Pharma AG Basle, Switzerland to M/s Novartis Pharma AG Basle, Switzerland for the products mentioned in sr. no. 1 &2.

ii. Subsequently, on 12.06.1998 the firm submitted a letter for shifting of Sandostatin from M/s Novartis Pharma AG Basle, Switzerland to M/s Novartis Pharma AG Stein, Switzerland but release and shipment point will remain as M/s Novartis Pharma AG Basle, Switzerland for the products mentioned in sr. no. 1 &2. No approval under rule 30 (2) was sought by the company/granted by the registration board.

iii. Renewal applications for year 2013 and 2023, wherein the manufacturing site submitted by the firm is M/s Novartis Pharma AG Stein, Switzerland, have been submitted within time.

The request of the firm for change of Mfg. site was considered in 79th & 80th meeting of Post Registration Variation Committee (PRVC) and referred to Registration Board. The Board in its 323rd meeting held on 6-8th December, 2022 deferred the case to seek legal opinion on above facts regarding change of manufacturing site from M/s Novartis Pharma AG Basle, Switzerland to M/s Novartis Pharma AG Stein, Switzerland without approval of DRAP.

Legal Opinion in the matter;

The company applied for change of manufacturing site earlier only to the extent for one strength. The remaining two said strengths were never applied by the company to the Registration board for change in manufacturing site. Therefore, these two strength becomes invalid to this extent. Further, if the company file application for change in manufacturing site afresh, the same may be processed in accordance with law.

As the Legal opinion has been received, hence the case is placed in the meeting of Registration Board for consideration of approval of new manufacturing facility i.e. M/s Delpharm Dijon 6 Boulevard de Europe 21800 Quetigeny France in light of following documents:

a. Full dossier on Form-5F (CTD) for new manufacturing site i.e., M/s Delpharm Dijon 6 Boulevard de Europe 21800 Quetigeny France.
b. Fee Rs. 150000/-
c. Renewal submission for year 2018 and 2023 (which are within time as required under the rules).
d. Legalized approval/CoPP by Swissmedic Switzerland for authorization of above-mentioned applied facility.
e. Legal opinion by Legal Affairs Division:

Decision:

Registration Board after deliberation and keeping in view the legal opinion of Legal Affairs Division these registration of the firm M/s Novartis Pharma Pakistan Limited Karachi become invalid. Registration Board decided as follows:

i. To refer back case to the legal affairs division for consolidated decision on the registration status of the products in question.

ii. **To approve the application submitted afresh and issue new registration certificates to the importer as per newly submitted CoPP accordingly.**

RRR Section

Case No.01: Regularization of Renewal of Registration for Contract manufacturing of M/s. Usawa Pharmaceuticals 146-Special Industrial Zone, (Export Processing Zone) Risalpur

Below mentioned product registered in name of M/s. Usawa pharmaceuticals, Risalpur was deferred in 7th meeting of renewal sub-committee held on held on 30th December 2022 for submission of fee Rs. 75000/- under SRO 1005(I)/2017 as renewal application was submitted on 21.12.2022 i.e. after due date but within 60 days. The firm has now submitted the fee details are as under:

Reg No.	Name of product	Initial date of Reg.	Date of application and Fee details	Decisions
085900	Ome-Stoch Injection 40mg	21-12-2017	Rs.75000/- Dy	Renewal is granted

	Each vial contains Omeprazole (as Sodium) …..40 mg (As per Innovator's Specifications) **Manufacturer:** M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad.		No.37274 Dated 21-12-2022 **Rs. 75000/- dated 09.02.2023**	w.e.f 21.12.2022 to 20.12.2027
Remarks: 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).				

Case No.02 Renewal applications of M/s. Roryan Pharmaceutical Industries (Pvt) Ltd. Plot No.85-B Industrial Estate Hayatabad, Peshawar submitted after due date but within sixty days

Sr. No.	Reg No.	Name of product	Initial date of Reg.	Date of application and Fee details	Decision
1.	078588	Clonazep 0.5mg Tablet Each tablet contains: Clonazepam……0.5mg (USP Specifications)	07/11/2014	Rs.10000/- Dy No.22970 Dated 07.11.2019 & **Rs.15000/- Dy No.20460 Dated 19.07.2022**	Renewal is granted w.e.f 07.11.2019 to 06.11.2024
2.	078589	Clonazep 2mg Tablet Each tablet contains: Clonazepam……2mg (USP Specifications)	07/11/2014	Rs.10000/- Dy No.22970 Dated 07.11.2019 & **Rs.15000/- Dy No.20460 Dated 19.07.2022**	Renewal is granted w.e.f 07.11.2019 to 06.11.2024
3.	078590	Olanzyan 5mg Tablet Each tablet contains: Olanzapine….5mg (USP Specifications)	07/11/2014	Rs.10000/- Dy No.22970 Dated 07.11.2019 & **Rs.15000/- Dy No.20460 Dated 19.07.2022**	Renewal is granted w.e.f 07.11.2019 to 06.11.2024
4.	078591	Olanzyan 10mg Tablet Each tablet contains: Olanzapine….10mg (USP Specifications)	07/11/2014	Rs.10000/- Dy No.22970 Dated 07.11.2019 & **Rs.15000/- Dy No.20460 Dated 19.07.2022**	Renewal is granted w.e.f 07.11.2019 to 06.11.2024

Item No. II Division of Biological Evaluation & Research

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Mr. Muhammad Kashif	DD-I	02
2.	Ms. Haleema Shareef	DD-II	17
3.	Mr. Hafiz Ahsan	DD-III	13
4.	Ms. Anam Saeed	DD-IV	15
Total			**47**

CASES OF DD-I (MR. MUHAMMAD KASHIF)

1. Case: ADDITION OF MANUFACTURING SITE.

M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi has applied for the addition of a manufacturing site for their already registered biological products as per the following details:

Reg. No. and date	Brand Name and Composition	Existing Registered Manufacturing Site	Demanded Additional Manufacturing Site
010204 Dated 11-11-2005	**Actrapid HM 100 IU/mL, 10 mL Vial** Suspension for injection in 10mL Vial.	M/s Novo Nordisk Production SAS, 45 Avenue d' Orleans, F-28000 Chartres, France.	M/s Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh.

The application has been evaluated as per approved SOPs and tabulated below:

Documents required as per SOP	Documents submitted by the firm	Remarks
Application on Form-5F	Submitted	
Required fee as per relevant SRO.	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 25106201728	
Copy of registration letter and last renewal status	Registration letter: dated 11-11-2005 Renewal application 13-05-2010 Renewal application 16-04-2015 Site change letter dated 06-03-2017 Copy of last renewal submission dated 04-05-2020	
Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	The firm has submitted legalized of CoPP (No. DA/6-39/05/2410) dated 19-01-2023 issued by the Directorate General of Drug Administration Mohakhali, Dhaka-1212. The CoPP specifies free sale status of the product in the exporting country. The CoPP also confirms the GMP status of the firm.	
Site master file of new manufacturing site in case of change of manufacturing site/ source	Submitted	
Revised Sole Agency Agreement when there is change in MAH	Submitted	
Undertaking that provided information/ documents are true & correct.	Submitted	

Form 5F Assessment report is as follows:

FORM 5-F ASSESSMENT REPORT
Actrapid® HM 100 IU/mL, 10 mL Vial

Documents required as per SOP	**Documents submitted by the firm**	**Remarks**
Name, address of Applicant / Marketing Authorization Holder	M/s Novo Nordisk Pharma (Private) Limited, 113, Shahrah-e-Iran, Clifton, Karachi-75600 Pakistan	
Details of Drug Sale License of Importer	Novo Nordisk Pharma (Pvt.) Limited **Address:** 113, Shahrah-e-Iran, Clifton, Karachi, Pakistan. **Address of go-down:** 208/1, Sector 23, KIA, Karachi Validity: 09-04-2023 Status: License to sell drugs by way of Wholesale.	
Name and address of marketing authorization holder/ Product License Holder (abroad)	M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.	
Name, address of manufacturer(s)	Eskayef Pharmaceuticals Limited 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh	
Name of exporting country	Bangladesh	
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** • Firm has submitted legalized copy of CoPP (No. DA/6-39/05/2410) dated 19-01-2023 issued by Directorate General of Drug Administration Mohakhali, Dhaka-1212. The CoPP specifies free sale status of the product in the exporting country. The CoPP also confirms the GMP status of the firm.	
Details of letter of authorization / sole agency agreement	Firm has submitted attested and legalized letter of product specific authorization from Senior Vice President (Submissions and Life Cycle Management) of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute and sale the registered product Actrapid® HM Vial 100IU/ml 10 ml Vial. The letter was issued on 07-February-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,	☒ Finished Pharmaceutical product import	

specify one the these	☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only	
Dy. No. and date of submission	Dy. No. 8141 dated 24-03-2023	
Details of fee submitted	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 25106201728	
The proposed proprietary name / brand name	**ACTRAPID® HM 100 IU/mL, 10 mL Vial** Solution for injection	
Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Active ingredient(s)** Insulin Human (rDNA) Ph.Eur. **Quantity /100Ml** 383.142 mg (Eq. to 350.000 mg as 100 % potency eq. to 10000 IU of Human insulin) **Human insulin is produced in Saccharomyces cerevisiae by recombinant DNA technology*	
Dosage form of applied drug	Solution for injection	
Pharmacotherapeutic Group of (API)	Drugs used in diabetes. Insulins and analogues for injection, fast-acting, insulin (human). ATC code: A10AB01.	
Reference to Finished product specifications	Ph. Eur. Specs	
Proposed Pack size	Each Pack contains: 1 x 10mL Vial®	
Proposed unit price	MRP already available Actrapid® HM Vial Reg.No.010204	
Shelf Life	30 Months	
Storage Conditions	Store in refrigerator (2°C – 8°C).	
The status in reference regulatory authorities	Novo Nordisk A/S holds registration in Reference Regulatory Authorities. Eg: EMA & FDA Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute and sale the registered product Insulatard®. The letter was issued on 07-February-2023	
For generic drugs (me-too status)	Not Applicable	
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, manufacturer, description of manufacturing process and process controls, control of materials, control of critical steps and intermediates, process validation and/or evaluation, manufacturing process development, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material ,container closure system and stability studies of drug substance and drug product. The firm has also submitted the	

	non-clinical and clinical overviews and summaries		
Name, address of drug substance manufacturer	**Address**	**Activity**	
	M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark	Production of Master cell bank and working cell bank. Storage of Master Cell Bank and Working Cell Bank.	
	M/s Novo Nordisk A/S, Novo Allé, 4400 Kalundborg, Denmark.	Storage and stability testing of Master Cell Bank and Working Cell Bank. Recovery from fermentation broth. Purification of insulin human Quality control of in-process samples and drug substance.	
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical state, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material, 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 long term and accelerated time conditions. The long term stability data is conducted at -18°C±2°C for 60 months with 3 batches as per claim shelf life of 60 months. The accelerated study conducted at +5 °C±3°C for 12 months.		
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, no change statement concerning to Actrapid® 100IU/ml,10 ml, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.		
Analytical method validation/verification of product	The firm has submitted analytical methods as per specifications/Ph. Eur. The methods are validated as per SOPs. The Analytical methods are listed below • Macroscopy (Ph. Eur.) • Microscopy (Ph. Eur.) • Identity of Human insulin (Ph. Eur.) • Assay of insulin (Ph. Eur.) • pH (Ph. Eur. / USP / JP) • Insulin in the supernatant (Ph. Eur.) • High molecular weight proteins (Ph. Eur. / USP) • A21 Desamido insulin (Ph. Eur.) • Other related impurities (Ph. Eur.) • Zinc total (Ph. Eur. / USP / JP) • Bacterial endotoxins (Ph. Eur. Method D)		

	• Sterility (Ph. Eur. / USP / JP) • Total dissolved insulin (A2619a) • Isophane confirmation (A2361a) • Identity of preservatives (A2461a) • Phenol (A2461a) • Metacresol (A2461a) • Particulate matter (Ph. Eur. / USP / JP)	
Container closure system of the drug product	The vial is made of colorless glass with a hydrolytic resistance as defined in Ph Eur and USP (type I glass). The plunger is made of bromobutyl rubber.	
Stability study data of drug product, shelf life and storage conditions	Firm has submitted comparability report for 3 PPQ batches of stability manufactured at site Chartres and at Contract Manufacturing Site Eskayef stored for 30 months at long term conditions at 5°C ± 3°C.	
Module 4 & Module 5 (Non-Clinical & Clinical Documentation)	No change Statement concerning to Module 4 and Module 5.	

Decision: Registration Board after thorough deliberation decided to defer the case for following:

- **Legal provision regarding grant of additional manufacturing site.**
- **Evidence of approval of product in Reference countries manufactured in the proposed manufacturing site i.e, M/s Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh**

2. Case: <u>ADDITION OF MANUFACTURING SITE – HUMAN INSULIN INSULATARD® HM 100IU/ML, 10 ML VIAL</u>.

M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi has applied for the addition of a manufacturing site for their already registered biological products as per the following details:

Reg. No. and date	Brand Name and Composition	Existing Registered Manufacturing Site	Demanded Additional Manufacturing Site
010205 Dated 11-11-2005	**Insulatard HM 100IU/ml, 10 ml Vial.** Suspension for injection in 10ml Vial.	M/s Novo Nordisk Production SAS, 45 Avenue d' Orleans, F-28000 Chartres, France.	Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh.

The applications have been evaluated as per approved SOPs and tabulated below:

Documents required as per SOP	Documents submitted by the firm	Remarks
Application on Form-5F	Submitted	
Required fee as per relevant SRO.	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 02835880	
Copy of registration letter and last renewal status	Registration letter: dated 11-11-2005 Renewal application 13-05-2010 Renewal application 16-04-2015 Site change 16-03-2017. Copy of last renewal submission dated 04-05-2020	
Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country	Firm has submitted legalized copy of CoPP (No. DA/6-39/05/2408) dated 19-01-2023 issued by Directorate General of Drug Administration. The CoPP specifies free sale of the product in exporting country. The	

of origin.	CoPP also confirms the GMP status of the firm	
Site master file of new manufacturing site in case of change of manufacturing site/ source	Submitted	
Revised Sole Agency Agreement when there is change in MAH	Submitted	
Undertaking that provided information/ documents are true & correct.	Submitted	

Form 5F Assessment report is as follows:

FORM 5-F ASSESSMENT REPORT
Insulatard® HM Vial 100IU/mL, 10 mL Vial.

Documents required as per SOP	**Documents submitted by the firm**	**Remarks**
Name, address of Applicant / Marketing Authorization Holder	M/s Novo Nordisk Pharma (Private) Limited, 113, Shahrah-e-Iran, Clifton, Karachi-75600 Pakistan	
Details of Drug Sale License of importer	Novo Nordisk Pharma (Pvt.) Limited **Address:** 113, Shahrah-e-Iran, Clifton, Karachi, Pakistan. **Address of go-down:** 208/1, Sector 23, KIA, Karachi Validity: 09-04-2023 Status: License to sell drugs by way of Wholesale.	
Name and address of marketing authorization holder/ Product License Holder (abroad)	M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.	
Name, address of manufacturer(s)	Eskayef Pharmaceuticals Limited 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh	
Name of exporting country	Bangladesh	
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** • Firm has submitted legalized copy of CoPP (No. DA/6-39/05/2408) dated 19-01-2023 issued by Directorate General of Drug Administration Bangladesh. • The CoPP specifies free sale of the product in exporting country. • The CoPP also confirms the GMP status of the firm.	
Details of letter of authorization / sole agency agreement	Firm has submitted an attested and legalized letter of product-specific authorization from Senior Vice President (Submissions and Life Cycle Management) of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute, and sale the registered product Insulatard® HM Vial 100IU/ml	

	10 ml Vial. The letter was issued on 07-February-2023.	
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)	
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐Domestic and Export sales	
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only	
Dy. No. and date of submission	Dy. No. 8142 dated 22-03-2023	
Details of fee submitted	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 02835880	
The proposed proprietary name / brand name	**INSULATARD® HM 100 IU/ml, 10 ml Vial** Suspension for injection	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Active ingredient(s)** Insulin Human (rDNA) Ph.Eur. [Suspension of isophane (NPH) insulin] **Quantity/100ml** 383.142 mg (Eq. to 350.000 mg as 100% potency eq. to 10000 IU of Human insulin) **Human insulin is produced in Saccharomyces cerevisiae by recombinant DNA technology*	
Dosage form of applied drug	Suspension for injection	
Pharmacotherapeutic Group of (API)	Drugs used in diabetes. Insulins and analogues for injection, Intermediate-acting, insulin (human). ATC code: A10AC01	
Reference to Finished product specifications	Ph. Eur Specs	
Proposed Pack size	Each Pack contains: 1 x 10ml Vial®	
Proposed unit price	MRP already available Insulatard® HM Vial Reg.No.010205	
Shelf Life	30 Months	
Storage Conditions	Store in refrigerator (2°C – 8°C).	
The status in reference regulatory authorities	Novo Nordisk A/S holds registration in Reference Authorities. Eg: EMA & FDA Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk	

	A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute and sale the registered product Insulatard®. The letter was issued on 07-February-2023		
For generic drugs (me-too status)	Not Applicable		
Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, manufacturer, description of the manufacturing process and process controls, control of materials, control of critical steps and intermediates, process validation and/or evaluation, manufacturing process development, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material, container closure system and stability studies of drug substance and drug product. The firm has also submitted non-clinical and clinical overviews and summaries		
Name, address of drug substance manufacturer	**Address**	**Activity**	
	M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.	Production of Master cell bank and working cell bank. Storage of Master Cell Bank and Working Cell Bank.	
	Novo Nordisk A/S Hallas Allé 4400 Kalundborg Denmark	Storage and stability testing of Master Cell Bank and Working Cell Bank. Recovery from fermentation broth. Purification of insulin human Quality control of in-process samples and drug substance.	
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical state, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material, 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 long term and accelerated time conditions. The long-term stability data is conducted at -18°C±2°C for 60 months with 3 batches as per claim shelf life of 60 months. The accelerated study conducted at +5 °C±3°C for 12 months.		
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical		

	development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Analytical method validation/verification of product	The firm has submitted analytical methods as per specifications/Ph. Eur. The methods are validated as per SOPs. The Analytical methods are listed below • Macroscopy (Ph. Eur.) • Microscopy (Ph. Eur.) • Identity of Human insulin (Ph. Eur.) • Assay of insulin (Ph. Eur.) • pH (Ph. Eur. / USP / JP) • Insulin in the supernatant (Ph. Eur.) • High molecular weight proteins (Ph. Eur. / USP) • A21 Desamido insulin (Ph. Eur.) • Other related impurities (Ph. Eur.) • Zinc total (Ph. Eur. / USP / JP) • Bacterial endotoxins (Ph. Eur. Method D) • Sterility (Ph. Eur. / USP / JP) • Total dissolved insulin (A2619a) • Isophane confirmation (A2361a) • Identity of preservatives (A2461a) • Phenol (A2461a) • Metacresol (A2461a) • Particulate matter (Ph. Eur. / USP / JP)	
Container closure system of the drug product	The vial is made of colorless glass with a hydrolytic resistance as defined in Ph Eur and USP (type I glass). The plunger is made of bromobutyl rubber.	
Stability study data of drug product, shelf life and storage conditions	Firm has submitted comparability report for 3 PPQ batches of stability manufactured at site Chartres and at Contract Manufacturing Site Eskayef stored for 30 months at long term conditions at 5°C±3°C.	
Module 4 & Module 5 (Non-Clinical & Clinical Documentation)	No change Statement concerning to Module 4 and Module 5.	

Decision: Registration Board after thorough deliberation decided to defer the case for following:

- **Legal provision regarding grant of additional manufacturing site.**
- **Evidence of approval of product in Reference countries manufactured in the proposed manufacturing site i.e, M/s Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh**

CASES OF DD-II (MS. HALEEMA SHAREEF)

Imported Veterinary Biologicals from Non-Reference Countries:

3.	**Name and address of Importer**	**M/s. Jovac Global-PAK,** Plot No. 17, Block D, EME, DHA Phase 12, Lahore
	Detail of DSL	M/s. Jovac Global-PAK Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore.

		Valid up to:15.06.2023
	Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Name of exporting country	Jordan
	Brand Name +Dosage Form + Strength	Poultry Eye drop Vaccine solvent
	Diary No. Date of R& I & fee	Dy. No. 13029 R&I Dated 28-05-2022 Rs. 150,000/- (Slip No. 3016579226)
	Composition	Each ml contains: Active ingredient ... none. Sodium chloride…8mg Potassium chloride… 0.2mg Potassium dihydrogen phosphate…0.35mg Disodium hydrogen phosphate…1.15mg Brilliant Blue strain…0.2mg EDTA….0.2mg Water for injection q.s……1ml
	Pharmacological Group	Veterinary sterile vaccine solvent for eye drop
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	5 years (store below 25^0C)
	Document Details	a. Valid legalized free sale certificate is submitted by the firm. b. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020. c. Firm has submitted distribution agreement(not product specific)
	Pack size	30ml bottle
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Not provided
	Remarks of Evaluator	Initially firm has applied for transfer of registration from M/s. Eros Pharmaceutical to M/s. Jovac Global Pak, however now the firm has submitted clarification vide their letter dated 11-03-23 that it is a new registration application and word transfer of registration was written erroneously.
	Discussion: Registration Board was apprised that initially firm has submitted application for transfer of registration from M/s. Eros Pharmaceutical to M/s. Jovac Global Pak. Later on, the firm clarified vide letter dated 11-03-23 that it is a new registration application and word transfer of registration has been written erroneously. The Board directed the Division of BE&R to verify the registration status of the instant product with Eros Pharmaceutical. As per available record, no such registration was found with BE&R Division.	
	Decision: Keeping in view legalized FSC indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance to current import policy for finished drugs.	

Miscellaneous/Deferred Cases

Imported Human Biological i.e. AdimFlu-S (QIV) applied by M/s ASTO Life Sciences Private Limited. Lahore deferred in 316th meeting of Registration Board.

Following product of M/s ASTO Life Sciences Private Limited. Lahore deferred in 316th meeting of Registration Board as per following details:

4.	**Name and address of Importer**	**M/s ASTO Life Sciences Private Limited.** Plaza No. 1, Block Orchard No.1 Paragon City, Barki Road, Dist. Lahore.
	Detail of DSL	Drug Sale License as a distributor No. 05-352-0068-045428D valid upto 21-09-2021
	Name and address of Manufacturer	**Product License Holder & Manufacturer:** M/s Adimmune corporation, No. 3 Section 1, Tanxing Road, Tanzi District,Taichung city 42743 Taiwan.
	Brand Name +Dosage Form +Strength	AdimFlu-S (QIV) Quadrivalent Influenza Vaccine
	Diary No. Date of R& I & fee	Dy. No. 31262 Dated 24-11-2020 (Rs. 100,000/- Dated 24-11-2020)
	Composition	Each 0.5ml PFS contains: Hemagglutinin of Influenza A Virus (H1N1) ..... 15µg HA Hemagglutinin of Influenza A Virus (H3N2) ..... 15µg HA Hemagglutinin of Influenza B Virus (Yamagata lineage)….15µg HA Hemagglutinin of Influenza B Virus (Victoria lineage) ….15µg HA
	Pharmacological Group	Human Influenza Vaccine
	Type of Form	Form-5F
	Finished Product Specification	EUR. Ph. JP and CP
	Shelf Life	24 months (2°C-8°C)
	Document Details	i. CoPP No. 080558 dated 13-10-2020 (Notarized but not legalized)ii.GMP valid till 5-9-2021(Notarized but not legalized) ii. Copy of Sole Agency Agreement
	Pack size/ Price	1's PFS/ As per SRO.
	International Availability	Vaxigrip Tetra of M/s Sanofi Pastures France
	Products already registered inPakistan	Vaxigrip Tetra of M/s Sanofi Aventis Pakistan Ltd.
	Initial Remarks of Evaluator (Khurram Khalid)	i. Notarized copy of Sole Agency/ Market Authorization certificate. ii. CoPP and GMP certificates are not legalized. iii. In stability data, following tests have not been performed in long termstability data; a. Fractionation test b. Test for freedom from Ether c. Test for freedom from abnormal toxicity d. Identity test e. Overall albumin content test. While accelerated studies of only one batch has been provided. iv. Clinical Trial Data a. Phase II: A Phase II, One arm, Single dose, Open label, Single center study, in120 subjects b. Phase III: As Phase III, Single Dose, Randomized Double blind, Multiple-centerStudy. in 710 subjects. c. Phase III: Open label, Multiple-center Study, 174 subjects.
	Decision of Registration Board (297th meeting) Registration Board deferred the product for submission of following by the firm: a. Valid legalized Certificate of Pharmaceutical Product (CoPP) OR valid legalized GMP Certificate & valid legalized Free Sale Certificate. b. Original or Notarized copy of sole Agency Authorization. c. Pharmacopoieal monograph of the product. d. Clarification regarding not performing Fractionation test, Test for freedom from Ether, Test for freedom from abnormal toxicity, Identity test, Overall albumin content test in	

	stability data. e. Accelerated stability data of three batches.

Evaluation by DBE&R for 308th Reg. Board meeting

It is submitted that It is submitted that in context to the decision of Reg. Board the firm replied on 08-06-2021. The case was evaluated and is summarized as under;

Document required as per decision of RB	***Response submitted by the firm***	***Remarks of Evaluator***
Valid legalized Certificate of Pharmaceutic8al Product (CoPP) OR valid legalized GMP Certificate & valid legalized Free Sale Certificate.	Manufacturer, has submitted that CoPP and GMP were notarized and legalized from notary public and ministry of foreign affairs of Taiwan.	The firm has not submitted any document regarding the legalization by the Pakistan embassy.
Original or Notarized copy of Sole Agency Authorization.	Provided	Provided
Pharmacopoieal monograph of the product.	The firm has submitted that they follow Chinese Pharmacopoeia in Taiwan which is the same as European Pharmacopeia. However, pH Value, Test for freedom from ether and Formaldehyde complies with JPXVII Influenza HA vaccine. Furthermore, all other have been referred to European Pharmacopoeia for which the firm has also submitted the monograph. The firm has also submitted the Japanese monograph which is not for the applied product.	No single Pharmacopeia is being followed. The reason for following two different standard pharmacopeias is not mentioned.
Clarification regarding not performing Fractionation test, Test for freedom from Ether, Test for freedom from abnormal toxicity, Identity test, Overall albumin content test in stability data.	These are the parameters that do not decrease and increase over time. All the results complied with specifications; therefore, they were only tested at release.	The firm has provided following tests in stability data; 1. Appearance 2. pH Value 3. Potency test 4. Sterility test 5. Bacterial endotoxin.
Accelerated stability data of three batches.	We only have one batch for accelerated stability data. Generally, we do not have accelerated stability as regular items, which also do not necessary in Taiwan, so we do not have the accelerated stability data for three batches.	Accelerated stability data of three batches is not available.

The firm was asked to provide following documents through letter dated 15th June 2021:

1. The CoPP is not legalized by Embassy of Pakistan.
2. Regarding specifications
   a. A comparative summary of specifications of Chinese and European Pharmacopeia in tabulated form to assess similarity.
   b. Why two different standard pharmacopeias are being followed i.e. Japanese & European Pharmacopeia for different tests.
   c. The provided Japanese Pharmacopeia monograph is not for the applied product.
3. Any documental evidence that accelerated stability data of only one batch is required.

The complete response by the firm is pending and the firm has only responded to query raised at Sr. No.1. The firm has submitted that there is no embassy of Pakistan in Taiwan, hence the documents are only legalized and Notarized by the Notary Public.

Decision of Reg. Board in its 308th Meeting

"Registration Board deferred the products for submission of following by the firm:
a. Tabulated comparison of finished product specifications with pharmacopoeia monograph.
b. Accelerated stability data of three batches for 06 months."

Evaluation by DBE&R for 313th Reg. Board meeting

The firm has submitted the following:

a. *Tabulated comparison of finished product specifications with pharmacopoeia monograph indicating that the product complies with Ph. Eur. Specifications.*
b. *The firm has submitted accelerated stability data of 3 months for 1 batch and 02 months for 02 batches and informed that they don't have 6 months data.*

Decision of Reg. Board in its 313th Meeting:

The case was deferred in 313th meeting of Registration Board as per following details:
Registration Board deferred the case in its 313th meeting for following:

i. *Confirmation from Ministry of Commerce regarding Trade of vaccines from Taiwan.*
ii. *Submission of valid CoPP legalized from Embassy of Pakistan by the firm.*
iii. *Submission of 6 months accelerated stability data of 03 batches by the firm.*

Evaluation by DBE&R for 316th Reg. Board meeting

In this context, it is submitted that in response following letter has been received from Ministry of Commerce:

3. According to Policy Guidelines on Taiwan, there are no restrictions on trade with Taiwan subject to the following conditions:

- Trade is conducted strictly on un-official basis and through private sector only.
- No direct contacts to be made with the Taiwan authority agencies.
- No Pakistan government functionary can visit Taiwan.
- No Taiwan authority functionary can visit Pakistan.
- Government/official investment from Taiwan is not allowed into Pakistan.
- Exchange of delegation(s) is not allowed.
- Holding of trade exhibitions, establishment of display is not allowed.
- No publicity is given to Pakistan's trade or commercial contacts with Taiwan.
- Private businessmen can, technically, interact with Taiwan parties.
- No Pakistan government functionary can visit Taiwan.

Moreover, the firm has not yet submitted any response.

Decision of Reg. Board in its 316th Meeting:

Keeping in view response from M/o commerce, Registration Board referred the case to DRAP Authority for seeking guidance whether to proceed with grant of registration of finished drugproduct from Taiwan or otherwise.

Evaluation by DBE&R for 328th Reg. Board meeting:

A. *The Authority, after detailed deliberations and discussions decided as under:*

1. *Approved following guidelines regarding import of therapeutic goods from Taiwan:*

i. *The consignments of raw materials imported from Taiwan will be cleared by the DRAP*

Field offices subject to fulfilment of requisite codal formalities.

ii. *Registration/Enlistment of finished therapeutic goods from Taiwan will be granted, subject to fulfilment of conditions of registration/enlistment, except those requiring mandatory inspections by government functionaries (through physical presence).*

2. *The decision of the Authority will be shared with MOFA / Ministry of Commerce for their input and advice to further refine / modify or change if required under the prevailing policy dealing with Taiwan for private business activity.*

B. *Firm has submitted 6 months accelerated stability data of 03 batches however SRD value (potency) is not within specification limits i.e.12µg HA/0.5ml dose from 2 months to onward in accelerated stability studies.*

C. *Firm has not yet submitted valid CoPP legalized from Embassy of Pakistan for which the firm has already submitted in their reply that Embassy of Pakistan does not exist in Taiwan.*

Decision in 329th Registration Board meeting: *Registration Board deferred the case for submission of legalized CPP either attested from the embassy of Pakistan in China or by Ministry of foreign Affairs of Taiwan or any web link to verify the approval of subject product in any reference regulatory authority.*

Evaluation by DBE&R:
Firm has submitted notarized CoPP No. 080558 dated 13-10-2020 and now the firm has also provided a weblink of Ministry of Foreign affairs of Taiwan for verification of document Authentication. It is submitted that the certificate is verifiable from the website. The weblink is given below. (https://docauth.boca.gov.tw/BOCAWeb/index4/detail) (accessed on 25/07/2023 at 11:06am)

Decision: Keeping in view submitted notarized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs.

Miscellaneous/ Deferred Cases:

Application for change in title of Importer from M/s. ICI Pakistan Limited to M/s. Lucky Core Industries Limited.

M/s. ICI Pakistan Limited has applied for change in title of importer.
Previous Title: M/s. I-C-I Pakistan Limited.
New Title: M/s. Lucky Core Industries Limited.

Sr. No.	Brand Name and composition	Fee for change in title	Status of Product
5.	**Fortegra vaccine** (Coccidiosis Vaccine Live Oocysts) The amount of antigenic material per dose in the final container: - Minimum of sporulated oocysts throughout dating: Eimeria acervulina….600 Eimeria maxima….. 200 Eimeria maxima MFP…… 100 Eimeria mivati….. 400 Eimeria tenella… 200	Fee of 150,000/-(slip No. 4551086834)	Approved in 282nd meeting of Registration Board
6.	**PoulShot® LaSota** Each dose contains: Newcastle disease virus (NDV, LaSota strain) ..... $\geq 10^{6.0}EID_{50}$	Fee of 150,000/-(slip No. 923694814780)	Approved in 321st meeting of Registration Board
7.	**PoulShot® LaSota+IB** Newcastle disease virus (NDV, LaSota strain) …… ≥106.0EID50 Infectious	Fee of 150,000/-(slip No. 28987422)	- do-

	bronchitis virus (IBV, H120 strain) …… ≥102.5EID50		
8.	**FeliShot® PHC** Inactivated viral vaccine Composition per dose: Feline panleukopenia virus (FPV, CU4 strain)…….≥$10^{4.8}$ $TCID_{50}$ Feline herpesvirus (FHV, FVR-G strain)…….≥$10^{6.2}$$TCID_{50}$ Feline calicivirus (FCV, FCV-255 strain)…….≥$10^{6.2}$$TCID_{50}$	Fee of 150,000/-(slip No. 908341038477)	Approved in 287th meeting of Registration Board
9.	**CaniShot® DHPPL** Composition per dose: Canine distemper virus (CDV, Onderstepoortstrain)…..…….30% Canine adenovirus type 2 (CAV-2, Manhattan strain)…….10% Canine parvovirus (CPV, 780916-LP strain)……20% Canine parainfluenza virus (CPIV, D008 strain)……..20% (Freeze dried vaccine) **CaniShot® Lepto** Leptospiracanicola……0.5ml Leptospiraicterohaemorrhagiae…….….0.5ml (Aqueous injection)	Fee of 150,000/-(slip No. 77911503)	- do-
10.	**CaniShot® RV-K** Composition per dose: Rabies virus(RV, Pasteur strain)……≥$10^{7.0}$FAID50	Fee of 150,000/-(slip No. 7289029657)	- do-
11.	**PoulShot® Flu H9N2+ND** Freeze dried vaccine Composition per dose: Avian influenza virus (AIV, H9N2, 01310 strain)…….≥$10^{9.5}$$EID_{50}$ Newcastle disease virus (NDV, LaSotastrain)……..≥$10^{9.5}$$EID_{50}$	Fee of 150,000/-(slip No. 13292995979)	- do-
12.	**ROTAVEC® CORONA** Emulsion for injection for cattle Each 2ml Dose contain: Bovine rotavirus strain UK-Compton, Serotype G6 P5…….$10^{7.6}$-$10^{7.9}$ TCID50 Bovine coronavirus, Strain Mebus (Inactivated)…...150-230ELISA units. E.Coli F5 (K99) adhesion…….100-200 Units.	Fee of 150,000/-(slip No. 97384010237)	Approved in 324th meeting of Registration Board
13.	**COVEXIN™ 8** Clostridial vaccine (40ml) Each ml contains: C. chauvoei whole culture ……sufficient to provide the required immunogenic activity per recommended animal dose C. haemolyticum toxoid and cells……. ≥10U/mL C. novyi toxoid and cells…….≥3.5 IU/mL C. perfringens type B toxoid and cells and Type C toxoid…….≥10IU/mL β C. perfringens type D toxoid…….. ≥5IU/mL Ɛ C. septicum toxoid ……≥2.5IU/mL	Fee of 150,000/-(slip No. 742401381583)	- do-

	C. tetani toxoid…….. ≥2.5IU/mL		

The firm has applied for the change in title of importer and submitted following with their application:

a. Fee of 150,000/- for each product
b. Apostille letter of authorization with new title M/s. Lucky Core Industries Limited for products at serial No. 1-7 and notarized letter of authorization for product at serial No. 8 but letter of authorization with new title is yet not submitted by firm for product at serial No. 9.
c. Previous DSL
d. New DSL valid

The details of previous and new DSLs are as under;

DSL	Title of the firm	Address
Previous	M/s. I-C-I Pakistan Limited.	5 West Wharf Karachi
New	M/s. Lucky Core Industries Limited.	5 West Wharf Karachi

It is submitted that firm has provided apostille letter of authorization with new title M/s. Lucky Core Industries Limited. and for acceptance of apostille documents following opinion of Legal affairs division is received:

The following Press Release (53/2023) has been issued by the Ministry of Foreign Affairs on 09.03.2023 regarding Pakistan's Accession to Apostille Convention which is available on its official website https://mofa.gov.pk/pakistans-accession-to-apostille-convention/

> ***"****Government of Pakistan has acceded to The Hague Convention Abolishing the Requirement of Legalization for Foreign Public Documents (Apostille Convention) of 1961. The convention shortens the public document authentication process to a single formality i.e. issuance of an authentication certificate called as 'Apostille' by the designated authority of the country where the document was issued. Thus Foreign public documents authenticated by Apostille can be directly presented to the concerned authorities without any other attestation requirement. In line with the obligations as contracting state of the Convention, concerned authorities of Pakistan will now accept the Foreign Apostille Certificates issued by the members/contracting States of the convention from the date of entry into force i.e. 9th March 2023, without any requirement of attestation from Ministry of Foreign Affairs or Pakistan Missions abroad. [...]"*

As per reservation / declaration of the Government of Pakistan while acceding the Convention, it shall not apply to ***India****, and/or entities not recognized by Pakistan* ***(like Israel).***

Furthermore, Article 12 of the Convention stipulates that any State not referred to in Article 10 may accede to the Convention after it has entered into force in accordance with the first paragraph of Article 11. Such accession shall have effect only as regards the relations between the acceding State and those Contracting States which have not raised an objection to its accession in the six months after the receipt of the notification referred to in sub-paragraph (d) of Article 15.

Eight contracting States including, ***Germany, Czech Republic, Poland, Austria, Finland, Netherland, Denmark, Hellenic Republic*** *have submitted objections to the accession of Pakistan in accordance with second paragraph of Article 12 of the Convention which means that Pakistan's accession to the Convention shall not have effect to the extent of these countries.*

In view of the above, DRAP may accept the Foreign Apostille Certificates issued by the members/contracting States of the convention (except those referred above) without any requirement of attestation from Ministry of Foreign Affairs or Pakistan Missions abroad.
The process of issuance of 'Apostille Certificates' by Pakistan (for export products) will commence upon completion of necessary legislation. In a proposed bill, the Ministry of Foreign Affairs is being authorized to issue Apostille Certificate from Pakistan.

Decision: Registration Board acceded to the request of firm for change of title from previous "M/s. I-C-I Pakistan Limited" to New title "M/s. Lucky Core Industries Limited subject to decision of Authority regarding acceptance of apostille documents."

Imported Veterinary Biological applied by M/s Niraav Pharma (Pvt). Ltd deferred in 317th meeting of Registration Board.

14.	**Name and address of Importer**	**M/s Niraav Pharma (Pvt). Ltd Horizon Tower, Office 204, Block 3 Clifton, karachi.**
	Detail of DSL	M/s Niraav Pharma (Pvt). Ltd authorized agent of M/s. Vet Pharma Trading Company. Address: Plot No. A-81, Eastern Industrial Zone, Port Qasim Authority, Karachi. Validity: 23-09-2020, 22-09-2022.
	Name and address of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** Address: No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	**Meilan L.V ND Clone 30 Live**
	Diary No. Date of R&I & Fee	Dy. No. 2778 Dated 25-01-2021 Rs. 100,000/- Dated 18-01-2021
	Composition	Each dose contains: New castle disease live virus strain clone 30 $\geq 10^6$ EID_{50}
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per Innovator's specifications
	Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2 ^{0}C-8^0C) for months.
	Document Details	Following documents are submitted: a. Original legalized CoPP dated 12-01-2022. b. Original legalized Sole agency agreement (validity was five years it is not valid now).
	Pack size	1000 doses vial
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Not verifiable.
	Remarks of Evaluator	In response to this division's letter dated 2nd November 2021 firm has submitted following: i. Clarification regarding difference in address on sole agency agreement DSL that sole agency agreement address of head office is mentioned.
		ii. Finished product Specifications; As per Innovator's. iii. Safety and efficacy data. iv. COPP with composition. Following documents are still required: i. Evidence of locally registered product for applied product is required. Sole agency agreement is not valid now.
	Decision in 317th RB meeting.	***Registration Board deferred the product for submission of following by the firm:*** **i.** ***Evidence of availability of formulation in Pakistan.*** **ii.** ***Valid Sole Agency Agreement.***

	Evaluation by DBE&R	Firm has submitted original valid Sole agency agreement. For evidence of local availability firm has submitted following product: **Intervac NDV Clone Vaccine (Reg. No.072668)** Freeze dried Newcastle Disease Virus clone strain not less than 10^6 $EID_{50.}$
	Decision: Keeping in view the legalized Certificate of Pharmaceutical Product indicating product availability in country of origin Registration Board approved the product subject to compliance of current import policy for finished drugs.	
15.	**Name and address of Importer**	**M/s Niraav Pharma (Pvt). Ltd Horizon Tower, Office 204, Block 3 Clifton, Karachi.**
	Detail of DSL	M/s Niraav Pharma (Pvt). Ltd authorized agent of M/s. Vet Pharma Trading Company. Address: Plot No. A-81, Eastern Industrial Zone, Port Qasim Authority, Karachi. Validity: 23-09-2020, 22-09-2022.
	Name and address of Manufacturer	**M/s. Shangqiu Meilan Biological Engineering Co., Ltd.** Address: No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	**Fowl Pox Vaccine, Live (Quail Attenuated)**
	Diary No. Date of R& I & fee	Dy. No. 2778 Dated 25-01-2021 Rs. 100,000/- Dated 18-01-2021
	Composition	Each dose contains: Fowl pox virus strain quail attenuated (CVCC AV 1003)$\geq 10^3$ $ELD_{50.}$
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per innovator's specifications
	Shelf Life	12 months (2^0C-8^0C)
	Document Details	Following documents are submitted: a. Original legalized CoPP dated 12-01-2022. Original legalized Sole agency agreement (validity was five years it is not valid now).
	Pack size	1000 doses vial
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Not verifiable with this strain
	Remarks of Evaluator	In response to this division's letter dated 2nd November 2021 firm has submitted following: i. Clarification regarding difference in address on sole agency agreement DSL that sole agency agreement address of head office is mentioned. ii. Finished product Specifications; As per Innovator's. iii. Safety and efficacy data. Following documents are still required: i. Evidence of locally registered product for applied product is required. ii. Sole agency agreement is not valid now.
	Decision in 317th RB meeting.	*Registration Board deferred the product for submission of following by the firm:* • *Immunological relevance of CVCC AV 1003 strain with circulating strains of Pakistan.* • *Valid Sole Agency Agreement.*

	Evaluation by DBE&R	• Firm has submitted original valid Sole agency agreement. • Firm has not submitted immunological relevance data rather submitted clarification that CCV AV1003 is the reference catalogue number of official Chinese veterinary culture used as reference for testing in Chinese pharmacopoeia. • For evidence of Me Too firm has submitted following product: **Registration No.** 007511 **Product Name:** Fowl Pox Antigen
	Decision: Registration Board referred the case to Ministry of National Food Security and Research for comments regarding immunological relevance and need of applied strain in Pakistan as well as for comments on No. CCV AV1003 whether it is Lab No. or strain type.	

CASES OF DD-III (MR. HAFIZ AHSAN)

16. M/s Hilton Pharma Pvt Ltd, Karachi – Request for Deregistration of Product "*Protexin Concentrate*" (Reg. No. 019907).

The firm has requested for deregistration of the product "**Protexin Concentrate**" via Letter No. MA/MN/230605-01 dated 05th June 2023. The composition of the product is as below:

Contents per kg

Enterococcus faecium	NCIMB1 30183 PXN® 33
Streptococcus thermophilus	NCIMB 30189 PXN® 66
Lactobacillus rhamnosus	NCIMB 30188 PXN® 54
Lactobacillus acidophilus	NCIMB 30184 PXN® 35
Lactobacillus bulgaricus	NCIMB 30186 PXN® 39™
Bifidobacterium bifidum	NCIMB 30179 PXN® 23™
Lactobacillus plantarum	NCIMB 30187 PXN® 47™

Summary of submitted are as follows:

a) Copy of initial Registration letter dated 18th September 1996.
b) Approval letter for Change of Brand name dated 08th January 2020.
c) Last Renewal dated 26th Feb 2020.
d) Approval letter for updating Nomenclature of two strains dated 17th April 2020.
e) Approval letter for change in company name of Manufacturer dated 05th October 2020.
f) Approval letter for change in company name of Manufacturer dated 11th September 2020.
g) Minutes of 320th meeting of Registration Board dated 29th-31st August 2022.
h) Copy of receiving of letter for deregistration letter No. MA/MN/230605-01 dated 05th June 2023 to The Chairman Registration Board, The Director Biological and The Secretary Registration Board.

The firm stated that in Europe the status of registration of "Protexin" was changed and the product is classified as a complimentary feed. Due to the change in classification, this product also does not require a marketing authorization within Europe. The firm further submitted that the application for the grant of additional pack size of Protexin Concentrate 1 Kg was applied vide letter no MN/MA/220307-01 dated 10th March 2022.

The above case was discussed in 320th meeting of Registration Board dated 29th-31st August 2022 and as per decision of registration board in Minutes of 320th meeting ***Protexin is a veterinary probiotic which does not come under the purview of Pharma Division.***

Decision: Registration Board after discussion on the matter decided to call the management of the firm for personal hearing under section 42 of the Drugs Act, 1976 of schedule VI of DRAP Act 2012 before cancellation of the above said product.

17. M/s Hipra Pakistan Pvt Ltd, Lahore – Request for Withdrawal of Product "*Toxipra S7".*

We M/S HIPRA Pakistan (Private) Limited had applied for the Registration of our product TOXIPRA S-7 (250 ml) and has been deferred in 323rd Registration Board Meeting on the basis of Stability Data. We were unable to provide the required information requested by DRAP.

The details of the product are as below:

Name of Importer	M/s Hipra Pakistan (Private) Limited, 3rd floor, plot no 8, block CCA, Phase 6-C, DHA, Lahore Go Down: 2nd Warehouse on Left side, Street no 5, Gajjumata Nadir Chowk, Hazara Chowk, Industrial Area Ferozpur Road, Distt Lahore
DSL details	License to sell the drug as distributor No. 05-352-0058-050528D valid till 19-Feb-2024
Name of Manufacturer	Laboratorios HIPRA, S.A, Avda. La Selva, 135 17170 Amer (Girona) Spain.
Brand Name + Dosage Form + Strength	TOXIPRA S-7, suspension for Injection (250 ml)
Composition	Composition per 2ml dose □□*toxoid of type B,C and D Clostridium perfingens.....≥ 10 IU □ *toxoid of type B,C and D Clostridium perfingens.....≥ 5 IU □ * toxoid of type B Clostridium novyi.....≥ 3.5 IU * Toxoid □□of Clostridium septicum.....≥ 2.5 IU ** Anaculture of Clostridium chauvoei.....100 % protection ** Toxoid of Clostridium sordellii.....100% protection International Units (antitoxin per ml of serum)* Protection level in guinea pig**
Finished product specifications	European Pharmacopeia specifications
Pharmacological Group	Inactivated vaccine against Enterotoxaemia Sudden Death, Black leg and Black Disease
Shelf life	24 Months (Store at 2°C - 8°C)
International availability	Spain
Products already registered in Pakistan	TOXIPRA S-7 (100 ml)
Dy. No. Date of Application, Fee submitted	Dy No. 20522 Dated: 28-07-2021 Fee Submitted: Rs. 150,000 /- dated 09-08-2021
Demanded Price / Pack size	250 ml/ Decontrolled
General Documentation	• Legalized Certificate of Pharmaceutical Product (CoPP) issued by Agencia Espanola de Medicamentos y productos sanitarios dated: 12-12-2017.

Decision: Registration Board acceded to the request of the firm and the application *"Toxipra S7 (250ml)"* of M/s Hipra Pakistan Pvt Ltd. stands withdrawn.

Case: Priority / Out of Queue consideration of Heparin & Enoxaparin Injections

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

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

i. Paracetamol (Tablets, lnfusion and Syrup / Suspension)
ii. Albumin bound Paclitaxel lnjection
iii. Heparin and Enoxaprin lnjection

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

Imported Heparin Injection from non-Reference countries:

18.	Name, address of Applicant / Importer	**M/s Fizon Pharma,** Akhai Arcade, 103-K, Block -2,

		P.E.C.H.S., Shahra-e-Qaideen, Karachi.
	Details of Drug Sale License of importer	License No: 0319 Address: Akhai Arcade, 103-K, Block -2, P.E.C.H.S., Shahra-e-Qaideen, Karachi. Validity: 22-02-2028
	Name and address of marketing authorization holder (abroad)	**M/s Kilitch Drugs (India) Ltd.** C-301/2, T.T.C Industrial area, M.I.D.C, Pawane, Navi Mumbai- 400 705, Maharashtra, INDIA.
	Name, address of manufacturer(s)	**M/s Kilitch Drugs (India) Ltd.** C-301/2, T.T.C Industrial area, M.I.D.C, Pawane, Navi Mumbai- 400 705, Maharashtra, INDIA.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (COPP/CERT/KD/123926 / 2023 / 11/44374 / 215403) issued by Food & Drug Administration Maharashtra State, Mumbai 400 051. The certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 06-10-2024.
	Details of letter of authorization / sole agency agreement	Notarized copy of product specific sole agency agreement from manufacturer abroad hereby authorizes M/s Fizon Pharma to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Diary No. 12110, Dated: 17-05-2023
	Details of fee submitted	Rs: 150,000/- Dated: 06-03-2023 Deposit Slip No. 23019263264
	The proposed proprietary name / brand name	KARIN INJECTION 5000 IU/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient per Unit	Each ml contains: Heparin Sodium……..5000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant agents
	Finished product specifications	BP specifications
	Proposed Pack size	1 × 5 ml vial

	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 20°C – 25°C
	Reference Regulatory Authorities	Heparin sodium Injection, USFDA Approved.
	For generic drugs (me-too status)	Heparin Injection 25000 IU/ 5ml of M/s Leo/ Zam Zam Pharma
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Gland Chemicals Limited, Plot No. 42-B, 2nd phase, KIADB Industrial area, Malur-563160, Kolar Dist, Karnataka , India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches at long term conditions at 25°C ± 2°C / 60% RH ± 5% RH for 60 months. The accelerated stability data is conducted at 40°C±2°C / 60%±5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	5ml flint vial USP Type-I, 20 mm. Grey Bromobutyl Rubber Plugs, Flip off seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Karin Injection at accelerated and real time conditions. The real time stability data conducted at 30°C ± 2°C / 65% RH ± 5%RH for 24 months and accelerated stability data conducted at 40°C ± 2°C/75% RH ± 5%RH for 06 months for 3 batches. KLRC9001 KLRC9002 KLRC9003
	Module-IV Non-Clinical	Published literature covering following aspects: Primary Pharmacodynamics

		Secondary Pharmacodynamics Safety pharmacology Pharmacodynamic interaction Pharmacokinetics Toxicity Single Dose toxicity Repeat dose toxicity Carcinogenicity
	Module-V Clinical	Reports of efficacy and Safety studies
	Remarks of Evaluator	Non- clinical and Clinical trial data are not submitted by the firm. Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.
Decision: Keeping in view legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs. **The Board also directed the division of BE&R to process the case without waiting for the formal approval of the minutes.**		

Imported human biological product from Non-reference countries:

19.	**Name, address of Applicant / Importer**	M/s RA Healtchare (SMC-Pvt) Ltd, 2nd Floor, Building # 50, Mir Arcade, Mini Commercial, Phase 7, Bahria Town, Rawalpindi.
	Details of Drug Sale License of importer	RA Healtchare (SMC-Pvt) Ltd Address: 2nd Floor, Building # 50, Mir Arcade, Mini Commercial, Phase 7, Bahria Town, Rawalpindi. License No.: 01-374-0176-99719D Valid till: 11-11-2027
	Name and address of marketing authorization holder (abroad)	Name: TOT BioPharma Co., LTD Address: No.120, Changyang Street, Industrial Park, Suzhou 215024, CHINA.
	Name, address of manufacturer(s)	Name: TOT BioPharma Co., LTD Address: No.120, Changyang Street, Industrial Park, Suzhou 215024, CHINA.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. JS20220005) valid till 23.01.2024 issued by Jiangsu Drug Administration situated at No.5 Gulou Street Nanjing, Jiangsu Province China. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection every 6 Months.
		DML: Firm has submitted original legalized drug Manufacturing Licence of manufacturer (No. Su 20160196) issued by JIANGSU DRUG ADMINITRATION situated at NO.5 GULOU STREET NANJING, JIANGSU PROVINCE CHINA. The certificate is valid till 16-12-2025.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original legalized letter of authorization from Associate Director of TOT

		BIOPHARM CO., LTD., According to the letter, the firm TOT BIOPHARM CO., LTD., authorizes "RA HEALTHCARE (SMC-Pvt.) Limited with its place of business at 2nd Floor building # 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town Islamabad, Pakistan as their business representative with undisputed powers authorized to deal with the product registration of Bevacizumab Injection in Pakistan as per mutually agreed terms and conditions by both companies. The letter was issued on April 26th, 2022. (Valid for 5 Years)
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. 23155 Dated: 16-08-2022
	Details of fee submitted	PKR 150,000/- Dated 16-08-2022
	The proposed proprietary name / brand name	**Arketin**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml vial contains: Bevacizumab……..100mg
	Pharmaceutical form of applied drug	Concentrate for Injection
	Pharmacotherapeutic Group of (API)	Monoclonal antibodies
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	4ml vial
	Proposed unit price	Will be provided at the time of pricing
	Shelf Life	24 months
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Avastin 100MG/4ML (ROCHE Pakistan)
	For generic drugs (me-too status)	Avastin (Roche 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.
	Name, address of drug substance	Name: TOT BioPharma Co., LTD

<table>
<tr><td></td><td>manufacturer</td><td>Address: No.120, ChangYang Street, Industrial Park, Suzhou, CHINA.</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>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.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions.
The accelerated stability study data is conducted at 5°C ± 3°C up to 6 months. The real time stability data is conducted at -20°C ± 5°C up to 30 months</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted analytical method validation studies for the applied product.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>The Bevacizumab DP is filled in
Neutral borosilicate glass vial for 100 mg presentation, closed with
Polytetrafluoroethylene film + chlorinated butyl rubber 20G050-A41-D1M. The rubber stoppers are sealed with PVC + aluminium cap.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>The accelerated stability study data is conducted at 25°C ± 2°C / 60% RH ± 10% RH up to 6 months.
The real time stability study data is conducted at 5°C ± 2°C up to 30 months.</td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in Biosimilarity data mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in Biosimilarity data mentioned below</td></tr>
<tr><td></td><td colspan="2">The firm has submitted Biosimilarity data as per following details:</td></tr>
<tr><td></td><td>Quality Comparison
1. Physicochemical Characterization</td><td>ARKETIN (bevacizumab) has been compared with Avastin – Reference Listed Drug (RLD)
<table>
<tr><th>Category</th><th>Quality Attributes</th><th>Analytical methods</th></tr>
<tr><td rowspan="2">Primary structure</td><td rowspan="2">Amino acid sequence</td><td>Intact molecular weight</td></tr>
<tr><td>Peptide mapping and full-length sequencing by LC-MS/MS</td></tr>
<tr><td rowspan="2">Higher order structure</td><td>Disulfide bond mapping</td><td>Partial reduction and LC-MS</td></tr>
<tr><td>Free thiols</td><td>Ellman's</td></tr>
</table></td></tr>
</table>

				assay
			Secondary, tertiary and quaternary structures	Far/Near-CD, fluorescence spectroscopy
		Charge heterogeneity	Charge variant	IEC-HPLC
		Hydrophobicity heterogeneity	Hydrophobic variants	Hydrophobic interaction chromatography
		Size heterogeneity	LMW and HMW impurities	Size exclusion chromatography coupled with multi-angle light scattering (SEC-MALS)
		In-solution stability	T_m	Differential scanning calorimetry (DSC)
		In-solution particle size homogeneity	Average size	Dynamic light scattering (DLS)
		In-Vitro Biofunctionality	Receptor binding assay	Surface Plasmon Resonance (SPR)
			Cell-based bioactivity assay	INSR/IGF-1R receptor phosphorylation assay
	Biological Activity	Cell based Bioactivity Assay – IEC-HPLC Method Bevacizumab injection is a therapeutic monoclonal antibody product that can achieve anti-tumor effect by specifically binding to vascular endothelial growth factor (VEGF) and blocking the biological activity of VEGF to inhibit angiogenesis. IEC-HPLC method was used to analyze acidic peaks, main peak and basic peaks of ARKETIN (bevacizumab) and reference Avastin. The results show that: (1) Main Peak of P2.0~P4.0 ARKETIN (bevacizumab) are consistent to reference Avastin, Content of acidic peaks are lower than Avastin, and basic peaks are larger than Avastin. Compare with P2.0~P3.0, P4.0 ARKETIN (bevacizumab) quality range is more closer to reference Avastin. (2) The content of basic peak 1 for ARKETIN (bevacizumab) in each stage of P2.0 to P4.0 is higher than reference Avastin. (3) In order to further understand the characteristics of basic peak 1, acidic peaks, basic peaks (total peak) and main peak, as well as the effects on biological activity, a semi preparative column Dionex Propac wcx-10 semi preparative column, 9×250 (ID×L mm), was used to collect peaks in P2 0-P4.0 ARKETIN (bevacizumab). The components of ARKETIN (bevacizumab) were collected, and analyzed by IEC, mass spectrometry, cell proliferation inhibition activity and antigen antibody		

		binding activity. See section 3.4.5.1~3.4.5.3.
	Immunochemical properties	In the below mentioned study immunochemical properties of ARKETIN (bevacizumab) are compared with the reference Aventis: Tissue Cross-Reactivity Study of Monoclonal Antibody ARKETIN (bevacizumab) Injection in Normal Human Tissues. Study Number: 013-47-lQT
	Impurities	**Product-related Impurities** Monomer and polymer content SEC-HPLC method was used to analyze monomer and polymer content of TAB008(P2.0~P4.0) and Avastin. Molar mass of monomer and polymer(SEC-MALLS) The mean square rotation radius, molecular weight and distribution of different components are measured by SEC-MALLS. Reduced CE-SDS Reduced CE-SDS were used to analyze NGHC, LMW+MMW and LC+HC for TAB008 and Avastin. Non-reduced CE-SDS Non-reduced CE-SDS were used to analyze low molecular weight and main peak for TAB008 and Avastin. IEC-HPLC IEC-HPLC method was used to analyze acidic peaks, main peak and basic peaks of TAB008(P2.0~P4.0) and Avastin. **Process-related Impurities** The below mentioned impurities were measured and compared: CHO host cell proteins(HCP) Protein A Host cell DNA Bacteria endotoxin
	Stability Studies	The firm has submitted stability studies of drug product.
	Non-clinical Comparison I. *In-vitro* Studies II. *In-vivo* Studies a) Biological / Pharmacodynamic activity b) Non- clinical Studies	Primary Pharmacodynamics: 1- Summary of Nonclinical Primary Pharmacodynamic Studies 2- Study on In Vitro Biological Activities and Mechanisms. Safety Pharmacology: A 4-Week Repeated Intravenous Infusion Toxicity Study in Cynomolgus Monkeys with A 4-week Recovery Period – Toxicokinetics Study Report CRO Study No.: D4101 Tissue Cross-Reactivity Study of ARKETIN (bevacizumab) Monoclonal Antibody Injection in Normal Human Tissues. In this study, immunohistochemical method was used to detect specific binding of ARKETIN (bevacizumab) monoclonal antibody injection with normal human tissues, and compared with the marketed

		comparator AVASTIN.
	Clinical Studies	To compare the pharmacokinetic and pharmacodynamic properties of ARKETIN (bevacizumab) with reference Avastin in healthy subjects. **Phase I**, single dose, Randomized, double-blind, parallel controlled study to compare the similarity in pharmacokinetics and safety of ARKETIN (bevacizumab) Monoclonal Antibody Injection with AVASTIN injection in healthy Chinese male subjects. (400 subjects consented to participate). **100 subjects** A randomized, double-blind, positive parallel controlled, nationwide, multi-centered, and equivalent **phase III** clinical study with a primary objective to determine the best objective response rate (ORR) within 6 treatment cycles by an Independent Review Committee and secondary objectives of comparing efficacy, safety, immunogenicity and pharmacokinetics. **Phase III** clinical Study of ARKETIN (bevacizumab) Monoclonal Antibody Combined with Paclitaxel and Carboplatin Versus Bevacizumab (Avastin®) Combined with Paclitaxel and Carboplatin in the First-line Treatment of Advanced or Recurrent Non-Squamous Non-Small Cell Lung Cancer. **548 patients**
	Decision: Keeping in view legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs.	
20.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (Pvt.) Ltd,** **2nd Floor Plaza 60, Commercial Block-K, Phase-1, DHA, District Lahore.**
	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.
	Name and address of marketing authorization holder (abroad)	M/s Qingdao Guanlong Biopharmaceutical Co. Ltd., No. 97, Zhuzhou Road, Laoshan District, Qingdao City, Shandong Province, China.
	Name, address of manufacturer(s)	M/s Qingdao Guanlong Biopharmaceutical Co. Ltd., No. 97, Zhuzhou Road, Laoshan District, Qingdao City, Shandong Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted Original legalized CoPP (Certificate # 20232018) for Chorionic Gonadotrophins, 2000 Units issued by Shandong Provincial Medical Products Administration dated 30-03-2023. The CoPP confirms free sale status of the product in the country of origin and the facilities and operations as recommended

		by the World Health Organization.
	Details of letter of authorization / sole agency agreement	The firm has submitted product specific sole agency agreement in which M/s Qingdao Guanlong Biopharmaceutical Co., Ltd referred to as Manufacturer authorizes Jilin North Biotech Pharma IMP & EXP Co. Ltd to Export the products listed in Annexure 1. The Jilin North Biotech pharma IMP & EXP CO., Ltd referred to as exporter hereby appoints AMB HK Enterprises (Private) Limited as agent to market, sell and distribute the Products.
	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. 23113 ; Dated 24-08-2021
	Details of fee submitted	Deposit Slip no.92358200; PKR 100,000: Dated: 27-04-2021 Deposit Slip no. 2431930769; PKR 50,000: Dated: 07-06-2021
	The proposed proprietary name / brand name	**Gonadotroph Injection 2000 units**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Chorionic Gonadotrophin …… 2000 units
	Dosage form of applied drug	Sterile freeze-dried powder for injection
	Pharmacotherapeutic Group of (API)	Gonadotropins ATC code: G03GA01
	Reference to Finished product specifications	USP
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	15 - 30 °C
	The status in reference regulatory authorities	Chorionic gonadotropin injection 2000 units/vial of Ferring, **Discontinued in FDA**.
	For generic drugs (me-too status)	Not confirmed.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Qingdao Kangyuan Biopharmaceutical Co. Ltd., Yinhai industrial Park, Jiaozhou City, Qingdao, Shandong, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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)	The firm has submitted long term Stability data for three batches conducted at 5°C ± 3°C for the period of 48 months. KC151001 KC151002 KC151003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection vials made of low borosilicate glass tubing, Halogenated butyl rubber plugs for freeze-drying for injection.
	Stability study data of drug product, shelf life and storage conditions	• The firm has submitted stability study data of three batches: 170404 170405 170406 Long term stability at 30°C ± 2°C / 65% ± 10% RH for 24 months Accelerated stability at 40°C ± 2°C / 75% ± 5% RH for 06 months
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.1 Primary Pharmacodynamics** • Diagnosis and treatment of cryptorchiasis before adolescence. • Male sterility caused by hypophysis can be used in combination with gonadotropin. • Patient s with long term low gonadotropin function should also be supplemented with testosterone; • The female anovulatory infertility due to the deficiency of the pituitary gonadotropins is often used in combination with the postmenopausal gonadotropin to

		promote ovulation after the treatment with clomiphene is ineffective • It is used in vitro to obtain multiple oocytes and needs to be used in combination with postmenopausal gonadotropin.; • hCG promotes testicular testosterone that acts on muscles to promote growth and anabolism in men. Interestingly, injections of hCG do not promote significant testosterone production in women. **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** • T1/2 is two phase,11 and 23 hours, respectively, and the plasma concentration reaches a peak of about 12 hours, and then drops to a stable low concentration at the time of 120 hours, and is ovulated for 32 36 hours. • Tissue distribution of exogenous HCG was studied in adult female mice injecting the animals with HCG I125, BSA I125, and I125 and determining in a scintillation counter the tissue radioactivity at various time intervals. The radioactive materials were extracted from the tissues and mixed with excess anti HCG serum. It was found that the exogenous human chorionic gonadotropin concentrates preferentially in the ovarian tissues of nonhypophysectomized mice, the maximum concentration occurring at 2 to 4 hours after injection. Ovar ies in hypophysectomized mice lack the ability to concentrate exogenous HCG to the same extent as the ovaries of nonhypophysectomized mice. • Within 24 hours, 10% of the prototype was excreted with urine through the kidney. **4.2.2.2 Other Pharmacokinetic Studies** • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male • Cynomolgus Monkeys with a 11-Day Observation Period **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • HCG treatment at different concentrations and time points activated JNK pathway and significantly increased its endogenous kinase activity along with up-regulated expression of steroidogenic enzymes (stAR, 3β-HSD) in a dose-dependent manner in the luteal GCs. **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A rat seminal vesicle weight bioassay with repeated intragastric adminisrations of Human Chorionic Gonadotrophin at a total dose of 20IU/rat was nagative.Since only one dose level was tested in a limited number of animals a NOVEL could not be derived • single intraperitoneal injection of 20-40 IU HCG (5-40 IU) on the first day of pregnancy caused almost total fetal loss, with 20 IU being the most severe. Given on Day 2, embryo loss was reduced. On the 3rd, 4th and 5th

		day, no embryo toxicity was observed. Study of embryo death before implantation, at implantation or after implantation, found that 20 IU on the first day of pregnancy, embryo survival on the 4th and 5th days almost reduced to zero, the impact began to occur before implantation. At the same time, serum estradiol concentration increased significantly and progesterone concentration decreased to a lesser extent. The results showed that the toxicity of HCG to embryo was time- and dose-dependent, mainly occurred before implantation, and the serum estradiol level increased significantly. **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.2 Embryo-fetal development** • Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta. Endogenously produced HCG interacts with the LHCG receptor of the ovary and promotes the maintenance of the corpus luteum during the beginning of pregnancy. This allows the corpus luteum to continuously secrete the hormone progesterone during the first trimester, which is required for maintenance of the l uterus and prevents menstruation. In males, HCG also stimulates the production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens, so HCG has no Genotoxicity. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.7 Other** • There have been sporadic reports of testicular tumors in otherwise healthy young men receiving HCG for secondary infertility. A causative relationship between HCG and tumor development in these men has not been established. Defects of for elimbs and of the central nervous system, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and HCG regimens. The dose of gonadotropin used was intended to induce superovulation. No mutagenic effect has been clearly established in humans.
	Module-V Clinical	• A single-centre, randomized, single-dose, three-way cross-over study in healthy female volunteers to compare the bioavailability of SC and IM administration of human chorionic gonadotrophin (HCG; Pregnyl®). 18 healthy pituitary suppressed volunteers were assigned to single HCG Injections of 5000 and 10,000 IU IM and 10,000 IU SC. Rate (Cmax, tmax) and extent [area under curve from zero to infinity (AUC0–∞`)] of absorption of HCG were determined. Intramuscular doses of 5000 IU and 10, 000 IU HCG were dose-proportional. • **Polycystic ovary syndrome: Seventy-two** polycystic ovary syndrome patients were randomly divided into the observation group (N = 36) and the control group (N = 36). The control group was treated with clomiphene citrate, and the observation group was treated with clomiphene citrate and chorionic gonadotropin. **Results:**

		The endometrial thickness was (5.26 ± 1.46) mm in follicular phase and (10.91 ± 2.65) mm in luteal phase in the Observation Group, which was significantly higher than that in the control group (4.60 ± 1.31) mm and (9.34 ± 2.01) mm, the difference was statistically significant ($p < 0.05$). **Conclusion:** The number of ovulation, dominant follicles and mature follicles in the observation group were less than those in the control group, but the incidence of follicles in the observation group (63.89%) was significantly higher than that in the control group (38.89%)($p < 0.05$). • A prospective, multicenter, randomised, investigator-blind, controlled, clinical study on the clinical efficacy and tolerability of two highly purified human menopausal gonadotrophin preparations administered subcutaneously in women undergoing IVF. **One hundred fifty-seven patients** were randomised in two parallel groups: 78 started COS with Merional-HG and 79 with Menopur. In conclusion, the results of this study support the efficacy and safety of Merional-HG administered subcutaneously for assisted reproduction techniques. Efficiency of Merional-HG appears to be higher due to reduced quantity of drug used and the higher yield of mature oocytes retrieved.

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Submit valid copy of drug sale license since already submitted copy is expired on 24-02-2023.	The firm has submitted copy of DSL valid till 08-05-2028 with following details: **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.
2.	Submit valid original legalized copy of CoPP issued by concerned regulatory authority of country of origin.	The firm has submitted Original legalized copy of CoPP for Chorionic Gonadotrophins, 2000 Units issued by Shandong Provincial Medical Products Administration. The CoPP confirms free sale status of the product in the country of origin and the facilities and operations as recommended by the World Health Organization.
3.	Submit details of letter of authorization / sole agency agreement for applied product.	The firm has submitted product specific sole agency agreement in which M/s Qingdao Guanlong Biopharmaceutical Co., Ltd referred to as Manufacturer authorizes Jilin North Biotech Pharma IMP & EXP Co. Ltd to Export the products listed in Annexure 1. The Jilin North Biotech pharma IMP & EXP CO., Ltd referred to as exporter hereby appoints AMB HK Enterprises (Private) Limited as agent to market, sell and distribute the Products.
4.	You have mentioned Chinese pharmacopoeia specifications (3.2.P.5.1) while the product gonadotropin for injection is present in USP. Clarification is required.	The firm has revised the specifications to USP and requested to grant Registration as per USP specifications for the applied product.
5.	Significant change in the assay results of	The firm has submitted that significant change in

	accelerated stability study data of different was observed. Clarification is required in this regard.	the assay results of accelerated stability data were observed however, the change was within the specification limits. Moreover, the shelf life of the product is assigned based on long term stability study data which shows the product is stable till shelf life.

Decision: Registration Board deferred the case for following:

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

21.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (Pvt.) Ltd,** **2nd Floor Plaza 60, Commercial Block-K, Phase-1, DHA, District Lahore.**
	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.
	Name and address of marketing authorization holder (abroad)	M/s Qingdao Guanlong Biopharmaceutical Co. Ltd., No. 97, Zhuzhou Road, Laoshan District, Qingdao City, Shandong Province, China.
	Name, address of manufacturer(s)	M/s Qingdao Guanlong Biopharmaceutical Co. Ltd., No. 97, Zhuzhou Road, Laoshan District, Qingdao City, Shandong Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted Original legalized CoPP (Certificate # 20232012) for Chorionic Gonadotrophins, 5000 Units issued by Shandong Provincial Medical Products Administration dated 08-02-2023. The CoPP confirms free sale status of the product in the country of origin and the facilities and operations as recommended by the World Health Organization.
	Details of letter of authorization / sole agency agreement	The firm has submitted product specific sole agency agreement in which M/s Qingdao Guanlong Biopharmaceutical Co., Ltd referred to as Manufacturer authorizes Jilin North Biotech Pharma IMP & EXP Co. Ltd to Export the products listed in Annexure 1. The Jilin North Biotech pharma IMP & EXP CO., Ltd referred to as exporter hereby appoints AMB HK Enterprises (Private) Limited as agent to market, sell and distribute the Products.
	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. 23114 ; Dated 24-08-2021
	Details of fee submitted	Deposit Slip no.5550516555; PKR 100,000: Dated: 27-04-2021 Deposit Slip no. 1937925350 PKR 50,000: Dated: 07-06-2021
	The proposed proprietary name / brand name	Gonadotroph Injection 5000 units
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Chorionic Gonadotrophin …… 5000 units
	Dosage form of applied drug	Sterile freeze-dried powder for injection
	Pharmacotherapeutic Group of (API)	Gonadotropins ATC code: G03GA01
	Reference to Finished product specifications	USP
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	15 - 30 °C
	The status in reference regulatory authorities	Chorionic gonadotropin injection 5000 units/vial of Ferring, USFDA approved.
	For generic drugs (me-too status)	Presage Injection of Genome Pharma (Reg # 059241)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Qingdao Kangyuan Biopharmaceutical Co. Ltd., Yinhai industrial Park, Jiaozhou City, Qingdao, Shandong, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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)	The firm has submitted long term Stability data for three batches conducted at 5°C ± 3°C for the period of 48 months. KC151001

		KC151002 KC151003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection vials made of low borosilicate glass tubing, Halogenated butyl rubber plugs for freeze-drying for injection.
	Stability study data of drug product, shelf life and storage conditions	• The firm has submitted stability study data of three batches: 170407 170408 170409 Long term stability at 30°C ± 2°C / 65% ± 10% RH for 24 months Accelerated stability at 40°C ± 2°C / 75% ± 5% RH for 06 months
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.2 Primary Pharmacodynamics** • Diagnosis and treatment of cryptorchiasis before adolescence. • Male sterility caused by hypophysis can be used in combination with gonadotropin. • Patient s with long term low gonadotropin function should also be supplemented with testosterone; • The female anovulatory infertility due to the deficiency of the pituitary gonadotropins is often used in combination with the postmenopausal gonadotropin to promote ovulation after the treatment with clomiphene is ineffective • It is used in vitro to obtain multiple oocytes and needs to be used in combination with postmenopausal gonadotropin.; • hCG promotes testicular testosterone that acts on muscles to promote growth and anabolism in men. Interestingly, injections of hCG do not promote significant testosterone production in women. **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** • T1/2 is two phase,11 and 23 hours, respectively, and the plasma concentration reaches a peak of about 12 hours, and then drops to a stable low concentration at the time of 120 hours, and is ovulated for 32 36 hours. • Tissue distribution of exogenous HCG was studied in adult female mice injecting the animals with HCG I125, BSA I125, and I125 and determining in a scintillation counter the tissue radioactivity at various time intervals. The radioactive materials were extracted from the tissues and mixed with excess anti HCG serum. It was found that the exogenous human chorionic gonadotropin

		concentrates preferentially in the ovarian tissues of non-hypophysectomized mice, the maximum concentration occurring at 2 to 4 hours after injection. Ovaries in hypophysectomized mice lack the ability to concentrate exogenous HCG to the same extent as the ovaries of non-hypophysectomized mice. • Within 24 hours, 10% of the prototype was excreted with urine through the kidney. **4.2.2.3 Other Pharmacokinetic Studies** • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male . • Cynomolgus Monkeys with a 11-Day Observation Period. **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • HCG treatment at different concentrations and time points activated JNK pathway and significantly increased its endogenous kinase activity along with up-regulated expression of steroidogenic enzymes (stAR, 3β-HSD) in a dose-dependent manner in the luteal GCs. **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A rat seminal vesicle weight bioassay with repeated intragastric adminisrations of Human Chorionic Gonadotrophin at a total dose of 20IU/rat was nagative.Since only one dose level was tested in a limited number of animals a NOVEL could not be derived • single intraperitoneal injection of 20-40 IU HCG (5-40 IU) on the first day of pregnancy caused almost total fetal loss, with 20 IU being the most severe. Given on Day 2, embryo loss was reduced. On the 3rd, 4th and 5th day, no embryo toxicity was observed. Study of embryo death before implantation, at implantation or after implantation, found that 20 IU on the first day of pregnancy, embryo survival on the 4th and 5th days almost reduced to zero, the impact began to occur before implantation. At the same time, serum estradiol concentration increased significantly and progesterone concentration decreased to a lesser extent. The results showed that the toxicity of HCG to embryo was time- and dose-dependent, mainly occurred before implantation, and the serum estradiol level increased significantly. **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.3 Embryo-fetal development** • Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta. Endogenously produced HCG interacts with the LHCG receptor of the ovary and promotes the maintenance of

		the corpus luteum during the beginning of pregnancy. This allows the corpus luteum to continuously secrete the hormone progesterone during the first trimester, which is required for maintenance of the l uterus and prevents menstruation. In males, HCG also stimulates the production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens, so HCG has no Genotoxicity. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.8 Other** • There have been sporadic reports of testicular tumors in otherwise healthy young men receiving HCG for secondary infertility. A causative relationship between HCG and tumor development in these men has not been established. Defects of for elimbs and of the central nervous system, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and HCG regimens. The dose of gonadotropin used was intended to induce superovulation. No mutagenic effect has been clearly established in humans.
	Module-V Clinical	• A single-centre, randomized, single-dose, three-way cross-over study in healthy female volunteers to compare the bioavailability of s.c. and i.m. administration of human chorionic gonadotrophin (HCG; Pregnyl®). 18 healthy pituitary suppressed volunteers were assigned to single HCG injections of 5000 and 10,000 IU i.m. and 10,000 IU s.c. Rate (Cmax, tmax) and extent [area under curve from zero to infinity (AUC0–∞`)] of absorption of HCG were determined. Intramuscular doses of 5000 IU and 10, 000 IU HCG were dose-proportional. • Polycystic ovary syndrome: **Seventy-two** polycystic ovary syndrome patients were randomly divided into the observation group (N = 36) and the control group (N = 36). The control group was treated with clomiphene citrate, and the observation group was treated with clomiphene citrate and chorionic gonadotropin. Results: The endometrial thickness was (5.26 ± 1.46) mm in follicular phase and (10.91 ± 2.65) mm in luteal phase in the Observation Group, which was significantly higher than that in the control group (4.60 ± 1.31) mm and (9.34 ± 2.01) mm, the difference was statistically significant ($p < 0.05$). The number of ovulation, dominant follicles and mature follicles in the observation group were less than those in the control group, but the incidence of follicles in the observation group (63.89%) was significantly higher than that in the control group (38.89%) ($p < 0.05$). • A prospective, multicenter, randomised, investigator-blind, controlled, clinical study on the clinical efficacy and tolerability of two highly purified human menopausal gonadotrophin preparations administered subcutaneously in women undergoing IVF. **One hundred fifty-seven patients** were randomised in two parallel groups: 78 started COS with Merional-HG and 79 with Menopur. In conclusion, the results of this study support the efficacy and safety of Merional-HG administered subcutaneously for assisted reproduction

		techniques. Efficiency of Merional-HG appears to be higher due to reduced quantity of drug used and the higher yield of mature oocytes retrieved.

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Submit valid copy of drug sale license since already submitted copy is expired on 24-02-2023.	The firm has submitted copy of DSL valid till 08-05-2028 with following details: **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.
2.	Submit valid original legalized copy of CoPP issued by concerned regulatory authority of country of origin.	The firm has submitted Original legalized CoPP (Certificate # 20232012) for Chorionic Gonadotrophins, 5000 Units issued by Shandong Provincial Medical Products Administration dated 08-02-2023. The CoPP confirms free sale status of the product in the country of origin and the facilities and operations as recommended by the World Health Organization.
3.	Submit details of letter of authorization / sole agency agreement for applied product.	The firm has submitted product specific sole agency agreement in which M/s Qingdao Guanlong Biopharmaceutical Co., Ltd referred to as Manufacturer authorizes Jilin North Biotech Pharma IMP & EXP Co. Ltd to Export the products listed in Annexure 1. The Jilin North Biotech pharma IMP & EXP CO., Ltd referred to as exporter hereby appoints AMB HK Enterprises (Private) Limited as agent to market, sell and distribute the Products.
4.	You have mentioned Chinese pharmacopoeia specifications (3.2.P.5.1) while the product gonadotropin for injection is present in USP. Clarification is required.	The firm has revised the specifications to USP and requested to grant Registration as per USP specifications for the applied product.
5.	Significant change in the assay results of accelerated stability study data of different was observed. Clarification is required in this regard.	The firm has submitted that significant change in the assay results of accelerated stability data were observed however, the change was within the specification limits. Moreover, the shelf life of the product is assigned based on long term stability study data which shows the product is stable till shelf life.

Decision: Keeping in view legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs.
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 13-07-2021.

22.	**Name, address of Applicant / Importer**	**M/s** SMS CORPORATION, **Plot No.** 13-B/1, Block 6, PECHS, Shahrah e Faisal Karachi – 75400, Pakistan

	Details of Manufacturer And Drug Sale License	***Manufacturer:*** **BIOFARMA PLASMA Limited Liability Company** 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine. **<u>Address of the place of activity:</u>** ***Manufacturing, primary packaging:*** *9, M. Amosov St., Kyiv, 03680, Ukraine.* ***Manufacturing, primary and Secondary packaging, Batch Certification:*** *37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.* **Importer:** **M/s** SMS CORPORATION **Plot No.** 13-B/1, Block 6, PECHS, Shahrah e Faisal Karachi – 75400, Pakistan DSL No.: 0256 Valid till: 12-08-2022
	Name and address of marketing authorization holder (abroad)	**BIOFARMA PLASMA Limited Liability Company** 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.
	Name, address of manufacturer(s)	**BIOFARMA PLASMA Limited Liability Company** 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine. **<u>Address of the place of activity:</u>** ***Manufacturing, primary packaging:*** *9, M. Amosov St., Kyiv, 03680, Ukraine.* ***Manufacturing, primary and Secondary packaging, Batch Certification:*** *37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.*
	Name of exporting country	Ukraine.
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. CPP/UA/10/19) dated 01-02-2019 issued by State Service of Ukraine on Medicines and Drug Control CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific authorization from Director, Exports of **M/s*:* BIOFARMA PLASMA Limited Liability Company** According to the letter, the firm **M/s *:* BIOFARMA PLASMA Limited Liability Company** authorizes "**M/s** SMS CORPORATION for the purpose of registration, import, promotion, marketing, quoting in private & public (Government) tenders and negotiation with Ministry of Health, Pakistan & Hospitals for the 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 ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy. No. 23079 Dated: 08-10-2019
	Details of fee submitted	Rs: 100,000/- Dated: 01-10-2019 Deposit Slip No.1955164
	The proposed proprietary name / brand name	RHESOGLOBIN, solution for injection, 1500 IU (300 mcg of immunoglobulin)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1 ampoule (1ml) contains: Specific antibodies to anti-Rh0 (D)…….……1500 IU (300 µg of immunoglobulin)
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Biological Product / Blood derivative
	Reference to Finished product specifications	European Pharmacopoeia specifications
	Proposed Pack size	• 1 mL [specific antibodies to anti-Rh0 (D) — 1,500 IU (300 µg of immunoglobulin)] • per ampoule. Box of 1 or 3 or 5 ampoules in a pack with a package insert.
	Proposed unit price	MRP per 1 Amp. as per the DRUG Pricing Policy 2018.
	Shelf Life	2 Years
	Storage Condition	2°C -8°C
	The status in reference regulatory authorities	Rhophylac IM/IV Inj 300mcg CSL Behring – USA
	For generic drugs (me-too status)	Rhophylac IM/IV Inj 300mcg Reg. No. 041161 Marketed by Hakimsons (Impex) Pvt. Ltd.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	**BIOFARMA PLASMA Limited Liability Company** 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine. **Address of the place of activity:** ***Manufacturing, primary packaging:*** *9, M. Amosov St., Kyiv, 03680, Ukraine.* ***Manufacturing, primary and Secondary packaging, Batch Certification:*** *37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.*

	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
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	• Sp. 5.14-01-140 Clear glass ampoules, 2 mL • Sp. 5.14-01-141 2 mL ampoules of glass USP-1, NS-3
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study testing carried out on pilot-scale batches during 12 months under the long-term storage conditions at a temperature of (5 ± 3) ºC and non-rated relative air humidity, and under the accelerated storage conditions for 6 months at a temperature of (25 ± 2°C) and relative air humidity of (60 ± 5) %.
	Module IV	Non clinical study In order to confirm the safety profile of the product, Reproductive Toxicity Study of Tri-n-butyl Phosphate + Polysorbate 80 After Intravenous Administration in Laboratory rats. Reproductive Toxicity Study of Tri-n-butyl Phosphate + Polysorbate 80 After Intravenous Administration in Laboratory rabbits
	Module V	A clinical trial of Rh prevention (300 µg of anti-Rh Ig was administered at weeks28 and 34 of gestation) reduced the development of Rh immunization during pregnancy from 1.8 to 0.14 %. The next single-dose studies (300 µg of IM or IV anti-Rh Ig at week 28) were also successful.

Company has submitted the followings on 24th November 2022 in reply of short coming letter dated 23rd September 2020:

S.No.	Observations	Response of the firm
Module-I		
i.	Site master file of manufacturer abroad is not submitted (1.3.8)	There is a change in company's structure and due to expansion plan, manufacture has separated the manufacturing sites and their activities and submitted updated SMF of the manufacturer in ANNEX I (1.3.8).
ii.	Clarification is required regarding two secondary packaging and batch certification sites mentioned on CoPP (1.3.2)	Company has already submitted manufacturer's clarification for two sites and activities there duly notarized on 15-11-2018 in reply of another products' query and copy of acknowledgement is

		provided in ANNEX II (1.3.2).
iii.	Copy of valid Drug Sale License (1.3.4)	Valid attested copy of DSL is provided in ANNEX III (1.3.4).
iv.	Intended market for the said product is not provided (1.4.1)	Intended market for the said product is "Domestic as well as for Exports (1.4.1)".
v.	Clarification is required regarding different route of administration of applied product from submitted pharmacopeial monograph (1.5.6 & 1.5.7)	Clarification letter from the manufacturer is enclosed in ANNEX IV (1.5.6 & 1.5.7).
Module-II		
i.	Quality over all summary (QOS) on template approved in 293rd meeting is required (2.3).	QOS (2.3) as per WHO format is provided in ANNEX V.

Moreover, the firm submitted Pre-Registration variation application of "Change in the name and address of the manufacturer" along with the short coming reply and provided the following details of pre-registration variation**:**

- First firm submitted Pre- Registration Variation Fee of Rs. 7,500/- deposit slip no. 8774928436 dated 22.11.2022 then submitted differential fee on 01st December 2022 by challan no. 05695820480 dated 30.11.2022 for Rs. 142,500/- (Total fee firm deposited to the DRAP i.e. Rs. 150,000/- by two challans as mentioned above).
- Revised FORM-5F in ANNEX VII and according to revised Form, the name and address of the manufacturer are as below:

Name and address of marketing authorization holder (abroad)	**Name: LLC BIOPHARMA PLASMA** **Legal Address:** 37-V, Street Kyivska., Bila Tserkva, Kyiv region, 09100, Ukraine.
Name, address of manufacturer(s)	**Name: LLC BIOPHARMA PLASMA** **Legal Address:** 37-V, Street Kyivska., Bila Tserkva, Kyiv region, 09100, Ukraine. **Address of the place of activity:** **Production, primary packaging:** 9, street M. Amosova., Kyiv, 03680, Ukraine. **Production, primary and Secondary packaging, Release of Series:** 37-V, Street Kyivska., Bila Tserkva, Kyiv region, 09100, Ukraine. **Quality Control:** 37, Street Kyivska., Bila Tserkva, Kyiv region, 09100, Ukraine.
Name of exporting country	Ukraine.
Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. CPP/UA/215/21) dated 16-11-2021, issued by State Service of Ukraine on Medicines and Drug Control, CoPP specifies free sale status of the product in country of origin alongwith its availability. The CoPP also confirms the GMP status of manufacturer.
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	☒ Finished Pharmaceutical product import

the these	☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and Date of submission	Dy. No. 34806, Dated: 24-11-2022
Details of fee submitted	Rs.7,500/- slip no. 8774928436 dated 22.11.2022 on 24-11-2022 & differential fee slip no. 05695820480 dated 30.11.2022 for Rs.142,500/- on 01st December 2022 (Total fee deposited Rs.150,000/- by two slips).
The proposed proprietary name / brand name	RHESOGLOBIN, solution for injection, 1500 IU (300 mcg of immunoglobulin)
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1 ampoule (1ml) contains: Specific antibodies to anti-Rh0 (D)…….……1500 IU (300 µg of immunoglobulin)
Pharmaceutical form of applied drug	Solution for injection
Pharmacotherapeutic Group of (API)	Biological Product / (Blood derivative)
Reference to Finished product specifications	European Pharmacopoeia
Proposed Pack size	• 1 mL [specific antibodies to anti-Rho (D) — 1,500 IU (300 µg of immunoglobulin)] per ampoule. • Box of 1 or 3 or 5 ampoules in a pack with a package insert.
Proposed unit price	MRP per 1 Amp. As per the DRUG Pricing Policy 2018.
Shelf Life	2 Years
Storage Condition	2°C - 8 °C
The status in reference regulatory authorities	Rhophylac IM/IV Injection 300mcg CSL Behring – USA
For generic drugs (me-too status)	Rhophylac IM/IV Inj 300mcg Reg. No. 041161 Marketed by Hakimsons (Impex) Pvt. Ltd.

- Updated valid legalized original CoPP with the new name and address of the company in ANNEX VIII.
- Approval of change in manufacturer's name and address in the country of origin, original legalized copy in ANNEX IX.
- Site master file of the new manufacturing site in ANNEX I.

Later, following document also submitted by the firm on 22-03-2023:

- Description and Justification of changes in RHESOGLOBIN (Production Site) including the details of Comparative Manufacturing Process at two sites and Batch analysis and Comparative data including the following details:
    1. Introduction of new manufacturing site
    2. Purpose
    3. Description of the changes to be made with all details of current and proposed edition.
        3.1 Product of API
        3.2 Finished Drug product production
    4. Analysis of possible impacts on the target product
        4.1 Production of active substance (API)
        4.2 Finished drug product
    5. Production technology scheme

5.1. Technological schemes of production of active substance (API)
5.2. Technological schemes of finished drug product production

6. Equipment details
7. Premises details
8. Validation of the technological process of API as well as FDP
9. Quality Control of intermediate product, unpacked product as well as finished product including comparative data of analysis of bulks and the drug product "RHESOGLOBIN" batches on current and proposed production sites.
10. Stability data

In conclusion, manufacturer claimed that in introduction of an additional production site and technology transfer for the drug product «**RHESOGLOBIN, solution for injections 1500 IU (300 µg of immunoglobulin)**» was carried out without changes in the manufacturing technology: the sequence of technological operations, process parameters, specifications for intermediate, bulk, finished products have not changed, which is confirmed by comparing the data of analyzes of intermediate products, bulk products, finished drug product at the ***current production site*** (Kyiv) and the ***proposed production site*** (Bila Tserkva) and tables of stability studies of validation batches. The introduction of an additional production site did not affect the quality, efficacy and safety of the finished drug product «RHESOGLOBIN, solution for injections 1500 IU».

Deliberation: Registration Board was apprised that as per CoPP the firm claimed two production sites for the applied product "RHESOGLOBIN, solution for injections 1500 IU". The Board discussed the matter and directed the firm to select one manufacturing site for the instant product. Accordingly, the firm clarified that *LLC BIOPHARMA PLASMA* have three manufacturing sites with the below cited activities:
Production, primary packaging: *9, M. Amosov St., Kyiv, 03680, Ukraine.*
Secondary packaging and Batch certification: *37-V, Street Kyivska., Bila Tserkva, Kyiv region, 09100, Ukraine.*
Quality control: *37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.***"**

Decision: Keeping in view legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy:

Case: Application of Ready to Fill Bulk Import, Local formulation, filling by M/s Sami Pharmaceuticals (Pvt.) Ltd, Karachi.
DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, export facilitation desk vide letter No. F.1-6/2019-PR-I (EFD) dated 2nd June, 2023 informed that the following firm has achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2020-2021** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board, please.

23.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name and address of marketing authorization holder (abroad)	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland.
	Name, address of manufacturer(s)	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland.
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 716/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082

		Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 14-03-2024.
	Details of letter of authorization / sole agency agreement	N/A.
	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. 14911 Dated 06-06-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN R 100 IU/ml Injection (rDNA origin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin ……..……100IU (rDNA origin)
	Pharmaceutical form of applied drug	Colorless liquid, free from turbidity and foreign matter, during storage traces of very fine sediments may be deposited.
	Pharmacotherapeutic Group of (API)	Insulin and analogues for injection, fast acting ATC: A10AB01
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	10 ml vial × 1's
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin® R [REGULAR insulin human Injection, USP (rDNA origin)] 100 units/ml (U-100) by Lilly USA, LLC, Indianapolis, USA
	For generic drugs (me-too status)	Insuget R by M/s Getz Pharma, Reg. No. 050647
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**BIOTON S.A.,** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20°C ± 5°C for 60 months Accelerated: 5°C ± 3°C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G).
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary packaging is 10ml clear glass vial, bromo-butyl rubber stopper and aluminum seal with secondary packaging unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C/ 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Detailed in Biosimilarity data mentioned below
	Module V	Detailed in Biosimilarity data mentioned below
	The firm has submitted Biosimilarity data as per following details:	

<table>
<tr><th>WHO Biosimilarity Guidelines</th><th>Data Submitted by M/s SAMI Pharmaceutical (Pvt) Ltd.</th></tr>
<tr><td>Quality Comparison
2. Physicochemical Characterization</td><td>Regular Human Insulin produced by Bioton S.A. has been compared with the reference drug, Humulin® R, produced by Eli Lilly and Company
<table>
<tr><th>Category</th><th>Quality Attributes</th><th>Analytical methods</th></tr>
<tr><td rowspan="2">Primary structure</td><td rowspan="2">Amino acid sequence</td><td>Peptide mapping</td></tr>
<tr><td>Edman method of the peptide N-terminal sequencing</td></tr>
<tr><td>Higher order structure</td><td>Secondary, tertiary and quaternary</td><td>Far UV Circular Dichroism spectra (far UV CD)</td></tr>
</table></td></tr>
</table>

		structures	Fourier Transformed Infra-Red spectra (FTIR) Near UV Circular Dichroism (near UV CD) Nuclear Magnetic Resonance analysis (NMR)
	Hydrophobicity	Hydrophobic variants	Near UV Circular Dichroism (near UV CD) Nuclear Magnetic Resonance analysis (NMR)
	Size heterogeneity	HMW impurities	Size exclusion chromatography
	In-solution particle size homogeneity	Average size	Laser diffraction
	In-Vitro Biofunctionality	Receptor binding assay	Surface Plasmon Resonance (SPR)
		Cell-based bioactivity assay	INSR/IGF-1R receptor phosphorylation assay
Biological Activity	Cell based Bioactivity Assay – Surface Plasmon Resonance (SPR) Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors. The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake.		
Immunochemical properties	For determination of HCP a specific ELISA method was developed using antibodies obtained by the immunogenization of rabbits by *E. coli* strain used during the drug substance manufacturing process. The application of specific antibodies ensured the selectivity of the method. During the validation process, the LOQ and LOD were set to 1.25 ppm and 0.625 ppm respectively. Analysis of samples revealed that HCP levels in the final drug substance were, in most cases, bellow the limit of detection. In 9 out of 101 cases, results were higher than 1.0 ppm and the highest value equals 1.7 ppm. We have set an upper limit for HCP at 10 ppm for dry substance.		
Impurities	Process-related impurities/Product-related impurities: • E. coli proteins (HCP) from the host cells • Residual DNA from the host cells • Carboxypeptidase B (specific enzyme used for insulin precursor digestion) • Zinc (used in the insulin precipitation step) • Inorganic residues determined by Sulphated ash method • Related proteins – insulin derivatives formed as side-products or degradation products during manufacture, determined by HPLC according to Ph. Eur. • HMWP include insulin oligomers and protein impurities with molecular masses greater than that of insulin determined by HPLC in accordance with Ph. Eur.		

	• A21-desamido insulin – product-related substance identified in the chromatogram in the system for related proteins and human insulin assay based on the Ph. Eur. • Single chain precursor – residual protein that has not undergone the enzymatic digestion, specific to the particular step
Stability Studies	The firm has submitted stability studies.
Non-clinical Comparison III. *In-vitro* Studies IV. *In-vivo* Studies c) Biological / Pharmacodynamic activity d) Non- clinical Studies	The principles of pharmacodynamic in vitro studies on insulin products are set out in ICH guidelines2,3. Considering these guidelines, the following set of *in-vitro* pharmacodynamic studies was adopted for comparison of Biological Product with Comparator: • Binding to IR-A and IR-B (SPR) • Tyrosine phosphorylation/dephosphorylation of IR-A and IR-B • Glycogen formation in adipocytes • Lipolysis rate • Glucose uptake An indirect evaluation of Biological Product vs. Comparator was performed including the recommended in vitro studies. Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors. The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake. Evaluation of Biological Product and Comparator biological attributes was indirect in such a way that instead of the composite products, their particular components were used for comparison. Both Biological Product and Comparator are biphasic isophane insulin injections including human insulin and protamine sulphate complex suspended in a solution of insulin of the same species. Reasoning on the Biological Product and Comparator similarity of the kinetics of binding to IR-A and IR-B is based on the comparison of their components represented by Gensulin N and Humulin N (isophane insulin) and Gensulin R and Humulin R (soluble insulin). The same set of products represented Biological Product and Comparator in the tyrosine phosphorylation and dephosphorylation.
Clinical Studies	A double blind, mono-centric, randomized crossover clinical trial with administration of a single subcutaneous dose to compare the pharmacokinetics (PK) and pharmacodynamics (PD) of two recombinant regular human insulins, the test drug being the Regular Human Insulin produced by Bioton S.A. and the reference drug, Humulin® R, (produced by Eli Lilly and Company, packaged and registered by Eli Lilly do Brasil Ltda) in patients with Type 1 Diabetes using euglycemic and hyperinsulinemic CLAMP technique. From the results obtained with this study, it is concluded that the test treatment : Regular Human Insulin produced by Bioton S.A. and the comparator treatment : Humulin ® R – Regular Human Insulin (produced by Eli Lilly and Company, packaged and registered by Eli Lilly do Brasil Ltda) are bioequivalent when considering the pharmacokinetics and pharmacodynamic parameters.

Discussion:

Registration Board was apprised that the bulk concentrate manufacturer submitted the in-vitro pharmacodynamics studies rather than in-vivo animal studies. Accordingly, the firm was asked to provide clarification on the matter. In response, the firm submitted rationale for waiving off in-vivo animal studies

taking the support of guidelines of WHO, FDA and MHRA. The detailed response is as below:

Recent changes in global regulatory guidelines, such as those issued by the World Health Organization (WHO), FDA and the United Kingdom's Medical and Healthcare products Regulatory Agency (MHRA), have recognized the potential to waive in-vivo animal studies for biosimilar approval.

WHO:
Guidelines on evaluation of Biosimilars
Replacement of Annex 2 of WHO Technical Report Series, No. 977
"If the quality comparability exercise and the nonclinical in vitro studies have shown high similarity and the level of residual uncertainty is considered acceptable to move to the clinical phase of the similarity exercise then an additional in vivo animal study is not considered necessary."
https://cdn.who.int/media/docs/default-source/biologicals/bs-documents-(ecbs)/annex-3---who guidelines-on-evaluation-of-biosimilars_22-apr-2022.pdf
MHRA:
Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues
EMEA/CHMP/BMWP/42832/2005 Rev1 4.
Non-clinical studies
….In vitro pharmacotoxicological studies should be conducted first and a decision then made as to the extent of what, if any, in vivo work in animal studies will be required….. (page 5 of 13)
https://www.ema.europa.eu/en/documents/scientificguideline/guideline-similar-biological-medicinalproducts-containing-biotechnology-derived-proteins-active_en-2.pdf
FDA:
S.5002 - FDA Modernization Act 2.0
S.5002 — 117th Congress (2021-2022)
"(z) NON CLINICAL TEST DEFINED.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug, and may include animal tests, or non-animal or human biology-based test methods, such as cell-based assays, microphysiological systems, or bioprinted or computer models.".
https://www.congress.gov/bill/117th-congress/senate-bill/5002/text

Decision: Keeping in view the Biosimilarity data submitted by the bulk concentrate manufacturer (Poland) in the light of guidelines of 297th meeting, Registration Board approved the registration of SAMULIN R 100 IU/ml Injection (rDNA origin).

Imported veterinary Biologicals from Non-Reference countries:

24.	**Name of Importer**	**M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha**
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November, 2023
	Marketing authorization holder	M/s Vetal Hayvan Sagligi Urunleri A.S., (Vetal Animal Health Products S.A), Organize Sanayi Bolgesi, Petrol Mah.14 Cad. No.1/1, Adiyaman, Turkey
	Name of Manufacturer	M/s Vetal Hayvan Sagligi Urunleri A.S., (Vetal Animal Health Products S.A), Organize Sanayi Bolgesi, Petrol Mah.14 Cad. No.1/1, Adiyaman, Turkey
	Name of exporting country	Turkey
	Brand Name +Dosage Form + Strength	AFTOVAC PLUS (Inactivated gel adjuvant FMD vaccine)
	Diary No. Date of R& I & fee	Dy No. 20103 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.83393421059)
	Composition	Each 2mL contains: Inactivated Foot and mouth disease virus…….. ≥ $6PD_{50}$

		Potency: Serotype O……. 6µg Serotype A……. 3µg Serotype Asia-1……. 3µg
	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	50 ml / vial; Decontrolled
	International availability	N/A
	Products already registered in Pakistan	FMD Vaccine of FGBI Arriah, Russia (Local agent: Mustafa Brothers, Reg# 052400) Decivac FMD Doe of Intervet, USA (Local Agent: Vety-care (Pvt) Ltd., Reg#028594)
	Stability data of finished product	The firm has submitted long term stability study data of 24 months' conducted at 2°C to 8°C for three batches (5000ml each) and accelerated stability data of 1 week at 30°C ± 2°C / % 2 ± % 0.1 as below: 03/AF-P/01 03/AF-P/02 03/AF-P/04
	Document Details	• Legalized GMP Certificate (GMP/TR/V/YI/S0195.R1 /2019) issued by Ministry for Agriculture and Forestry of Turkey on 07-06-2022. • Legalized FSC (No. 04058) issued on 09-05-2023 by Ministry of Agriculture and Forestry, Directorate General of Food and Control, Turkey confirms that product is on free sale in the market of Turkey. • Copy of product specific sole agency agreement.
	Remarks of Evaluator:	
	Decision: Keeping in view legalized FSC indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance to current import policy for finished drugs. Moreover, the firm shall provide information of sub-serotypes of FMD vaccine.	
25.	**Name of Importer**	**M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha.**
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November, 2023
	Marketing authorization holder	M/s Vetal Hayvan Sagligi Urunleri A.S., (Vetal Animal Health Products S.A), Organize Sanayi Bolgesi, Petrol Mah.14 Cad. No.1/1, Adiyaman, Turkey
	Name of Manufacturer	M/s Vetal Hayvan Sagligi Urunleri A.S., (Vetal Animal Health Products S.A), Organize Sanayi Bolgesi, Petrol Mah.14 Cad. No.1/1, Adiyaman, Turkey
	Name of exporting country	Turkey
	Brand Name +Dosage Form + Strength	AFTOVAC OIL PLUS (Inactivated Oil adjuvant FMD vaccine)
	Diary No. Date of R& I & fee	Dy no. 20103 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.22630400352)
	Composition	Each 2mL contains: Inactivated Foot and mouth disease virus…….. ≥ $6PD_{50}$ Potency: Serotype O……. 5µg Serotype A……. 3µg Serotype Asia-1……. 3µg

	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	50 ml /vial; Decontrolled
	International availability	N/A
	Products already registered in Pakistan	ARRIAH-VAC (Inactivated oil adjuvant FMD Vaccine) of FGBI Arriah, Russia (Local agent: Mustafa Brothers, Reg # 088822)
	Stability data of finished product	The firm has submitted stability study data of 24 months' observation period conducted at 2°C to 8°C for three batches as below: 03/AF-OIL/03 03/AF-OIL/05 03/AF-OIL/06
	Document Details	• Legalized GMP Certificate (GMP/TR/V/YI/S0195.R1 /2019) issued by Ministry for Agriculture and Forestry of Turkey on 07-06-2022. • Legalized FSC (No. 04058) issued on 09-05-2023 by Ministry of Agriculture and Forestry, Directorate General of Food and Control, Turkey confirms that product is on free sale in the market of Turkey. • Copy of product specific sole agency agreement.
	Remarks of Evaluator:	
	Decision: Keeping in view legalized FSC indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance to current import policy for finished drugs. Moreover, the firm shall provide information of sub-serotypes of FMD vaccine.	
26.	**Name, address of applicant / Importer**	**M/s Inouko Animal Health (Private) Limited., Address: 3rd Floor, Plaza No. 3 D-Block, DHA Phase 5 Cantt, District Lahore.**
	DSL details	License to sell drug as distributor No. 05-352-0058-043305D valid till 18-07-2023.
	Name of Manufacturer	**Ceva Animal Health Inc.** 131 Malcolm Road, Guelph, Ontario, Canada N1K1A8.
	Name of exporting country	Canada
	Brand Name +Dosage Form + Strength	Eimeria Acervulina-Brunetti-Maxima-Necatrix –Tenella Vaccine, Live oocysts Immucox ® 5
	Diary No. Date of R& I & fee	Dy. No. 13045 (R&I); Dated 08-06-2020 Rs.100,000 (Slip No.2015398) dated 08-06-2020
	Composition	Each dose of vaccine contains: *Eimeria acervulina*…….at least 151 oocysts/dose *Eimeria brunetti*……..at least 40 oocysts/dose *Eimeria maxima*……..at least 50 oocysts/dose *Eimeria necartrix*…….at least 51 oocysts/dose *Eimeria tenella*…….at least 25 oocysts/dose
	Pharmacological Group	Live veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	6 months (2°C - 8°C)
	Pack size and demanded price	1000 dose; Decontrolled
	International availability	Canada
	Stability data of finished product	The firm has submitted stability study data of 06 months for three batches under storage conditions of 2°C - 8°C: 553-H-003 553-H-004

		553-H-004
	Document Details	The firm has submitted original legalized **Free Sale certificate** (CCVB File No. CO.V1) issued by Canadian Food Inspection Agency dated 14-02-2019. The certificate confirms that Ceva Animal Health Inc., 131 malcolm Road, Guelph, Ontario, Canada is licensed to manufacture and sell for use in Canada and exportation of the product. **Veterinary Biologics certificate:** Firm has submitted Veterinary Biologics certificate issued by Canadian Food Inspection Agency dated 14-02-2019 which certify that Ceva Animal Health Inc., Canada is licensed to manufacture, package and sell immunological veterinary biological products as specified in Canadian Veterinary Biologics Establishment License Number 23 and related Veterinary Biologics Product License issued under the Authority of the Canadian *Health of Animals Act and Regulations.* This is also to certify that the above facility is inspected annually and complies with the requirements of the Health of Animal Act and Regulations and follows the general principles and practices of good manufacturing through the implementation of satisfactory quality management, quality control and quality assurance programs for veterinary biologics. Product specific **sole agency agreement** with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. Ceva Animal Health Inc. 131 Malcolm Road, Guelph, Ontario, Canada N1K1A8

Sr. No.	Observations	Response by the Firm
1.	Separate application alongwith full registration fee with relevant data for each pack size.	The firm has specified following pack size for instant application: 1000 doses
2.	The submitted Form-5A is incomplete and information against points 20, 21, 23, 24, 25, 27, 28 and 29 of Form 5A are required to be submitted.	The revised Form-5A containing complete details have been submitted.
3.	Valid drug sale license.	License to sell drug as distributor No. 05-352-0058-043305D valid till 18-07-2023.

Decision: Keeping in view legalized FSC indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for finished drugs.
The firm shall submit fee of 7500/- for correction/pre-approval change in Form-5A as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Deferred cases (Veterinary Biologicals):

27.	**Name of Importer**	**M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha**
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November 2023

	Marketing authorization holder	M/s Komipharm International Co. Ltd. 17,Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of Manufacturer	M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of exporting country	South Korea
	Brand Name +Dosage Form + Strength	PRO-VAC H5-AINK Inactivated poultry vaccine
	Diary No. Date of R& I & fee	Dy no. 20105 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.64205171)
	Composition	Each 0.5mL contains: HA Recombinant antigen of H5 type highly pathogenic Avian Influenza virus [(H5N1), (H5N6) derived HA protein] ……$\geq 2^{9.0}$ HA Unit Newcastle Disease virus (Ulster 2C strain), before inactivation……$\geq 10^{8.5}$ EID_{50}
	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	500 ml PP bottles / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Gallimune Flu H5N9 injectable vaccine of Saadat International (Reg#043501)
	Stability data of finished product	The firm has submitted stability study data of 24 months' observation period conducted at 2°C to 8°C for three batches as below: KM-H5ANK-01 KM-H5ANK-02 KM-H5ANK-03
	Document Details	• Legalized GMP Certificate (No. M2203483) issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea on 15-03-2022. • Legalized FSC (No. M2203493) issued on 15-03-2022 by Animal and plant quarantine agency, Ministry of Agriculture, Food and Rural affairs of Republic of Korea, confirms that product is on free sale in the market of Republic of Korea. • Copy of product specific sole agency agreement.
	Remarks of Evaluator: The locally available strain is H5N9 while applied vaccine strains are H5N1 and H5N6.	
	Previous Decision: Registration Board after discussion on the matter decided to defer the case for further deliberations (M-326). **Evaluation by BE&R:** The firm has submitted that according to Pakistan Veterinary Journal, MDPI Viruses International Journal, Poultry world, Reuters and various other well-known international research papers report that High pathogenic avian influenza (HPAI) H5N strains causing diseases in poultry flocks of Pakistan are H5N1 & H5N6. Therefore, vaccine containing these strains should only be used in Pakistan. There is not a single authentic research found which demonstrate that HPAI disease in Pakistan's poultry due to H5N9 strain.	
	Decision: Registration Board referred the case to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the vaccine in Pakistan.	
28.	**Name of Importer**	**M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha**
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November, 2023

	Marketing authorization holder	M/s Komipharm International Co. Ltd. 17,Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of Manufacturer	M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of exporting country	South Korea
	Brand Name +Dosage Form + Strength	PRO-VAC FT-Oil Inactivated poultry vaccine
	Diary No. Date of R& I & fee	Dy no. 20104 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.411547807965)
	Composition	Each 0.5mL contains: Inactivated Salmonella enterica serovar gallinarum culture (6.3×10^{10} / mL ~ 6.9×10^{10} / mL)……39.7%
	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	500 ml PP bottles / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Avisan Secure of M/s Hipra laboratories, Spain
	Stability data of finished product	The firm has submitted stability study data of 24 months' observation period conducted at 2°C to 8°C for three batches as below: 54FTOV06 54FTOV07 54FTOV08
	Document Details	• Legalized GMP Certificate (No. M2203483) issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea on 15-03-2022. • Legalized FSC (No. M2203490) issued on 15-03-2022 by Animal and plant quarantine agency, Ministry of Agriculture, Food and Rural affairs of Republic of Korea, confirms that product is on free sale in the market of Republic of Korea. • Copy of product specific sole agency agreement.
	Remarks of Evaluator:	
	Previous Decision: Registration Board after discussion on the matter decided to defer the case for further deliberations (M-326).	
	Decision: Keeping in view legalized FSC indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance to current import policy for finished drugs.	

Registrations of products from M/s Marush Pvt Ltd, Lahore to M/s Inouko animal Health (Private) Limited, Lahore.

Writ petition: 164277 before The Honorable Chief Justice
(Petitioner Seeks direction upon respondents to definitely decide the pending applications of the petitioner for registration and transfer of registration of drugs and medicines in the upcoming meeting of Registration Board.)

M/s Inouko animal Health (Private) Limited, Lahore applied for registration of following veterinary biological in their name from M/s Marush Pvt Ltd, Lahore:

29.	Name, address of applicant / Importer	**M/s Inouko Animal Health (Private) Limited.,** Address: 3rd Floor, Plaza No. 3 D-Block, DHA

		Phase 5 Cantt, District Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0066-072607D valid till 15-06-2023.
	Name of Manufacturer	M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary.
	Name of exporting country	Hungary
	Brand Name +Dosage Form + Strength	**Cevac Transmune Live freeze dried complex vaccine**
	Diary No. Date of R& I & fee	Dy. No. 13406 (R&I); Dated 30-05-2023 Rs.75,000 (Slip No.1582146785)
	Composition	Each dose contains: Infectious bursal disease virus (IBDV), Winterfield 2512 strain, G-61……..min 0.1 CID_{50}
	Pharmacological Group	Live Freeze dried complex vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's Specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	2500 doses vial ; Decontrolled
	Products already registered in Pakistan	Cevac Transmune Live freeze dried complex vaccine (Reg # 104001)
	Stability data of finished product	Not submitted
	Document Details	d. Valid legalized free sale certificate issued by The Directorate of Veterinary Medicinal Products, Hungary confirm free sale status of the product. The certificate is valid till 11-01-2026. e. Legalized GMP certificate issued by Directorate of Veterinary Medicinal Products, Hungary dated 19-07-2019 declares that guidelines of Good Manufacture Practice are followed. f. Product specific sole agency agreement with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary is located in Hungary. The firm has submitted following: Copy of Registration letter Termination/change of Distribution letter from manufacturer. NOC from the existing registration holder (M/s Marush Private. Limited, Lahore).
	The submitted Form-5A is incomplete and information against following points are required to be submitted: • Outline of method of manufacture of applied vaccine • A full description of the specifications and analytical methods to assure identity, strength, quality, purity and homogeneity throughout the shelf life of the product. • Labelling and prescribing information shall be submitted • Description of the equipment to be used for the quality control of the active raw material and the finished products. • Facility of the water processing, with specifications. • Environment control processing with details • Field trial data / clinical data to justify the need and immunological relevance of applied vaccine • Stability study data of applied product till claimed shelf life.	

	Decision: Registration Board deliberated the matter and decided to defer the case for submission of shortcomings.	
30.	Name, address of applicant / Importer	**M/s Inouko Animal Health (Private) Limited.,** Address: 3rd Floor, Plaza No. 3 D-Block, DHA Phase 5 Cantt, District Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0066-072607D valid till 15-06-2023.
	Name of Manufacturer	M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary.
	Name of exporting country	Hungary
	Brand Name +Dosage Form + Strength	**Cevac Mass L Live freeze dried vaccine**
	Diary No. Date of R& I & fee	Dy. No. 13404 (R&I); Dated 30-05-2023 Rs.75,000 (Slip No. 90422838833)
	Composition	Each dose of vaccine contains: Infectious bronchitis virus (IBV), Massachussetts type strain B-48..……..min 2.8log10 EID_{50}
	Pharmacological Group	Live Freeze dried complex vaccine
	Type of Form	Form-5A
	Finished Product Specification	BP Specification
	Shelf Life	18 months (2°C-8°C)
	Pack size and demanded price	2500 doses vial ; Decontrolled
	Products already registered in Pakistan	Cevac Mass L Live freeze dried vaccine (Reg # 104000)
	Stability data of finished product	Not submitted
	Document Details	a. Valid legalized free sale certificate issued by The Directorate of Veterinary Medicinal Products, Hungary confirm free sale status of the product dated 12-01-2021. b. Legalized GMP certificate issued by Directorate of Veterinary Medicinal Products, Hungary dated 19-07-2019 declares that guidelines of Good Manufacture Practice are followed. c. Product specific sole agency agreement with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary is located in Hungary. The firm has submitted following: Copy of Registration letter Termination/change of Distribution letter from manufacturer. NOC from the existing registration holder (M/s Marush Private. Limited, Lahore).
	The submitted Form-5A is incomplete and information against following points are required to be submitted: • Outline of method of manufacture of applied vaccine • A full description of the specifications and analytical methods to assure identity, strength, quality, purity and homogeneity throughout the shelf life of the product. • Labelling and prescribing information shall be submitted • Description of the equipment to be used for the quality control of the active raw material and the finished products. • Facility of the water processing, with specifications. • Environment control processing with details	

	• Field trial data / clinical data to justify the need and immunological relevance of applied vaccine • Stability study data of applied product till claimed shelf life.	
	Decision: Registration Board deliberated the matter and decided to defer the case for submission of shortcomings.	
31.	Name, address of applicant / Importer	**M/s Inouko Animal Health (Private) Limited.,** Address: 3rd Floor, Plaza No. 3 D-Block, DHA Phase 5 Cantt, District Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0066-072607D valid till 15-06-2023.
	Name of Manufacturer	M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary.
	Name of exporting country	Hungary
	Brand Name +Dosage Form + Strength	**Cevac I-Bird Live freeze dried vaccine**
	Diary No. Date of R& I & fee	Dy. No. 13404 (R&I); Dated 30-05-2023 Rs.75,000 (Slip No. 90422838833)
	Composition	Each dose of vaccine contains: Avian Infectious bronchitis virus, variant strain 1/96 ..……..at least 2.8log10 EID_{50}
	Pharmacological Group	Live Freeze dried vaccine
	Type of Form	Form-5A
	Finished Product Specification	BP Specification
	Shelf Life	18 months (2°C-8°C)
	Pack size and demanded price	2500 doses vial ; Decontrolled
	Products already registered in Pakistan	Cevac I-Bird Live freeze dried vaccine (Reg # 103999)
	Stability data of finished product	Not submitted
	Document Details	a. Valid legalized free sale certificate issued by The Directorate of Veterinary Medicinal Products, Hungary confirm free sale status of the product dated 12-01-2021. The certificate is valid till b. Legalized GMP certificate issued by Directorate of Veterinary Medicinal Products, Hungary dated 19-07-2019 declares that guidelines of Good Manufacture Practice are followed. c. Product specific sole agency agreement with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary is located in Hungary. The firm has submitted following documents: Copy of Registration letter Termination/change of Distribution letter from manufacturer. NOC from the existing registration holder (M/s Marush Private. Limited, Lahore).
	The submitted Form-5A is incomplete and information against following points are required to be submitted: • Outline of method of manufacture of applied vaccine • A full description of the specifications and analytical methods to assure identity, strength, quality, purity and homogeneity throughout the shelf life of the product. • Labelling and prescribing information shall be submitted	

	• Description of the equipment to be used for the quality control of the active raw material and the finished products. • Facility of the water processing, with specifications. • Environment control processing with details • Field trial data / clinical data to justify the need and immunological relevance of applied vaccine • Stability study data of applied product till claimed shelf life.	
	Decision: Registration Board deliberated the matter and decided to defer the case for submission of shortcomings.	
32.	Name, address of applicant / Importer	**M/s Inouko Animal Health (Private) Limited.,** Address: 3rd Floor, Plaza No. 3 D-Block, DHA Phase 5 Cantt, District Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0066-072607D valid till 15-06-2023.
	Name of Manufacturer	M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary.
	Name of exporting country	Hungary
	Brand Name +Dosage Form + Strength	**Vectormune ND Live, frozen vaccine**
	Diary No. Date of R& I & fee	Dy. No. 14111 (R&I); Dated 06-06-2023 Rs.75,000 (Slip No. 792400133)
	Composition	Each dose of vaccine contains: Live recombinant turkey herpes virus with inserted NDV..……..at least 2500 PFU
	Pharmacological Group	Live, recombinant frozen vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per Innovator's Specification
	Shelf Life	24 months (stored in nitrogen container)
	Pack size and demanded price	2000 doses glass ampoule; Decontrolled
	Products already registered in Pakistan	VECTORMUNE ND Live, recombinant frozen vaccine (Reg # 107877)
	Stability data of finished product	Not submitted
	Document Details	d. Valid legalized free sale certificate issued by The Directorate of Veterinary Medicinal Products, Hungary confirm free sale status of the product dated 12-01-2021. The certificate is valid till e. Legalized GMP certificate issued by Directorate of Veterinary Medicinal Products, Hungary dated 19-07-2019 declares that guidelines of Good Manufacture Practice are followed. f. Product specific sole agency agreement with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. M/s. Ceva-Phylaxia Veterinary Biologicals Co., Ltd. 1107 Budapest, Szallas u.5. Hungary is located in Hungary. The firm has submitted following documents: Copy of Registration letter Termination/change of Distribution letter from manufacturer. NOC from the existing registration holder (M/s Marush Private. Limited, Lahore).
	The submitted Form-5A is incomplete and information against following points are required to be submitted: • Outline of method of manufacture of applied vaccine	

	• A full description of the specifications and analytical methods to assure identity, strength, quality, purity and homogeneity throughout the shelf life of the product. • Labelling and prescribing information shall be submitted • Description of the equipment to be used for the quality control of the active raw material and the finished products. • Facility of the water processing, with specifications. • Environment control processing with details • Field trial data / clinical data to justify the need and immunological relevance of applied vaccine • Stability study data of applied product till claimed shelf life.
	Decision: Registration Board deliberated the matter and decided to defer the case for submission of shortcomings.

CASES OF DD-IV (MR. ANUM SAEED)

33. Imported veterinary biological applied by M/s Snam Pharma, Lahore deferred in 323rd meeting of Registration Board.

Following product of M/s Snam Pharma, Lahore was deferred in 323rd meeting of Registration Board as per following details:

Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14 November, 2022.
Name and address of Manufacturer	M/s Sante Animale, Lot 157, zone industrielle Sud-Ouest B.P.278- C.P 28 810 Mohammedia-Morocco.
Name of the exporting country	Morocco.
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (10 doses)
Diary No. Date of R& I & fee	Dy. No. 9929R&I Dated 19-04-2022 Rs. 75,000/- (Slip No. 6035676445)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain ≥ $10^{3.5}$ TCID50 **Solvent:** Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection …s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent.
Pack size	10 doses 20ml solvent
Reference Regulatory Authority Availability	N/A

Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: Notarized copy of product specific sole agency agreement. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	Firm has submitted original legalized FSC which does not indicate product availability in country of origin.
Previous Decision in 321st RB meeting	*Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.*
Evaluation by DBER	Firm has submitted that Bovivax LSD-N vaccine is registered and exported to in following countries: Bulgaria Kenya Egypt UAE To support above statement firm has also submitted copies of registration letters of subject product in Bulgaria, Kenya, Egypt and UAE. The firm has further submitted that the manufacturer of Bovivax LDS-N vaccine ca also be verified from the site of FAO (Food and Agriculture Organization of United Nations) and shared following link: https://www.fao.org/3/cb1892en/cb1892en.pdf
Previous Decision in 323rd RB meeting	*Registration Board deferred the case for further deliberation as FAO is not a regulatory organization and advised to confirm free sale status in reference / non-reference regulatory authorities.*
Evaluation by DBER	The firm has submitted a letter from "The Moroccan Food Safety Office" (ONSSA) who is responsible for veterinary medicine registration and animal health surveillance in Morocco. According to the letter "Bovivax LSD-N" vaccine was registered in Morocco mainly to prevent the risk of an LSD outbreak in the country, which would require a rapid response. However, there have been no cases reported of LSD in Morocco or North African Region. The firm has also submitted a letter from the manufacturer which states that their product "Bovivax LSD-N Vaccine" is sold in following countries: • BULGARIA

	• SERBIA • UKRAINE • BANGLADESH • MALAYSIA • EGYPT • UAE • KENYA • OMAN
Decision: Registration Board deferred the case for submission of free sale in the country of origin or in RRA or in any three European countries.	

34. Imported veterinary biological applied by M/s Snam Pharma, Lahore deferred in 323rd meeting of Registration Board.

Following product of M/s Snam Pharma, Lahore was deferred in 323rd meeting of Registration Board as per following details:

Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14th November, 2022.
Name and address of Manufacturer	M/s Sante Animale Lot 157, zone industrielle Sud
Name of exporting country	Morroco
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (50 doses)
Diary No. Date of R& I & fee	Dy. No. 8315R&I Dated 30-03-2022 Rs. 75,000/- (Slip No. 10439736)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain ≥ $10^{3.5}$ TCID50 **Solvent:** Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection …s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively. For GMP of manufacturer firm has referred to Eudra GMP Certificate No. 118/2020/GMP. Which is verifiable from the site.
Pack size	50 doses 50ml solvent
Reference Regulatory Authority Availability	N/A

Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: Notarized copy of product specific sole agency agreement. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: (a) Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. (b) Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	Firm has submitted original legalized FSC which does not indicate product availability in country of origin.
Previous Decision in 321st RB meeting	*Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.*
Evaluation by DBER	Firm has submitted that Bovivax LSD-N vaccine is registered and exported to in following countries: Bulgaria Kenya Egypt UAE To support above statement firm has also submitted copies of registration letters of subject product in Bulgaria, Kenya, Egypt and UAE. The firm has further submitted that the manufacturer of Bovivax LDS-N vaccine ca also be verified from the site of FAO (Food and Agriculture Organization of United Nations) and shared following link: https://www.fao.org/3/cb1892en/cb1892en.pdf
Previous Decision in 323rd RB meeting	*Registration Board deferred the case for further deliberation as FAO is not a regulatory organization and advised to confirm free sale status in reference / non-reference regulatory authorities.*
Remarks of Evaluator	The firm has submitted a letter from "The Moroccan Food Safety Office" (ONSSA) who is responsible for veterinary medicine registration and animal health surveillance in Morocco. According to the letter "Bovivax LSD-N" vaccine was registered in Morocco mainly to prevent the risk of an LSD outbreak in the country, which would require a rapid response. However, there have been no cases reported of LSD in Morocco or North African Region. The firm has also submitted a letter from the manufacturer which states that their product "Bovivax LSD-N Vaccine" is sold in following countries: • BULGARIA

	• SERBIA • UKRAINE • BANGLADESH • MALYSIA • EGYPT • UAE • KENYA • OMAN
Decision: Registration Board deferred the case for submission of free sale in the country of origin or in RRA or in any three European countries.	

35. Imported veterinary biological applied by M/s Vet Line International, Lahore deferred in 317th meeting of Registration Board.

Following product of M/s Vet Line International, Lahore was deferred in 317th meeting of Registration Board as per following details:

Name and address of Importer	M/s Vet Line International, Plot No. 939-A,Block-J, Phase-I,LDA Avenue, Lahore
Detail of DSL	No. 05-352-0066-040712D dated 09-02-2019 renewed upto 09-02-2021
Name and address of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arched'Oe 2,37390, Notre Dame D' Oe, France. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
Brand Name +Dosage Form + Strength	ITA New Flu H9
Diary No. Date of R& I & fee	Dy. No. 23585(R&I) dated 09-07-2018 Rs. 100000/- dated 09-07-2018
Composition	Each dose (0.2mL) of vaccine contains: Inactivated Avian Influenza virus, type A, sub-type H9N2…. min. 8log2 HI Inactivated Newcastle disease virus, LaSota strain…. min. 5log2 HI
Pharmacological Group	Veterinary Vaccine
Type of Form	Form-5A
Finished Product Specification	As per Innovator.
Shelf Life	24 months (2^0C-8^0C)
Document Details	i. Valid Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-07-2017 issued by Directorate of ii). Veterinary Medicinal Products, Hungary ii. Valid Legalized FSC No. 02.2/2397-2/2018 dated 20-04-2018 issued by Directorate of **iii).** Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
Pack size	500ml(2000 doses)
International Availability	UEMOA (West African community including 8 countrie)
Products already registered in Pakistan	AI-OLVAC of M/s Forward Solutions.
Decision of RB in 313th meeting	*Registration Board deferred the case for confirmation of Influenza disease status in country of origin and reference regulatory authorities.*

Remarks of evaluator	The firm submitted the references from UK, European Union & Hungary along with weblinks of official websites. **UK:** In UK, the vaccination against Avian Influenza is not permitted. Stamping out is the most effective means of controlling an outbreak. In England vaccination is only available for zoo birds. Vaccination of zoo birds against avian influenza is currently not permitted in Scotland or Wales. **European Union & Hungary:** Vaccination against Avian Influenza is prohibited on their territory, except for following: **a. Emergency Vaccination:** A Member state may introduce emergency vaccination in poultry or other captive birds as a short-term measure to contain an outbreak when a risk assessment indicates there is a significant and immediate threat of avian influenza spreading within or into the Member State concerned. **b. Preventive Vaccination:** Member States may introduce preventive vaccination in poultry or other captive birds as a long-term measure in accordance with this Section where they deem that on the basis of a risk assessment certain areas of their territory, type of poultry husbandry or certain categories of poultry or other captive birds or the poultry or other captive birds' compartments are exposed to the risk of avian influenza.
Decision of RB in 316th meeting	*"Registration Board deferred the case for further deliberation in next meeting as neither product is on Free Sale in country of origin nor formulation is available in RRAs"*
Remarks of evaluator	The firm has now submitted that vaccines manufactured in reference countries only for export are registered & marketed in Pakistan and the firm requested that if DRAP can't allow them to register their product on the point of non-availability in country of origin & RRAs, DRAP kindly cancel all registration of same products.
Decision of RB in 317th meeting	*Registration Board deferred the product for submission of following by the firm:* **i.** *Valid legalized CoPP OR Free Sale Certificate issued by regulatory authority of country of origin indicating reason of non-availability of product in country of origin* **ii.** *Details of last usage of the product in country of origin or in any reference regulatory authority.*
Remarks of evaluator	The firm has submitted FSC which states that the product "ITA NEW FLU H9" vaccine is licensed for manufacture in the country of origin i.e. Hungary, without being used on the Hungarian market. However, it can be sold freely in the countries where the vaccine has valid marketing authorization. The firm has also submitted the references from UK and European Union along with web-links of official websites which show that vaccination against Avian Influenza is prohibited on their territory.
Decision: Deferred for submission of free sale in the country of origin or in RRA or in three European countries.	

36. Imported veterinary biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 323rd meeting of Registration Board.

Following product of M/s Vety Care (Pvt.) Ltd. was deferred in 323rd meeting of Registration Board as per following details:

Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018.

	Copy of Renewal receipt dated 26-12-2018
Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands
Brand Name +Dosage Form + Strength	**Nobilis IB Primo QX** Lyophilisate for suspension for spray
Composition	Each dose of reconstituted vaccine contains: Live attenuated avian infectious bronchitis virus, strain D388…$10^{4.0}$105.5 EID50* *50% egg infective dose
Finished Product Specification	Innovator Specs
Pharmacological Group	Veterinary Vaccine
Shelf Life	15 months (2^0C-8^0C)
International availability	Not Provided.
Products already registered in Pakistan	Not Available as per record.
Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 5721(R&I) Dated 16-02-2018 Rs. 100000/- 16-02-2018
Demanded Price / Pack size	10Cups x 10000 doses
General documentation	Valid legalized CoPP No. 01/17/113770 dated 13-10-2017 issued by EMA indicating product availability in exporting region.
Remarks of Evaluator	Real time stability data provided is of 0, 6, 11, 18 months instead of appropriate time intervals and only **titer and residual humidity** are tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:
	Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate
Decision of RB in 288th meeting:	*"Registration Board deferred the case for submission of complete stability data indicating all the parameters tested in COA.*
Evaluation by DBER	The firm has now submitted that as per Intervet the stability data already provided as per European Union Guidelines and is being accepted all over the world.
Decision of RB in 292nd meeting:	*Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.*
Evaluation by expert working group on veterinary drugs	*Referred the case for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Decision of RB in 313th meeting:	*Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Evaluation of DBE&R	*Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting:* *Already D274 strain is present which gives protection against D388 because* *D388 is IB variant equal to QX virus it may be recommended for import*

	but in killed form not in live form.
Decision of RB in 317th meeting:	As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317th decided as under: ***Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.***
Evaluation by DBE&R	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin. (firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP).* *European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation* are at *0, 6, 11, 18 months' time intervals*
Decision of RB in 323rd meeting:	Deferred for the following: For submission of complete stability data indicating all the parameters tested in COA and on all time points as recommended by European Union Guidelines. For clarification regarding status of product would it be in combo pack or otherwise as firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP.
Evaluation by DBE&R	The firm has submitted that stability data already provided is according to European Pharmacopeia and demonstrate adequate stability of the product. While EU guidelines state that products with expected shelf life of greater than one year, the studies should be conducted every three months during the first year of storage, every six months during the second year, and annually thereafter. So, the testing frequency should have been 0,3,6,9,12,18,24…..months but the stability data provided by the firm is at 0,6,11,18 months. Moreover, the stability data does not include all parameters tested in COA. (only titer and residual humidity are tested as per data). The firm further submitted that the product Nobilis IB Primo QX is not a combo pack and they need approval of lyophilized part only. However, the CoPP is for lyophilisate and solvent both.
Decision: Deferred for the following; **i. Clarification on the point that the CoPP is of combo pack (Lyophilisate and solvent both) but the firm has applied for registration of lyophilized part only.** **ii. The stance of the firm on the expert opinion of Ministry of National Food Security and Research which is as; *"Already D274 strain is present which gives protection against D388 because D388 is IB variant equal to QX virus it may be recommended for import but in killed form not in live form."***	

37. Imported veterinary biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 312th meeting of Registration Board.

Following product of M/s Vety Care (Pvt.) Ltd. was deferred in 312th meeting of Registration Board as per following details:

Name of Applicant	**M/s Vety Care (Pvt.) Ltd., Plot #77, St#6, I-10/3, Islamabad.**
DSL details	DSL No. 156 ICT/2013 dated 31-12-2014 valid till 20-12-2022.
Name of Manufacturer	**Product License Holder:** M/s Intervet Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands Manufacturer: M/s Intervet International B.V. Wim de Korverstraat 35 5831, AN Boxmeer, Netherland
Brand Name +Dosage Form + Strength	Nobilis Rismavac

Composition	Each dose contains: Live Chicken Herpes Virus, Strain CVI988……at $3.0 \log_{10} TCID_{50}$
Finished product specifications	Ph. Eur. Specifications
Pharmacological Group	Veterinary Vaccine
Shelf life	60 months (Liquid Nitrogen □□-100°C)
International availability	Netherland
Alternate Products already registered in Pakistan	Cevac MD Rispens (Reg. No. 077532)
Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 17772 (R&I) Date: 15-01-2020 &24-06-2021 Rs. 100000/-
Demanded Price /Pack size	1000 Doses Ampoule/ De-controlled
General documentation	Legalized COPP No. 251446 dated 28-05-2019
Evaluation by DBER	i. Only Virus Titer has been performed in stability studies. The manufacturer has submitted that they only virus titration might change during stability studies therefore only one test is performed. ii. The firm has applied for two pack sizes against one CoPP while pack sizes are not mentioned on CoPP. The firm was asked for evidence and the firm submitted that product is available in country of origin. iii. No. of doses/ pack is not mentioned in stability studies. iv. Stability study data provided is of only last time point.
Decision of RB in 312th meeting:	Registration Board deferred the product for submission of following by the firm: *a. Stability data indicating pack size of the product including all parameters as mentioned in finished product specifications for appropriate time intervals i.e. 0, 3, 6, 9, 12, 18…….months.* *b. Valid Legalized CoPP indicating desired pack sizes as two different pack sizes are applied.*
Evaluation by DBER	**1.** The firm has now provided the stability data of 3 random batches of 2000 doses at following time intervals and only virus titration and identification tests are performed; Batch A2904: 0,9,15,21,27,33,35,42 months Batch A760A: 0,24,36,48,60 months Batch A8584: 0,12,24,36,48 months. **However, stability data of 3 commercial batches of 1000 doses pack size, including all parameters as mentioned in Finished Product Specifications for appropriate time intervals, is still not provided.** **2.** Regarding CoPP, the firm informed that the COPP is on WHO approved format and pack sizes are not mentioned in COPP. The firm has submitted valid legalized COPP No. 258907 dated 1st March,2023.
Decision: **Deferred for submission of stability data of 03 commercial batches of applied pack size indicating all parameters as mentioned in Finished Product Specifications and on all time points as recommended by the European Union guidelines.**	

38. Imported veterinary biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 312th meeting of Registration Board.

Following product of M/s Vety Care (Pvt.) Ltd. was deferred in 312th meeting of Registration Board as per following details:

Name of Applicant	**M/s Vety Care (Pvt.) Ltd., Plot #77, St#6, I-10/3, Islamabad.**

DSL details	DSL No. 156 ICT/2013 dated 31-12-2014 valid till 20-12-2022.
Name of Manufacturer	**Product License Holder:** M/s Intervet Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands Manufacturer: M/s Intervet International B.V. Wim de Korverstraat 35 5831, AN Boxmeer, Netherland
Brand Name +Dosage Form + Strength	Nobilis Rismavac
Composition	Each dose contains: Live Chicken Herpes Virus, Strain CVI988……at least $3.0\log_{10}TCID_{50}$
Finished product specifications	Ph. Eur. Specifications
Pharmacological Group	Veterinary Vaccine
Shelf life	60 months (Liquid Nitrogen ❑ -100°C)
International availability	Netherland
Alternate Products already registered in Pakistan	Cevac MD Rispens (Reg. No. 077532)
Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 17772 (R&I) Date: 15-01-2020 &24-06-2021 Rs. 100000/-
Demanded Price /Pack size	2000 Doses Ampoule/ De-controlled
General documentation	Legalized CoPP No. 251446 dated 28-05-2019
Remarks of Evaluator	i. Only Virus Titer has been performed in stability studies. The manufacturer has submitted that they only virus titration might change during stability studies therefore only one test is performed. ii. The firm has applied for two pack sizes against one CoPP while pack sizes are not mentioned on CoPP. The firm was asked for evidence and the firm submitted that product is available in country of origin. iii. No. of doses/ pack is not mentioned in stability studies. iv. Stability study data provided is of only last time point.
Decision of RB in 312th meeting:	Registration Board deferred the product for submission of following by the firm: *a. Stability data indicating pack size of the product including all parameters as mentioned in finished product specifications for appropriate time intervals i.e. 0, 3, 6, 9, 12, 18……..months.* *b. Valid Legalized CoPP indicating desired pack sizes as two different pack sizes are applied.*
Evaluation by DBER	**1.** The firm has now provided the stability data of 3 random batches of 2000 doses at following time intervals and only virus titration and identification tests are performed; (Batch size is not mentioned) Batch A2904: 0,9,15,21,27,33,35,42 months Batch A760A: 0,24,36,48,60 months Batch A8584: 0,12,24,36,48 months. **However, the stability data of 3 commercial batches of desired pack size including all parameters as mentioned in Finished Product Specifications at appropriate time intervals is still required.** **2.** Regarding CoPP, the firm informed that the CoPP is on WHO approved format and pack sizes are not mentioned in CoPP. The

	firm has submitted valid legalized CoPP No. 258907 dated 1st March,2023.
Decision: **Deferred for submission of stability data of 03 commercial batches of applied pack size indicating all parameters as mentioned in Finished Product Specifications and on all time points as recommended by the European Union guidelines.**	

APPLICATIONS FOR REGISTRATION OF A DRUG FOR LOCAL MANUFACTURE

Sr. No.	Brand Name & Composition	Pack size	Name of Manufacturer	Dy. No. Date of Application Fee Status
39.	UVAS FMD Vaccine Each 3ml dose contains: FMD Type "O" "A" & "Asia-1" (OIE)…….4.5µg 146S protein Mineral oil (USP)…….1.5ml Thiomersal sodium (USP)…….0.004% **For Virus Inactivation** Binaryethyleneimine	Multi-dose vial 15ml (5mlx3ml)	M/s. University of Veterinary and Animal Sciences (UVAS), Training Center for Biologics Production (TCBP-FMD), Ravi Campus, Pattoki.	Dy. No.17019 dated 07-07-2023 Fee Rs. 30,000 (Deposit slip# 2604288415)
40.	UVAS FMD Vaccine Each 3ml dose contains: FMD Type "O" "A" & "Asia-1" (OIE)…….4.5µg 146S protein Mineral oil (USP)…….1.5ml Thiomersal sodium (USP)……...0.004% **For Virus Inactivation** Binaryethyleneimine	Multi-dose vial 30ml (10mlx3ml)	M/s. University of Veterinary and Animal Sciences (UVAS), Training Center for Biologics Production (TCBP-FMD), Ravi Campus, Pattoki.	Dy. No.17020 dated 07-07-2023 Fee Rs. 30,000 (Deposit slip# 8117588306)
41.	UVAS FMD Vaccine Each 3ml dose contains: FMD Type "O" "A" & "Asia-1" (OIE)…….4.5µg 146S protein Mineral oil (USP)…….1.5ml Thiomersal sodium (USP)……...0.004% **For Virus Inactivation** Binaryethyleneimine	Multi-dose vial 50ml (16mlx3ml)	M/s. University of Veterinary and Animal Sciences (UVAS), Training Center for Biologics Production (TCBP-FMD), Ravi Campus, Pattoki.	Dy. No.5823 dated 01-03-2023 Fee Rs. 30,000 (Deposit slip# 98002976400)
42.	UVAS FMD Vaccine Each 3ml dose contains: FMD Type "O" "A" & "Asia-1" (OIE)…….4.5µg 146S protein Mineral oil (USP)…….1.5ml Thiomersal sodium (USP)……...0.004% **For Virus Inactivation** Binaryethyleneimine	Multi-dose vial 75ml (25mlx3ml)	M/s. University of Veterinary and Animal Sciences (UVAS), Training Center for Biologics Production (TCBP-FMD), Ravi Campus, Pattoki.	Dy. No.17018 dated 07-07-2023 Fee Rs. 30,000 (Deposit slip# 17866042254)

Remarks of Evaluator:

All the four above mentioned applications are incomplete and the enclosures/documents required under Form-5 of DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976 are not attached with the dossiers. Details of the documents required under Form 5 are as under;

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF A DRUG FOR LOCAL MANUFACTURE

Dosage Form: ----------

i). Name and address of the manufacturer (applicant).
ii). Brand (Proprietary) name of Drug.
iii). The chemical name(s) and, as appropriate and available the established (generic) names and synonyms of the drug.
iv). Strength of active ingredient(s) per unit, e.g. each tablet or 5 ml, etc. contains.
v). Pharmacological group.
vi). Recommended clinical use.
vii). Proposed route of administration.
viii). Proposed dosage.
ix). Proposed shelf life of the drug.
x). Proposed storage conditions of finished product.
xi). Unit price of the drug, e.g. per tablet, per capsule, per 5ml, etc.
xii). In case of international availability, provide the following information, namely: -
   a. name of the drug;
   b. country where sold/registered; and
   c. name of the company selling the drug or having registration to manufacture (include supporting documents/proof of international registration.
xiii). Brand name(s) of drug available in Pakistan.
xiv). Name(s) of company(s) manufacturing in Pakistan.
xv). Composition (actives &excipients) including statement of the quantitative composition, giving the weight or measure for each active substance used in the manufacture of the dosage form.
xvi). Outline of the method of manufacture.
xvii). Persons under whose direct supervision and control the drug is manufactured with the following details, namely:-
   a. total number of technical staff; and
   b. name, qualification, and designation of the persons directly supervising the manufacture of the drug applied for registration, and any change shall be properly documented and record maintained by the manufacturer.
xviii). Name of equipment that will be used in the manufacture of the drug applied for registration:

	cGMP compliant	
1. _____	Yes	No
2. _____	Yes	No
3. _____	Yes	No
4. _____	Yes	No

xix). Full descriptions of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.
xx). Name, qualification and designation of the persons who will be responsible for the quality control of the drug.
xxi). Description of the equipment to be used for the quality control of the active raw material and the finished products.
xxii). Labeling and prescribing information (to be mentioned on the pack/leaflet) specimen or draft shall be submitted for the following class as of drugs, namely: -
   a. C.N.S. stimulants;
   b. drugs affecting uterine motility;
   c. drugs inhibiting hormonal production;
   d. hormones and other steroidal preparation excluding preparations for external and topical use;
   e. narcotic drugs as per Single Convention on Narcotic Drugs 1961; and

f. psychotropic substances mentioned as per convention on psychotropic substances, 1971.
(Specimen of label to be submitted as soon as production starts)

xxiii). Facility of water processing with specifications.
xxiv). Environment control processing with details.
xxv). Type of container/packaging.
xxvi). A copy of last Inspection Report conducted by the Ministry of Health.

Decision: Products from Serial No. 39-42 are deferred for submission of documents/enclosures required under Form-5 of Drugs (Licensing, Registering And Advertising) Rules, 1976.

43. Imported veterinary biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 323rd meeting of Registration Board.

Following product of M/s Vety Care (Pvt.) Ltd. was deferred in 323rd meeting of Registration Board as per following details:

Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands.
Brand Name +Dosage Form + Strength	**Nobivac Tricat Trio** Lyophilisate and solvent for suspension for injection
Composition	After Freeze-drying Each dose contains: Live FCV strain F9……at least 4.6 log10 PFU Live FVR strain G2620A……at least 5.2 log10 PFU Live FPLV strain MW-1……at least 4.3 log10 TCID50 Nobivac Solvent: Each ml contains: Disodium phosphate dihydrate.....0.31mg Potassium dihydrogen Phosphate ….0.21mg Water for injections to 999.16 mg
Finished Product Specification	Innovator Specs
Pharmacological Group	Veterinary Vaccine
Shelf Life	33 months (2-8^{0}C)
International availability	Not Provided.
Products already registered in Pakistan	Not Available as per record.
Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 11336(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
Demanded Price / Pack size	1's Vial Powder 1's Vial Solvent
General documentation	Valid legalized CoPP No. 249028 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
Remarks of Evaluator	The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration. Real time stability data provided is of 0,9,15,21,27,36 months instead of appropriate time intervals and only titer and residual moisture is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at

	regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.
Decision of RB in 288th meeting:	*"Registration Board deferred the case for submission of following by the firm:* *Approval status of above product registration by reference regulatory authorities.* *Complete stability data indicating all the parameters tested in COA."*
Evaluation by DBER	*The firm has now submitted the following:* *Copy of modification approval in Nobivac Tricat Trio indicating registration number of said product issued by Ministry of Economic Affairs, Chief Veterinary Officer of The Netherlands, The Hague. However, as per submitted CoPP the product is not registered in country of origin.* *As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.*
Decision of RB in 292nd meeting:	*Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.*
Evaluation by expert working group on veterinary drugs	*Referred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Decision of RB in 313th meeting:	*Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Evaluation of DBE&R	*Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting:* *Feline (cat)vaccine.* *It is a routine combination, already many companies have this combination, therefore, may be recommended for import.*
Decision of RB in 317th meeting:	As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317th decided as under: *Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.*
Evaluation by DBE&R	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin, but the word "live" is missing in it however it is live as per information available on following web link* https://db.cbg-meb.nl/marketedauth/v10471-90wr-29012014.pdf *European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation* are at *0,9,15,21,27,36 months' time intervals.*
Decision of RB in 323rd meeting:	Deferred for submission of complete stability data indicating all parameters tested in COA and on all time points as recommended by European Union Guidelines.

Evaluation by DBE&R	Now the firm has submitted the stability data of Nobivac Tricat Trio and the parameters tested are Appearance, Residual moisture, Assay, Virus content (FCV), Virus content (FVR), Virus content (FPLV) and Container closure test at time intervals 0,12,24and 33 months. While EU guidelines state that products with expected shelf life of greater than one year, the studies should be conducted every three months during the first year of storage, every six months during the second year, and annually thereafter. So, the testing frequency should have been 0,3,6,9,12,18,24…..months.
Decision: Keeping in view legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to current import policy for Finished Drugs.	

Miscellaneous Cases:

Exemption of Drugs (Labelling and Packaging) Rules, 1986 and permission for Local Printing of Labelling Particulars of imported Registered Biological Products.

Following product of M/S Lab Diagnostic SMC Pvt. Ltd. Rawalpindi was approved in 321st meeting of Registration board and Registration Letter was issued vide Letter# F.3-88/2015-DDC(BD)V-II(M-321) dated 02nd December,2022 as per detail mentioned below:

Sr. No.	Registration No.	Name of Drug(s) and composition	Packing	MRP	Approved Shelf life
44.	115087	Vinox 40mg Each 0.4ml Pre-filled syringe contains 40mg enoxaparin sodium injection **Ph.Eur. Specification**	2's PFSs	Rs. 813.67/-	36 months (Below 30^0C)
45.	115088	Vinox 60mg Each 0.6ml Pre-filled syringe contains 60mg enoxaparin sodium injection **Ph.Eur. Specification**	2's PFSs	Rs. 1044.46/-	36 months (Below 30^0C)

(**Product License Holder and Manufacturer**: Nanjing King-Friend Biochemical Pharmaceutical co. ltd. located at No. 16 Xuefu Road, Nanjing High and New Technology Development Road, Nanjing, China.)

On request of the firm, a corrigendum letter was issued vide Letter# F.3-88/2015-DDC(BD)V-II dated 11th January,2023 for correction in Specification from **Ph.Eur. Specification** to **USP Specification** after approval by the Chairman Registration Board.

Now, M/S Lab Diagnostic Systems SMC (Pvt.) Ltd has applied for exemption of Drugs (labelling and packaging) Rules, 1986 and permission for local printing of labelling particulars of following batches at the licensed premises M/S NovaMed Pharmaceuticals 28-KM, Ferozepur Road Lahore (DML # 000590).

Batch details as per COAs are as;

i. **Product Name**: Enoxaparin Sodium Injection 40mg/0.4mL
Batch No. A1F2110V3 **Mfg date** 26-02-2023 **Exp date** 31-01-2026

ii. **Product Name**: Enoxaparin Sodium Injection 60mg/0.6mL
Batch No. A1A0310K1 **Mfg date** 23-02-2023 **Exp date** 31-01-2026

The firm further stated that "*The product is currently unavailable in market and to meet the patient need, we will import it from China. As the product is newly registered, the packs with information according to Drugs Labelling and Packaging Rules is not ready. Given the current situation, we request you to kindly exempt the labelling & packaging requirement for the batches mentioned above for one time only and allow us to get the batch printed locally from a DML Holder".*

Accordingly, the firm has submitted following documents:

a) Application for exemption of Drugs Labelling Rules, 1986.
b) Copy of registration letter.

c) Copy of agreement with M/s NovaMed Pharmaceuticals, 28-Km, Ferozepur Road Lahore (DML # 000590) for local printing of MRP and Drug Registration Number.
d) Copy of valid DML # 000590 of M/S NovaMed Pharmaceuticals 28-KM, Ferozepur Road Lahore.
e) Original fee challan No. 76775487045 of Rs 7,500/-

Evaluation by DBER:

- Total quantity for which one-time exemption is required is not mentioned anywhere in the application.
- Brand name is not mentioned on COAs rather generic name is written.
- Fee challan of only Rs 7500/- is attached while the firm is seeking exemption approval for two products.

Decision: Registration board acceded to the request of the firm for one time import permission of Vinox 40mg (Enoxaparin sodium), Batch No. A1F2110V3, Mfg date: 26-02-2023, Exp date: 31-01-2026 and Vinox 60mg, Batch No. A1A0310K1, Mfg date: 23-02-2023, Exp date: 31-01-2026 and local printing of MRP, Registration No. and other parameters, as per Drugs (Labelling & Packing) Rules, 1986 before sale in market, at the premises of M/s Novamed Pharmaceuticals, 28-km Ferozpur Road, Lahore having DML # 000590 subject to the submission of Fee required for exemption.

46. Virtual GMP Inspection Report of M/s Virchow Biotech Private Limited India for Imported Human Biological (Rasburant 1.5mg/vial)

Following biological product approved in 312th meeting of Registration Board subject to the inspection of manufacturer abroad as per import policy.

Name of Importer/ Manufacturer & meeting number	**Name of Drug &Composition**	**Panel of Inspector(s)/ Date of inspection**
M/s Lab Diagnostic Systems (SMC) Pvt Ltd Rawalpindi. **Manufacturer:** Virchow Biotech Private Limited, Survey No. 172 Parts, Gagillapur (V) Dundigal–Gandimaisamma (M), Medhchal–Malkajgiri (D), Telangana (State) – 500043, INDIA **(M-312).**	Rasburant 1.5mg/vial (Lyophilized Powder for Injection) Each vial contains; Rasburicase (r-DNA origin)…..1.5mg	i Mr. Muhammad Kashif, Deputy Director (BE&R) ii Mr. Abdullah Abro, Deputy Director (CD) **31-01-2023 and 11-04-2023**

Accordingly, an inspection was carried out by inspection panel dated 31-01-2023 & 11-04-2023 and final remarks of the panel are as under: -

Recommendations of the panel:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, and considering the fact it's a urate oxidase enzyme (no killed/attenuated organism in final product), the panel has come to the conclusion that the firm has adequate systems to manufacture **Rasburant** and appeared to comply the GMP requirements. Hence, the panel recommends the grant of registration of the applied product namely **Rasburant 1.5mg/vial (Lyophilized powder for injection)** to **M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.**

However, the panel strongly recommends **on-site inspection** in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace physical/ in-person inspection.

Decision: Registration Board decided to refer back the case to the panel for clear and candid recommendations regarding registration of the product "Rasburant 1.5mg/vial (Lyophilized Powder for Injection)".

Miscellaneous Cases:

47. Personal hearing of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi and M/s Hakimsons (Impex) Pvt Ltd. Karachi regarding Biofactor Streptokinase 15,00,000 Powder for infusion

The following product of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi was approved by the Registration Board in its 295th meeting as per following details;

Manufacturer	Brand Name & Composition	Documents details	Decision
Manufacturer: M/s Lyocontract GMBH Pulverwiese, Trift, Ilsenburg, D-38871, Germany **Marketing Authorization Holder:** M/s Karma-Medica, GMBH Emil-Von-Behring Strasse 76, Marburg, D-35041, Germany	Biofactor Streptokinase 15,00,000 Powder for infusion Each vial contains: Streptokinase...15, 00,000 IU	COPP No. PP10161996 dated 22 July 2019 issued by MHRA UK legalized from Germany Price / Pack size: 1's vial	**M-295:** Keeping in view the valid legalized CoPP indicating product availability in country of origin & approval of MHRA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

a) During processing for issuance of Registration Letter to the firm, it was noted that in the COPP provided for the product, it was clearly mentioned that name of the product for United Kingdom is Biofactor Streptokinase 1500,000 powder for infusion & name of the product for Pakistan is Streptofactor 1500,000 powder for infusion.

b) The firm i.e. M/s Lab Diagnostic Pvt. Ltd. Rawalpindi had applied for registration of the product with brand name Biofactor Streptokinase 1500,000 powder for infusion which is the brand name for United Kingdom as per COPP while the product with brand name for Pakistan is Streptofactor 1500,000 powder for infusion as per COPP which is already registered in the name of M/s Hakimsons (Impex) Pvt Ltd. Karachi with registration number 028474.

c) The firm was asked vide Letter# F.No.3-88/2015DDC(BD)V-I dated 8th November,2021 to clarify whether the applied product is the same as registered in the name of M/s Hakimsons (Impex) Pvt Ltd. Karachi or otherwise and clarification regarding the brand name i.e. Biofactor Streptokinase which is the name of the product for UK as per provided COPP was also sought.

d) The firm vide letter No. Nil dated 10th November,2021 and Letter No. Nil dated 28th December,2021 submitted that the applied product is same which is already registered in the name of M/s Hakimsons (Impex) Pvt. Ltd, Karachi. The firm also stated that the Marketing Authorization has been transferred from M/s Biofactor GmbH, Germany to current MAH Karma Pharmatech, Germany. As the previous company, M/s Biofactor GmbH, no longer has the marketing rights of this product, the authorizations issued by them cannot be considered valid any longer. Regarding clarification on brand name, the firm informed that they have been authorized by the new MAH on Brand name "Streptokinase Karma 1,500,000 Powder for Infusion" as mentioned in Letter of Authorization (LOA). So the firm requested to keep the brand name as mentioned in LOA and COPP.

e) The firm i.e. M/s Hakimsons (Impex) Pvt Ltd. Karachi was asked vide letter# F.No.3-48/2014DDC(BD)(Vol-IV) dated 15th April,2022 to submit valid sole agency agreement & valid COPP/evidence of registration of their registered product i.e. Streptofactor 1500,000 powder for infusion registration number 028474 manufactured by M/s Biofactor GmbH Pharmaceutical Import-Export, Germany. A reminder was also issued on 16th June,2022 in order to expedite the process but the firm did not submit any reply.

f) A **Show Cause Notice** was issued to the firm M/s Hakimsons (Impex) Pvt Ltd. Karachi vide Letter# F.No.3-48/2014DDC(BD)Vol-IV) dated 27th July 2022 as per approval by the Chairman Registration Board.

g) M/s Hakimsons (Impex) Pvt Ltd. Karachi submitted reply of the Show Cause vide Letter No. Nil dated 01-08-2022 received on 05-08-2022 and the firm did not provide valid Free Sale Certificate/COPP and valid sole agency agreement.

h) M/s Hakimsons (Impex) Pvt Ltd. Karachi and M/s Lab Diagnostic Pvt. Ltd. Rawalpindi were called for **personal hearing** in 323rd meeting of Registration Board vide Letter # F.No.3-48/2014-DDC(BD)V-IV dated 18th November,2022. However, the case was not discussed in the said meeting as per available record.

i) Now both the parties are again called for personal hearing after approval by the Chairman Registration Board.

Decision: Registration Board decided that the product "Streptofactor" of M/s Hakimsons (Impex) Pvt Ltd. Karachi and the product "Biofactor Streptokinase" of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi, which was approved in 295th meeting of Registration Board, are having different Marketing Authorization Holders with different brand names and manufacturing sites. Thus, the Board decided to process registration of "Biofactor Streptokinase" of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi in the light of decision of 295th meeting of Registration Board.

48. One Time Approval of International Pack for Life Saving Drug Heparin Leo Injection 5000IU Reg#000854 with exemption of Urdu text and printing of MRP and Registration Number in local facility

M/s Zam Zam Corporation, Karachi has requested for "One Time Import Approval" of International UK pack of following product with exemption of Urdu text and printing of MRP and registration number in local facility.

Brand Name	Pack size	Manufacturer
Heparin (Mucous) Injection BP 5000 Units/ml Heparin Sodium Solution for Injection	10 vials of 5ml	Leo Pharma A/S DK 2750, Ballerup, Denmark.

The firm further stated that they are unable to import their registered product Heparin Leo Injection 5000 IU Registration No. 000854 from Denmark because the supplier has refused to supply stock in Pakistan due to unstable currency and volatile market and low pricing factor. However, keeping in view the importance of Drug availability, the supplier is agreed to supply UK International Packs in Pakistan on a "One Time Basis Deal".

Evaluation by DBER:

M/s Zam Zam Corporation has registration of Heparin Injection 5000IU/ml as per following details;

Reg #	Brand Name	Pack size	Manufacturer
000854	Heparin Injection 5000 IU/ml **Brand Name on renewal applications:** "Heparin Leo Injection"	1's	M/s Leo Pharmaceutical products, Denmark

The label specimen attached with the case shows the product is of "**Leo Laboratories Limited Hurley, Berkshire SL6 6RJ, UK**"; which is not registered with DRAP.

Clarification required for;

- Brand name
- Manufacturer name
- Pack size of 10's
- Quantity details to be imported.
- Premises where printing as per LRA Rules will be performed locally.

Decision: Registration Board deferred the case for submission of evidence whether the applied product and manufacturer is same as registered with the DRAP and further clarification for following particulars of the product:
Brand Name, Manufacturer's Name, Pack size, Details of DML holder for local printing

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

S. NO.	CASE TITLE
	QUALITY CONTROL SECTION
AGENDA ITEM NO. 01 - PERSONAL HEARING CASES	
01	MANUFACTURE & SALE OF ADULTERATED & SUBSTANDARD ABEX INJECTION, BATCH NO. 21AL2 MANUFACTURED BY M/S. SEMOS PHARMACEUTICALS (PVT.) LTD., KARACHI.
02	MANUFACTURE & SALE OF SUB-STANDARD MEFCO SUSPENSION BATCH NO. 21053 MANUFACTURED BY M/S EROS PHARMACEUTICALS (PVT) LTD., KARACHI.
AGENDA ITEM NO. 02- ROUTINE CASES	
03	MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. LI-961 MANUFACTURED BY M/S. SAFE PHARMACEUTICAL PAKISTAN LTD. KARACHI.
04	SEIZURE AND ORDER NOT TO DISPOSE OFF STOCK M/S ONCOLINK PHARMA DISTRIBUTOR.
05	SUBSTANDARD NYLOZ CAPSULE MANUFACTURED BY M/S. ZEPHYR PHARMATEC (PVT) LTD. KARACHI (03-28/2021-QC).
	QUALITY ASSURANCE SECTION
06	ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S HAWK BIO PHARMACEUTICALS (PVT) LTD, PLOT NO. 10, S-6, NIZ, RCCI RAWAT, ISLAMABAD.
07	ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMACEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD

AGENDA ITEM NO. 01 - PERSONAL HEARING CASES

CASE NO. 01: MANUFACTURE & SALE OF ADULTERATED & SUBSTANDARD ABEX INJECTION, REG. NO. 086072, BATCH NO. 21AL2, MFG. DATE 02-21, EXP. DATE 02-23, MANUFACTURED BY M/S. SEMOS PHARMACEUTICALS (PVT.) LTD., KARACHI.

FID, DRAP, Karachi inspected the premises of M/s. JPMC, (Central Pharmacy) Rafeeqi Shaheed Road Karachi. on 23-04-2021, wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Federal Government Analyst, CDL, Karachi declared the above said sample as "Adulterated and Sub-Standard" quality vide their test report No.KQ.100/2021 (Initial) and (Final) dated 26th May 2021 and 15th June 2021**.** Details are**:**

S. No.	Name of Drug	Reg. No	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Result of CDL	Basis of Result
01	Injection Abex	086072	21AL2	02/2021	02/2023	M/s. Semos Pharmaceuticals (Pvt) Ltd. Plot #11, Sector	Adulterated & Sub-standard	**After reconstitution, containing black**

						121-A, North Karachi. Industrial Area, Karachi.		**particles visible to naked eye.**
02	Ampoule of Water for Injection	026762	WF2-243C	JAN-2021	JAN-2026	M/s. Surge Labortories (Pvt) Ltd. 10th Km, Faisalabad Road, Bikhi, District Sheikhupura	Standard	-

02. M/s. Semos Pharmaceuticals (Pvt) Ltd., Karachi requested for retesting of Drug Abex Injection Batch No. 21AL2 from NIH Islamabad.

03. Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided to ask/request Federal Government Analyst, Karachi to provide OOS investigation and complete testing record on which the product is declared as of Adulterated and Substandard quality.

04. The decision of Board has been communicated dated 16-12-2022 after approval of minutes.

05. M/s. Semos Pharmaceuticals, Pvt Ltd., Karachi dated 27-12-2021, the firm mentioned that they have checked retention samples and recall samples as described process but didn't see any particles after reconstitution.

Firm also highlighted the remarks of CDL report reproduced as:

- As per requirements of USP general chapter <790> additional units may be inspected (As per ANSI/ASQ Z 1.4 or ISO 2859-1 standard for sampling) to gain further information on the risk of particulates in the batch.
- It is also mentioned in USP <790> that because of complaint and regulatory concern inspect 20 units, but they have received 10 units only. That's why they have requested to inspect more samples as per CDL remarks.

For the greater public interest and precautionary measures, they revalidated the Cephalosporin sterile area after replacing the filters where necessary i.e. HEPA filters for tunnel sterilization etc and other HEPA filters were also re-validated where necessary. They conducted DOP test on the filters. They further requested for appellate testing under section 22(4) of the Drugs Act 1976.

06. Response received from Central Drugs Laboratory, Karachi dated 14-03-2022 wherein the remarks of OOS Investigation Form are reproduced as : "Adulterated and Substandard".

07. Technical Evaluation of the case:

- Product is declared as adulterated and substandard after reconstitution, containing black particles visible to naked eyes.
- Firm has conducted risk assessment however the risks are defined by firm in low to moderate range. DOP test was also conducted but no remarks was mentioned in the report.
- Defects may not be equally distributed over the batch that's why it's not necessary for a Board portion or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.
- Moreover, the remarks of CDL may be considered for further investigation of quality defect.

08. Decision of 316th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided:

i. To issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Semos Pharmaceuticals (Pvt.) Ltd., Karachi and called them for personal hearing before Registration Board

Mr. Adnan Rizvi, Member of Board has recorded his note of dissent i.e. the sample should be sent to NIH for appellate testing.

09. Decision of 316th meeting of Registration Board has been communicated vide letter No. F.03-11/2022-QC (316-RB) dated 27-05-2022.

10. Firm has replied vide Ref. No. SP/LTR/062 dated 01-06-2022 wherein they again requested to send sample for appellate testing to NIH for physical testing and ready to appear before the Board.

11. Firm has been called for personal hearing.

12. Proceedings and Decision of 320th Meeting of Registration Board.

M/s. Semos Pharmaceuticals, Pvt Ltd., Karachi submitted vide Ref No. SP-LTR/065 dated 31-08-2022 that

their flight had been delayed at the last moment and no other flight was available in short span of time. They further requested for another date for personal hearing.

Decision: "The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."

13. In view of decision of 320th meeting, they have been called for personal hearing.

14. Proceedings and Decision of 321st Meeting of Registration Board

Mr. Mutti-Ur-Rehman, Director and Mr. Waqas Kamil, QA Manager appeared before the Board. They inform that they have tested the retained sample of product and found it satisfactory and request to send the Board's portion for Appellate testing.

15. Registration Board after detailed discussion and considering the facts of the case decided: "Sample of Abex Injection Batch No. 21AL2 M/s. manufactured by Semos Pharmaceuticals (Pvt.) Ltd., Karachi will be sent to appellate lab for testing of visible particulate matter on which the sample was declared as adulterated and substandard by CDL, Karachi."

16. As per Board's decision, sample has been sent to NIH, Islamabad after approval of minutes vide letter no. F.03-17/2021-QC dated 28-11-2022. NIH Islamabad vide letter No.F.1-20/04-M/2-22-DC&TMD dated 24-01-2023 submitted the test report No. 04-M/2022 of Abex Injection batch no 2IAL2 and declared the sample as substandard.

17. In view of NIH report, a show cause notice has been issued to Ms. Semos Pharmaceuticals Pvt Ltd., Karachi vide office letter of even numbers dated 16-05-2023. Ms. Semos Pharmaceuticals Pvt Ltd., Karachi replied dated 25-05-2023 that sample was tested just before 14 days of expiry and only 10 samples are inspected whereas criteria is of 20 packs, and no black particles present as per previous CDL report but fibers have seen which may be expected due to syringe used for reconstitution or water used for reconstitution. They requested actions such as cancellation, prosecution in drug court and other action should not be taking against them.

18. Firm has been called for personal hearing.

19. Proceedings and Decision of 330th Meeting of Registration Board

M/s. Semos Pharmaceuticals Pvt Ltd., Karachi submitted their reply vide letter no SP-LTR/101 dated 25-05-2023 that their representative was not well and unable to appear before the Board. They further requested for another date for personal hearing.

Registration Board considered request of the firm and decided to provide last chance of personal hearing to the firm M/s. Semos Pharmaceuticals Pvt Ltd., Karachi.

Case No. 02: MANUFACTURE & SALE OF SUB-STANDARD MEFCO SUSPENSION BATCH NO. 21053 MANUFACTURED BY M/S EROS PHARMACEUTICALS (PVT) LTD., KARACHI.

The Federal Inspector of Drug, DRAP, Karachi inspected M/s Sindh Government Children Hospital, North Nazimabad, Karachi on 14-11-2022 wherein following sample along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL remarks
MEFCO suspension	Ms. Eros Parmaceuticals (Pvt.) Ltd., Karachi	067106	21053	09-2022	09-2024	Substandard on the basis of pH.

02. CDL Karachi declared MEFCO suspension as of substandard quality vide report No. KQ.11-22-000222 dated 19-01-2023. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

S.No.	Test	Aceptance creteria	Result	Reference
1	**Description**	White to off white viscous suspension	Complies	Mfg. Specs.
2	**Identification**	The identification test must identify Mefenamic acid.	Complies	Mfg. Specs.
3	pH	4.5 to 6.5	**3.7-Does not comply.**	Mfg. Specs.

4	**Assay** Mefenamic acid. (Label claim 50mg/5ml)	95.0% to 105.0%	96.52% complies	Mfg. Specs.

Remarks: 1) The sample is **"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 test results during method validation. Additional period for testing (as required undersection 22 (2) of the Drugs Act, 1976) was requested from concerned quarter vide letter No.5-3(K)/2023-CDL/S-75 dated 12-01-2023.

03. FID, DRAP, Karachi informed that the firm did not request for retesting. In view of CDL report, a show cause notice has been issued to the firm vide office letter of even numbers dated 01-06-2023.

04. Ms. Eros Parmaceuticals (Pvt.) Ltd., Karachi replied vide letter no nil dated 05-06-2023 wherein they submitted that sample in question declared substandard on the basis of very meager difference in pH and found in accordance with the standard. They also requested for personal hearing.

05. In addition, another sample of MEFCO suspension batch no. 2J041 has also been declared substandard on the basis of pH by CDL, Karachi. A show cause notice has been issued to the firm vide office letter of even numbers dated 19-07-2023.

06. Firm was called for personal hearing.

07. Proceedings and Decision of 330th Meeting of Registration Board.

No one appeared before the Board on behalf of M/s. Eros Pharmaceuticals Pvt Ltd., Karachi.
Registration Board decided to provide last chance of personal hearing to the firm M/s. Eros Pharmaceuticals Pvt Ltd., Karachi.

AGENDA ITEM NO. 02- ROUTINE CASES

CASE NO. 03: MANUFACTURE & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. LI-961 MANUFACTURED BY M/S. SAFE PHARMACEUTICAL PAKISTAN LTD. KARACHI.

FID, DRAP, Karachi inspected M/s. Safe Pharmaceuticals Pvt Ltd., Karachi on 14-01-2022; wherein following sample of drugs along with other drugs were taken for the purpose of test/analysis on prescribed Form-3:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Result of CDL
Noran-40 Injection (vial)	M/s. Safe Pharmaceuticals Pvt Ltd., Karachi.	093293	LP-255	09-21	09-23	Standard
Water for injection (ampuole)	M/s. Safe Pharmaceuticals Pvt Ltd., Karachi.	020632	LI-961	03-21	03-24	Sub-Standard

02. The Government Analyst, Central Drugs Laboratory, Karachi vide test report No.KQ-1-22-000016 dated 28-02-2022 declared the sample of water for injection as **"Sub-Standard"** quality under the Drugs Act, 1976, which is violation of Section 23(1) (a) (v) of Drugs Act, 1976 and rules framed there under.

03. FID issued an explanation letter of even numbers dated 08-03-2022 and reminder dated 19-04-2022. No reply received. Afterwards, FID-II Karachi vide letter No.F.000349/2018-FID-II (K) dated 26-05-2022 submitted names of technical persons and reply of M/s. Safe Pharma where firm challenged the test report of CDL and requested for retesting of sample.

04. It is observed that no date was mentioned on firm's letter, however, the diary No 999 of Karachi office nd date 26-05-2022 mentioned on the letter. As per Section 22 (4) of Drugs Act 1976, the firm should apply within 30 days of the receipt of a copy of the report. The firm's request was not acceded.

05. A show cause notice has been served after approval dated 25-08-2022. Firm had been called for personal hearing in 321st meeting of Registration Board.

06. Proceedings and Decision of 321st Meeting of Registration Board.

Mr. Muhammad Shahid, Regulatory Manager appeared before the Board on behalf of M/s. Safe Pharmaceuticals Private Limited, Karachi. He submitted that technical persons were coming but their flight

was delayed and requested to provide some time as they reached by 4:00 PM. The Board after discussion allowed them to be appeared by 4 PM or ex-parte decision will be taken. No one appeared before the board till end of the meeting.

07. Decision: Registration Board after considering the facts of the case and after thorough deliberations decided:

i. Immediate suspension of the registration of Water for injection (ampoule) (Registration No. 020632) for a period of six months from the date of communication of decision.

ii. Submission of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by the firm and its verification by following panel.

- Mr.Abdur Rasool Shaikh, Additional Director, DRAP, Karachi.
- Mr. Awais Ahmad, Assistant Director, CDL, Karachi.

iii. Recommendations of panel will be placed before Registration Board for decision.

08. Decision was communicated vide letter No. F.03-45/2022-QC (321-RB) dated 23-11-2022.

09. Additional Director Karachi submitted Product Specific Inspection report vide letter No. F.000349/2018-FID-II (K) dated 08-06-2023. Conclusion of the report is

" After in depth evaluation of the above mentioned documents, interviews of the technical staff, root cause analysis, and trend history, panel could not identify any potential discrepancy of WFI failure or OOS of any other sterile injection manufactured by M/s. Safe Pharma, however, some minor documentation errors were identified and recorded to the management and firm showed commitment for an earlier compliance. Keeping in view above mentioned facts *"The panel is of the opinion that, no potential risk for said product failure could be identified, hence recommended that their suspended registration of WFI 5ml may be resumed with the condition to retest their first batch of WFI again for better safety and quality of the products manufactured by the firm".*

10. Proceedings and Decision of 330th Meeting of Registration Board.

Registration Board after deliberation, considering facts of the case and report of PSI conducted by Additional Director, Karachi decided to revoke the orders of suspension of registration of product Water for injection (ampoule), Registration No. 020632. However, the firm shall submit validation report of water system from a certified source. The Area FID shall take samples of first three batches of WFI for the purpose of test / analysis.

Case No. 04: SEIZURE AND ORDER NOT TO DISPOSE OFF STOCK M/S ONCOLINK PHARMA DISTRIBUTOR. (F. No. 13-56/2022-QC)

01. Federal Inspector of Drugs Lahore-II Lahore vide letter No. 10350/2022-FID (L-II) dated 15-09-2022 inform regarding the "seizure" and "order not to dispose of" following stocks during his visit at M/s. Oncolink Pharma Distributor 216-A, New Muslim town Lahore on 14-09-2022 due to the reason that these stocks had "Government Property Not for Sale" stamp of M/s. Gulab Devi Teaching Hospital on their packs:

S. No.	Brand Name	Batch No.	Mfg. Date	Exp. Date	Mfg. by
01	Linox 400mg tab	(10)LND001	05-21	05-23	M/s. Nabiqasim industries (Pvt,) Ltd., Karachi
02	Lasoride tab	AA006	07-22	06-25	M/s. Sanofi Aventis Pakistan Ltd. Karachi
03	Cordarone 200mg tab	AA005	06-22	05-25	-do-

02. FID-II Lahore informed that investigation is under process and requested for grant of safe custody of seized stocks and extension in grant of permission of order not to dispose of vide letter No. 13-56/2022-QC on 04-10-2022.

03. FID-II Lahore vide letter No. 10751/2022-FID (L-II) dated 29-09-2022 provided initial investigation report wherein he presented the stance of M/s. Oncolink Pharma and submitted as under:

"[…] 4. Ms Oncolink Pharma distributor, submitted in the their clarification that tablet Linox 400mg has been mistakenly issued from Ms Nabi Qasim Karachi instead of stocks of Linox 600mg Tablet to be supplied to M/s Ghulab Devi Hospital. Lahore. M/s Nabi Qasim Karachi as per copy of letter enclosed also endorsed the same. M/s Ghulab Devi Hospital, Lahore issued purchase order of tablets Linezolid 600 mg, Tegzot 600 mg with delivery date 04-02-2022 to M/s M/s Oncolink

Pharma distributor.

5. M/s Oncolink Pharma distributor also submitted that PIC Pharmacy drugs are for sale from PIC Pharmacy and not meant as GOVT Property. They also submitted that they are authorized distributor of M/s Sanofi Aventis, Karachi and same fact was endorsed by the M/s Sanofi Aventis, Karachi as per copy of attached letter dated 19-09-2022 herewith. In contrast M/s Snaofi-Aventis Pakistan had issued invoice in the name of PIC Pharmacy instead of M/s. Oncolink Pharma. As submitted by M/s. Oncolink Pharma; due to non-printing of PIC Pharmacy on the blisters; PIC Pharmacy returned the stocks which was available at the warehouse of M/s Onclink Pharma. However, M/s Onclolink Pharma could not produces the warranty of said drugs. It is also mentioned that the purchase order of PIC pharmacy was directly to M/s Sanofi Aventis instead of any of their distributor including M/s Oncolink Pharma (Copies of all attested documents attached for perusal please).

6. The drugs mentioned above were stocked and being sold in violation of the DRAP Act, 2012 which is punishable under Schedule-Ill of DRAP Act. 2012.

7. Case is forwarded under section 19 (7) of Drugs Act 1976 and Schedule V of DRAP Act 2012 to seek further orders as to the action to be taken in respect of above mentioned contraventions against M/s. Oncolink Pharma Distributor 216-A, New Muslim Town, Lahore and following persons of said firm who were involved in above mentioned contraventions.

1. *Mr. Muhammad Sajid S/o Fazal Ahmad (35200-1411239-1) (Partnert)*
   Residence H. No. 79-80,
   Mohallah Nishter Colony, Data Nagar. Badmi Bagh, Lahore.
2. *Mr. Zaheer Ahmad s/o Fazai Ahmad (35202-3052710-9)) (Proprietor)*
   Residence House No. 80. Nishter Colony. Data Nagar. Badami Bagh. Lahore.
3. *Muhammad Haseeb ur Rehman s/o Muhammad Ikram Shehzad, (35202-9040202-7*
   Residence House No. 390. Block 4 Strcet-B 1, Township. Lahore (Qualified Person)."

04. In view of above mentioned report, FID-II Lahore was once again requested to provide detailed investigate the matter at hospital level and take the opinion of M/s. Gulab Devi hospital and M/s. PIC Lahore regarding the stance submitted by the firm and the distributor.

05. FID-II Lahore vide No. 1462/2023-DRAP (L-IV) dated 12-05-2023 submitted complete investigation of matter. In the instant report, FID provided reply of M/s. Oncolink Pharma Distributors Lahore, M/s. Sanofi Aventis Pakistan Karachi, and Medical Superintendent, Punjab Institute of Cardiology Lahore. In the said letter, FID Lahore endorsed the stance provided by the firm and distributor and confirmed that the products in question were supplied by the companies to their distributor and institutional business representatives. Firm has also explained in their replies that the stocks were supplied by the companies for onward delivery to M/s. PIC Model Pharmacy, Lahore as a result, M/s. PIC Model Pharmacy, Lahore is still waiting for the stocks therefore, the stocks may be released in the best interest of public or any other decision as the Board may deemed fit.

06. In the light of investigation report provided by FID Lahore, matter is submitted before the Board under Section 19 (5) (a) of the Drugs Act 1976 / Schedule-V, Section (5) (a) of the DRAP Act 2012 for further directions in the matter.

Proceedings and decision of the 330th meeting of Registration Board:

The Board thoroughly deliberated on the case and considered the investigation report submitted by FID Lahore vide No. 1462/2023-DRAP (L-IV) dated 12-05-2023. The Board noted the information and decided to direct the FID to proceed under Section 19(5)(a) of the Drugs Act, 1976 and Rules framed thereunder.

Case No. 05: SUBSTANDARD NYLOZ CAPSULE MANUFACTURED BY M/S. ZEPHYR PHARMATEC (PVT) LTD. KARACHI (03-28/2021-QC).

01. Federal Government Analyst CDL Karachi vide test report No. F. 5-3(K)/2021-CDL/S-870 dated 30-07-2021 informed that the sample of product "Nyloz capsule (Esomeprazole 20mg)" Batch No. C01358 (Mfg. date 05-2021, Exp date 04-2023) sent to CDL Karachi by FID-II Karachi has been declared as of substandard quality. Details of the test report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Hard gelatin capsule consist of yellow coloured body and green coloured cap	Complies	Mfg. Specs

		containing white enteric coated pellets		
2.	Identification	Identification test must identify Esomeprazole Magnesium	Complies	USP 43
3.	Dissolution	Each unit is not less than 80%	Complies	USP 43
4.	Uniformity of dosage units by content uniformity	Acceptanc value of the 30 dosage units is less or equal L1% and no individual content of "any" dosage unit is less than [1-(0.01)(L2)]M not more than [1+(0.01(L2)]M	**L1=22.24 – <u>Does not comply.</u>**	USP 43
5.	**<u>Assay.</u>** Esomeprazole. (20mg/cap)	90.0% to 110.0%	Complies	USP 43

02. FID-II Karachi vide letter No. F. 000403/2018-FID-II (K) (Zephyr) dated 07-09-2021 forwarded the request of for appellate testing of Board's portion of sample of their product namely "Nyloz capsule" batch No. C01358 declared substandard by CDL Karachi on 30-07-2021.
03. Registration Board in its 313th meeting decided to fulfill the codal formalities. In compliance Letter vide No. F. 03-28/2021-QC dated 31-12-2022 was issued to M/s. Zephyr Pharmatech Karachi for submission of OOS investigation and complete testing record of the concerned batch and to Federal Government Analyst CDL Karachi for submission of OOS investigation and complete testing record of report vide No. F. 5-3(K)/2021-CDL-S-870 dated 30-07-2021.

Technical evaluation of OOS report by QC section:

04. M/s. Zephyr Pharmaceuticals Karachi vide letter ZP/0398/2022 dated 05-01-2022 provided the OOS investigation report. On technical evaluation of CDL Karachi OOS investigation report and OOS investigation report provided by manufacturer it was observed that both have performed the content uniformity test according to USP 43 specifications. However, the manufacturer claims the product to be of standard quality while CDL Karachi has reported the product to be substandard.
The case was presented in the 320th meeting of the Registration Board but was deferred due to paucity of time.

05. The matter was placed before the Board in its 321st meeting. However, keeping in view position narrated above, the Board did not accede the firm's request of appellate testing and decided to issue show cause notice and called them for personal hearing before Registration Board.

06. In compliance to the decision of RB, show Cause notice was issued to firm vide letter No. 03-45/2022 QC dated 21-nov-22 to which M/s. Zephyr Pharmaceuticals Karachi vide letter ZP/0435/2022 dated 22-11-2022 requested for personal hearing.

<u>Proceedings and Decision of 324th Meeting of Registration Board.</u>
07. Mr Asif Khitab (Sr. Manager Regulatory Affairs) along with QC Manager, Mr Zubair Ahmed Khushhali appeared before the Board for Personal hearing. They reiterated the same stance submitted earlier and requested to send the Board's portion for Appellate testing The Board after considering the facts of the case and thorough deliberations decided as follows:

i. **Registration of "Nyloz capsule (Esomeprazole 20mg)" Mfg by M/s. Zephyr Pharmatec (pvt) ltd. Karachi shall remain suspended for a period of six months or till satisfactory Product Specific Inspection report and verification of CAPA by panel (constituted by Director QA&LT) whichever is later.**

08. In compliance to the above-stated decision of the Board, the Director QA&LT vide letter No. 03-04/2023-QC (234-RB) dated 03-04-2023 nominated Mr. Abdul Rasool Shaikh, Additional Director DRAP Karachi and Mst. Hira Bhutto, Assistant Director DRAP Karachi for PSI and CAPA verification of M/s. Zephyr Pharmatec (Pvt.) Ltd., Karachi.
10. The mentioned panel inspected the firm on 06-07-2023 and submitted the report vide No. F. 000403/2018-FID-II(K)(Zephyr) dated 14-07-2023. The panel verified the CAPA submitted by the firm and unanimously recommended the resumption of production of Nyloz 20mg capsule (Reg. No. 055013).

<u>Proceedings of the Board:</u>
10. In the light of decision of the 324th meeting of the Board, the report submitted by the panel was

discussed in detail. Mr. Aslam, Additional Draftsman M/o Law & Justice (Member Registration Board) was of the opinion that since the panel has unanimously recommended the resumption of production of product "Nyloz 20mg capsule", there is no requirement to further delay the resumption and the Board should accede with the recommendations of the panel and allow resumption of production of product namely "Nyloz 20mg" capsule manufactured by M/s. Zephyr Pharmatec (Pvt.) Ltd., Karachi.

Decision of the 330th meeting of Registration Board

The Board after deliberation decided to;

i. allow the resumption of production of product namely "Nyloz 20mg" capsule manufactured by M/s. Zephyr Pharmatec (Pvt.) Ltd., Karachi.

ii. Destroy stock of product *"Nyloz capsule (Esomeprazole 20mg) Batch No. C01358 (Mfg. date 05-2021, Exp date 04-2023) mfg by M/s. Zephyr Pharmatec (Pvt.) Ltd., Karachi"*, by area FID or any officer nominated by the Additional Director, DRAP, Karachi.

Case No. 06: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S. EG PHARMCEUTICALS 13-A INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

BACKGROUND

Federal Inspector of Drugs-I Islamabad inspected the premises of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad on 25th January 2022 to investigate PM portal complaint regarding the import of illegal raw material, lack of qualified persons and non-compliance of GMP by M/s. EG Pharmaceuticals Islamabad. During the inspection following Raw Material was recovered from the Raw Material Store (RMS) of the M/s EG Pharmaceutical Islamabad without import documents/NOCs issued by DRAP R&I Section as well as evidence of purchase:

S.	Name of Drug	Batch No.	Quantity	Mfg. by
01.	Amlodipie Besylate powder	AMB/057/03/21	0.29kg	M/s. Prudunce Chemical
02.	Diclofenac Potassium	20190810	109.125	M/s. Zanghai Gindjiuzhou Pharma Henan Dongtai Pharma Co Ltd
03.	Diclofenac Sodium	20200520	3.135	N/A
04.	Tizanidine powder	N/A	2.50	N/A
05.	Ketorolac Trometamol/ Tronethamine	0361220	0.800	M/s. Satyalidivis Pharma
06.	Lidocaine HCl	N/A	0.804	N/A
07.	Metronidazole		13.000	N/A
08.	Paroxetine Calcium		1.000	N/A
09.	Rosuvastatine Calcium		36.0 gm	N/A
10.	Vitamin B3		3.10gm	N/A
11.	Valsartan		0.36	N/A
12.	Metformin	MEF/1010233	598.950	AARTI Begus Ltd India
13.	Loratidine	NRHB0534	5.000	Morepan Lab India
14.	Sitagliptin		3.734	N/A

ACTION TAKEN BY QA&LT

2. The mentioned raw materials were ordered "Not to Dispose of' on Form-1 dated 25-01-2022 under Schedule-V Section (l)(i) of DRAP Act 2012. Permission in order not to dispose of was granted to FID I Islamabad vide letter F.03-05/2021-QC dated 21st February 2022.

3. M/s. EG Pharmaceuticals Islamabad was directed by FID I to submit import documents/NOCs issued by the DRAP I&E Department or as well as evidence of purchase of the above-mentioned raw materials vide letter No. F. 03-07/2004-FID-I(ISD) dated 31st January, 2022 with subsequent reminders on 17th March 2022 and 13th April 2022.

REPLY OF THE FIRM

4. The firm replied vide letter dated 12th April 2022 and admitted that they are obtaining raw material on loan from the local manufacturers/local markets as they are producing their products in small

quantities to fulfill institutional commitments and to avoid market shortage and hence small amount required did not warrant import. Furthermore, Reference to the letter No. F.03-07/2004-FID-1(ISD) dated 13th April 2022, M/s EG Pharmaceuticals through its letter dated 12th April 2022, stated, "we have to get locally either because of their equipment in very low quantity, hence not possible to import, or we had to get them to avoid shortage in the market. As you know that because of International scenario, consignments now a days are delayed and even cancelled. Almost all Pharmaceutical companies do this in Pakistan and Internationally."

CORRESPONDENCE BY QA&LT & ITS REPONSE

5. In light of the firm's response, FID I Islamabad directed the firm vide letter No. F.03-07/2004-FID-I(ISD) dated 25th April 2022 to disclose the sources from which they had procured the above-mentioned raw material on loan in order to identify the culprits & to discourage such practices since it is violation of Import & Export rules 1976 & Section 23(l)(e) and punishable under Section 27(c) of the Drugs Act, 1976. The firm was further directed to provide complete information regarding batch sizes of the aforementioned items as well as the institutional orders placed with the firm. The firm has failed to respond till date and verbally the representatives of the firm refused to provide further cooperation in this matter.

6. Considering the circumstances mentioned above, FID-I Islamabad has concluded that the firm is in violation of Import & Export rules 1976 & Section 23(1)(e) of the Drugs Act, 1976 read with Schedule-II(1)(A)(x)(e) punishable under Section 27(c) of the Drugs Act, 1976 read with Schedule-III(l)(c) of the DRAP Act, 2012 and cognizable under Section 30(1)(a) of Drugs Act,1976 read with Schedule-lV (l)(a) of the DRAP Act, 2012, and has requested as under:
   i. Cancellation of Registration of the above-mentioned products
   ii. Cancellation of DML of M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad
   iii. Grant permission for prosecution M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad through its CEO Mr. Shaukat Hayat Khan and its QC manager Mr. Ihtisham-ul-Haq.

7. In light of above the firm has violated Section 23(1) of Drug Act 1976 punishable under section 27 of Drug Act 1976 and violated the section 6 of Schedule B-II of Drugs (LR&A) rules 1976.

DECISION OF 289TH CLB MEETING

8. The case was discussed and deliberated in detail and the Central Licensing Board directed the Division of Quality Assurance & Laboratory Testing (QA&LT) to issue show cause notice and personal hearing to M/s EG Pharmaceutical, 13-A Industrial Triangle Kahuta Road Islamabad, regarding illegal import/storage of raw materials without Drug Import Licence (Form-5) and clearance certificate from DRAP.
9. In light of the decision of 289th CLB meeting, M/s EG Pharmaceutical 13-A Industrial Triangle Kahuta Road Islamabad was issued show cause notice and personal hearing.

RECOMMENDATIONS

10. In view of the scenario detailed above under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 28.04.2023*

DECISION OF 290TH MEETING OF CLB: -

11. The Board after thorough deliberation on the facts of the matter; after hearing the stance of Mr. Ihtischam-ul-haq (QC In-charge) on behalf of the firm concluded that firm has contravened the section 23(1)(b)of the Drug Act, 1976 read with DRAP Act, 2012 and Rules framed thereunder and decided as under :

i) Destruction of raw material, which were ordered not to dispose of on Form-2by the FID, as per guidelines issued by the Division of QA&LT.

ii) Refer the matter to the Registration Board with the recommendation to suspend the Registration of all the products, the formulation of which contains above-mentioned illegally procured raw materials, for a period of not less than 18months.

PROCEEDINGS FROM QA:

12. The matter was placed before the Registration Board with the recommendations made in 290th meeting of CLB.

Proceedings and Decision of 330th meeting of Registration Board:

The Registration Board as recommended by the Central Licensing Board in its 290th meeting decided to suspend the Registration of products (formulations) of M/s. EG Pharmaceuticals Islamabad containing below mentioned APIs for a period of 18 months from the date of communication of this decision. As area FID reported that the firm M/s. EG Pharmaceuticals, Islamabad was found involved in the procurement / purchase of said APIs without import documents /evidence of purchase andNOCs issued by DRAP:-

"Amlodipie Besylate, Diclofenac Potassium, Diclofenac Sodium, Tizanidine Hcl, Ketorolac Trometamol/ Tronethamine, Lidocaine HCl, Metronidazole, Paroxetine, Rosuvastatine Calcium, Vitamin B3, Valsartan, Metformin, Loratidine Hcl & Sitagliptin."

Case No. 07: ILLEGAL IMPORT OF RAW MATERIAL WITHOUT CLEARANCE FROM DRAP BY M/S HAWK BIO PHARMACEUTICALS (PVT) LTD, PLOT NO. 10, S-6, NIZ, RCCI RAWAT, ISLAMABAD.

BACKGROUND

1. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad's Inspection was conducted by Federal Inspector of Drugs-III Islamabad on 14th October, 2019. The FID has reported that 07 raw materials stored in Raw Material Store were not purchased directly from producer or established supplier. The firm failed to produce any evidence for import or local purchase such as invoice or any other purchase documents for these raw materials. List of raw materials is as follows:

S.	Name of Drug	Batch No.	Quantity	Mfg. by
01.	Invermectin	201808021	1.7Kg	Unknown
02.	Bismuth Subnitrate	19030211	4.1Kg	-do-
03.	Ferrous Sulphate	00118-060	22.250Kg	-do-
04.	Copper Sulphate	RLFX-873-18	19.90Kg	-do-
05.	Zinc Sulphate	JXBHB2019-014	17.7Kg	-do-
06.	Magnesium Sulphate	Not know.	50Kg	-do-
07.	Manganese Sulphate MnSo4	10819-019	2.4Kg	-do-

ACTION TAKEN BY QA&LT

2. M/s Hawk Bio Pharmaceuticals (Pvt) Ltd, Plot No. 10, S-6, NIZ, RCCI Rawat, Islamabad's was issued show cause notice and personal hearing.

proceedings AND DECISION OF 297TH,307thand 324th MEETING OF REGISTRATION BOARD:

3. **Decision of 297th meeting of Registration Board**: -

"The Board after detailed deliberations and considering the facts of the case decided to issue show cause notice for cancelation/suspension of products to the accused."

4. In compliance to the decision of Registration Board, the accused was issued a show cause notice vide No. F. 03-56/2021-QC (Pt-I) (297-RB) dated 05-04-2021. The accused has replied vide ref. No. HBP 4 / 2021 dated 15-04-2021 which is given as under:

"This refer to your letter No. F.03-56/2021-QC(Pt-I) (297-RB) dated April 05,2021 via ums services, which we received on dated April 12,2021 on Subject cited above.

- Please provide us an opportunity to be heard in person in response to above show cause notice.
- We want to submit justification / clarification in person."

5. Keeping in view of above-mentioned reply, the representatives of the firm are called before the Board for personal hearing.

Decision of 307th meeting of Registration Board:

6. Dr. Javed Saeed (CEO M/s. Hawk Bio Pharma, Islamabad) along with QC Manager, Mr. Ajmal and Production Manager, Mr. Zia Hussain appeared before the Board for Personal hearing. They pleaded that they have submitted evidence to FID that their imports were done as per legal procedures. They submitted a written reply and supporting documents. The Board after considering the facts of the case and thorough deliberations decided as follows:
    i. Refer the case back to area FID for complete investigation.
    ii. Suspend all registered products of the firm (as identified by area FID) that were manufactured by the raw materials in question

Decision of 324th Meeting of Registration Board:

7. Registration Board after discussion, considering the facts of the case decided as under: i. Import and export of raw materials does not fall under the mandate of Registration Board. Hence, the case is referred back to QA< Division to decide the case under the Drugs (import & Export) Rules, 1976 under Drugs Act, 1976. Till that decision, registration of all products shall remain suspended as per decision of the 307th meeting of Registration Board communicated vide letter No.F.03-15/2021-QC (307-RB) (Pt-I) dated 03-08-2021.

RECOMMENDATIONS

8. In view of the scenario detailed above under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 28.04.2023*

9. Representative of the firm M/s. Hawk Bio Pharmaceuticals, National Industrial Zone Rawat, Islamabad was called upon for personal hearing.

DECISION OF 290TH MEETING OF CLB: -

10. The Board after hearing the stance of Dr. Javed Saeed (CEO) and Ms. Zia hussnain (Production In-charge) before the Board on behalf of the firm and thorough deliberation on the facts of the matter; concluded that the firm has contravened the Section 23(1)(4) of the Drug Act, 1976 read with DRAP Act, 2012 and the Rules framed thereunder and decided as under:
    i) Destruction of raw material, which were ordered not to dispose of on Form-2 by the FID, as per the guidelines issued by the Division of QA&LT.
    ii) Refer the matter to the Registration Board with the recommendation for revocation of Suspension of Registration of the suspended products issued vide letter dated i.e. 3rd August 2021.

Proceedings from QA:

11. The matter was placed before the Registration Board with the recommendations made in 290th meeting of CLB.

Proceedings and decision of 330th meeting of Registration Board:

The Registration Board deliberated on the matter. It was informed by the QA&LT Division that letter No.F.03-15/2021-QC (307-RB) was issued on 0.3.08.2021 for suspension of production for the products containing below mentioned APIs, which were procured illegally. The Board considered recommendations of 290th meeting of Central Licensing Board for revocation of Suspension of Registration of the suspended products issued vide letter dated 3rd August 2021. The Board decided to revoke the suspensions of registration orders of the products (formulations) containing following APIs:

"Invermectin, Bismuth Subnitrate, Ferrous Sulphate, Copper Sulphate, Zinc Sulphate, Magnesium Sulphate and Manganese Sulphate."

Item No. IV Additional Agenda of PEC

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
15.	Mr. Adil Saeed	Evaluator PEC-IX
16.	Ms. Najia Saleem	Evaluator PEC-X
17.	Mr. Ammar Ashraf	Evaluator PEC-II
18.	Dr. Farhad Ullah	Evaluator PEC-XI
19.	Mr. Tahir Waqas	Evaluator PEC-XXI
20.	Ms. Sana Kanwal	Evaluator PEC-XX
21.	Dr. M. Haseeb Tariq	Evaluator PEC-III
22.	Ms. Saima Hussain	Evaluator PEC-XV
23.	Mr. Salateen Waseem Philip	Deputy Director PE&R

Deferred cases of Form-5F

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot A-115, S.I.T.E., Super Highway, Karachi Pakistan.
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot A-115, S.I.T.E., Super Highway, Karachi 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. 32414 Dated 29-11-2021
	Details of fee submitted	PKR 20,000/-: Dated 26-04-2021 PKR 10,000/- as differential fee: Dated 17-06-2021
	The proposed proprietary name / brand name	**Desvel 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains: 72mg of Desvenlafaxine succinate equivalent to Desvenlafaxine……50mg
	Pharmaceutical form of applied drug	White colored, round, biconvex, extended release and film coated tablet bisecting line on one side and other side is plain.
	Pharmacotherapeutic Group of (API)	Selective serotonin and norepinephrine reuptake inhibitors (SNRIs).
	Reference to Finished product specifications	In-house specification
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pristiq Tablet 50mg by M/s Pfizer Pharmaceuticals U.S.A., Inc., (USFDA Approved).
	For generic drugs (me-too status)	Lafaxine 50mg Tablet by M/s Genix Pharma, Reg. No. 070458
	GMP status of the Finished product manufacturer	New License granted on 07/10/2020 Tablet (General & General Antibiotic) section approved
	Name and address of API manufacturer.	M/s Aurore Pharmaceuticals Pvt. Ltd., Plot # 68, 69, 2nd floor Jubilee Heights, Madhapur, Hyderabad, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Desvenlafaxine is present in USP.

		The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: T-001, T-002, T-003
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Lafaxine 50mg Tablet by M/s Genix Pharma by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the said product in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & phosphate buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurore Pharmaceuticals Pvt. Ltd., Plot # 68, 69, 2nd floor Jubilee Heights, Madhapur, Hyderabad, India.		
API Lot No.	DVSF190003		
Description of Pack (Container closure system)	Alu-Alu 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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No. Accelerated	T-001	T-002	T-003
Batch Size	0.3Kg	0.3Kg	0.3Kg
Manufacturing Date	06-2020	07-2020	07-2020
Date of Initiation	07-07-2020	06-07-2020	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)	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.	The firm has submitted copy of license (No: 99/RR /AP/B/C) for M/s Aurore Pharmaceutical (Pvt) Ltd, Telangana State, India. The license is valid till 29-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying the import of Desvenlafaxine 1kg (batch # DVSP190003) attested by Assistant Director (I & E) dated 24-04-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets have been submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.

Remarks of Evaluator:

Sr.#	Section	Observation
1	1.5.2	The applied label claim shows 76mg of Desvenlafaxine succinate eq to 50mg of Desvenlafaxine while master formulation shows 72mg of Desvenlafaxine succinate eq. to 50mg of Desvenlafaxine. The applied label claim of Desvel 100mg Tablet shows 152mg of Desvenlafaxine succinate eq to 100mg of Desvenlafaxine while master formulation shows 144mg of Desvenlafaxine succinate eq. to 100mg of Desvenlafaxine.
2	1.5.3	The proposed brand name does not cover extended release pattern of applied formulation.
3.	3.2.S.4.1 & 3.2.S.4.2	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
4.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.
5.	3.2.S.7.3	The storage conditions under which stability study data of drug substance conducted is not as per Zone-IVA conditions.
6.	3.2.P.2.2.1	• Provide results of pharmaceutical equivalence data by performing all the quality tests of developed formulation and the innovator / reference / comparator product. • Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product. • Justify why comparative dissolution profile was not conducted in three BCS media across the physiological pH range.
7.	3.2.P.5.1	Justify the sampling time points for dissolution test which are not as per recommendations of FDA.
8.	3.2.P.6	Submit copy of COA of primary / secondary reference standard including source and lot number which is actually used in the testing of stability batches.
9.	3.2.P.8	• Specify the batch size of stability batches in terms of number of units produced. • Justify the significant change in assay value of real time and accelerated stability study data of batch no. T003. Reference of previous approval of applications with stability study data of the firm (if any).

Decision of 322nd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Section	Observation	Reply
1	1.5.2	The applied label claim shows 76mg of	The firm vide letter No. nil dated

		Desvenlafaxine succinate eq to 50mg of Desvenlafaxine while master formulation shows 72mg of Desvenlafaxine succinate eq. to 50mg of Desvenlafaxine. The applied label claim of Desvel 100mg Tablet shows 152mg of Desvenlafaxine succinate eq to 100mg of Desvenlafaxine while master formulation shows 144mg of Desvenlafaxine succinate eq. to 100mg of Desvenlafaxine.	11.07.2023 has stated that applied label claim is; Each extended release tablet contains; 76mg of Desvenlafaxine succinate eq to 50mg of Desvenlafaxine. There was a typographic mistake in formulation which is not corrected. It is further observed that in the reply of the firm that they have used CoatDry HPMC K15DC (Coadry 8800) in their formulation, its function is mentioned as ER Coating. Issue with this is that for extended release formulation, polymer is incorporated in the core of tablet, it is not coated over it. Further the Coatdry premix appears to be a mixture for enteric coating of tablets.
2	1.5.3	The proposed brand name does not cover extended release pattern of applied formulation.	The firm has stated that brand name of the product shall be revised to; DESVEL 50mg XR Tablet.
3.	3.2.S.4.1 & 3.2.S.4.2	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.	Copies are submitted
4.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted that drug substance is of USP specifications. The firm has submitted method verification report that includes; system suitability, specificity, accuracy, precision and repeatability.
5.	3.2.S.7.3	The storage conditions under which stability study data of drug substance conducted is not as per Zone-IVA conditions.	Stability data of drug substance as per Zone IVa is submitted for following batches; DSVF20054. DSVF20055. DSVF20056.
6.	3.2.P.2.2.1	• Provide results of pharmaceutical equivalence data by performing all the quality tests of developed formulation and the innovator / reference / comparator product. • Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product. • Justify why comparative dissolution profile was not conducted in three BCS media across the physiological pH range.	• Results of pharmaceutical equivalence with Lafaxine ER 50mg tablet batch No. 011T064 are submitted. • For not using innovator product frim has stated that it was not available at time of performance of CDP. • The firm vide letter No. nil dated 20.07.2023 has submitted CDP in 0.1N HCl, Acetate buffer and phosphate buffer at all-time points of dissolution profile. The results of CDP are similar to Lafaxime ER Tablet 50mg.
7.	3.2.P.5.1	Justify the sampling time points for dissolution test which are not as per recommendations of	As per provided data, samples were taken at time periods of 1h

		FDA.	(27%). 2h (45%), 4h (68%), 8h (88%), 12h(90%), 16h (92%), 20h(98%), 24h(99%).
8.	3.2.P.6	Submit copy of COA of primary / secondary reference standard including source and lot number which is actually used in the testing of stability batches.	Submitted
9.	3.2.P.8	• Specify the batch size of stability batches in terms of number of units produced. • Justify the significant change in assay value of real time and accelerated stability study data of batch no. T003. • Reference of previous approval of applications with stability study data of the firm (if any).	• The firm vide letter No. nil dated 20.07.2023 has submitted revised stability sheets wherein size of each stability batch is mentioned as 1704 tablets. • Difference of assay value are stated by the firm as a typographic error.

Decision: Registration Board approved the application of DESVEL 50mg XR Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product name as per SRO 496(I)/2023, before issuance of registration letter.

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

2.	Name, address of Applicant / Marketing Authorization Holder	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot A-115, S.I.T.E., Super Highway, Karachi Pakistan.
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Plot A-115, S.I.T.E., Super Highway, Karachi 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. 25415 Dated 13-09-2021
	Details of fee submitted	PKR 20,000/-: Dated 26-04-2021 PKR 10,000/- as Differential fee: Dated 17-06-2021
	The proposed proprietary name / brand name	**Desvel 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains: 144 mg of Desvenlafaxine succinate equivalent to Desvenlafaxine……100mg
	Pharmaceutical form of applied drug	Yellow colored, round, biconvex, extended release and film coated tablet, both sides are plain.
	Pharmacotherapeutic Group of (API)	Selective serotonin and nor-epinephrine reuptake inhibitors (SNRIs).
	Reference to Finished product specifications	In house Specifications
	Proposed Pack size	1 x 10’s
	Proposed unit price	As per SRO (not allotted yet)

	The status in reference regulatory authorities	Pristiq Tablet 100mg by M/s Pfizer Pharmaceuticals U.S.A., Inc., (USFDA Approved).
	For generic drugs (me-too status)	Lafaxine 100mg Tablet by M/s Genix Pharma, (Reg. No. 070473)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 30-09-2019. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Aurore Pharmaceuticals Pvt. Ltd., Plot # 68, 69, 2nd floor Jubilee Heights, Madhapur, Hyderabad, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Desvenlafaxine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: T-001, T-002, T-003.
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product Lafaxine 100mg Tablet (Batch # 011T064) by M/s Genix Pharma by performing quality tests like Identification, Assay, Dissolution, and Uniformity of dosage form. CDP has been performed against the same product in Acid media (pH 1.0-1.2), acetate buffer & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurore Pharmaceuticals Pvt. Ltd., Plot # 68, 69, 2nd floor Jubilee Heights, Madhapur, Hyderabad, India.		
API Lot No.	DVSF190003		
Description of Pack (Container closure system)	Alu-Alu 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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No. Accelerated	T-001	T-002	T-003
Batch Size	43 Blister	43 Blister	43 Blister
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	18-06-2020	07-07-2020	07-07-2020
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.	The firm has submitted copy of license (No: 99/RR /AP/B/C) for M/s Aurore Pharmaceutical (Pvt) Ltd, Telangana State, India. The license is valid till 29-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying the import of Desvenlafaxine 1kg (batch # DVSP190003) attested by Assistant Director (I & E) dated 24-04-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets have been submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) has been submitted.

Remarks of Evaluator:

Sr.#	Section	Observation
1	1.5.2	The applied label claim shows 76mg of Desvenlafaxine succinate eq to 50mg of Desvenlafaxine while master formulation shows 72mg of Desvenlafaxine succinate eq. to 50mg of Desvenlafaxine. The applied label claim of Desvel 100mg Tablet shows 152mg of Desvenlafaxine succinate eq to 100mg of Desvenlafaxine while master formulation shows 144mg of Desvenlafaxine succinate eq. to 100mg of Desvenlafaxine.
2	1.5.3	The proposed brand name does not cover extended release pattern of applied formulation.
3.	3.2.S.4.1 & 3.2.S.4.2	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
4.	3.2.S.4.3	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for

		both compendial as well as non-compendial drug substance(s) shall be submitted.
5.	3.2.S.7.3	The storage conditions under which stability study data of drug substance conducted is not as per Zone-IVA conditions.
6.	3.2.P.2.2.1	• Provide results of pharmaceutical equivalence data by performing all the quality tests of developed formulation and the innovator / reference / comparator product. • Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product. • Justify why comparative dissolution profile was not conducted in three BCS media across the physiological pH range.
7.	3.2.P.5.1	Justify the sampling time points for dissolution test which are not as per recommendations of FDA.
8.	3.2.P.6	Submit copy of COA of primary / secondary reference standard including source and lot number which is actually used in the testing of stability batches.
9.	3.2.P.8	• Specify the batch size of stability batches in terms of number of units produced. • Justify the significant change in assay value of real time and accelerated stability study data of batch no. T003. Reference of previous approval of applications with stability study data of the firm (if any).

Decision of 322nd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Section	Observation	Reply
1	1.5.2	The applied label claim shows 76mg of Desvenlafaxine succinate eq to 50mg of Desvenlafaxine while master formulation shows 72mg of Desvenlafaxine succinate eq. to 50mg of Desvenlafaxine. The applied label claim of Desvel 100mg Tablet shows 152mg of Desvenlafaxine succinate eq to 100mg of Desvenlafaxine while master formulation shows 144mg of Desvenlafaxine succinate eq. to 100mg of Desvenlafaxine.	The firm vide letter No. nil dated 11.07.2023 has stated that applied label claim is; Each extended release tablet contains; 152mg of Desvenlafaxine succinate eq to 100mg of Desvenlafaxine. There was a typographic mistake in formulation which is not corrected. It is further observed that in the reply of the firm that they have used CoatDry HPMC K15DC (Coadry 8800) in their formulation, its function is mentioned as ER Coating. Issue with this is that for extended release formulation, polymer is incorporated in the core of tablet, it is not coated over it. Further the Coatdry premix appears to be a mixture for enteric coating of tablets.
2	1.5.3	The proposed brand name does not cover extended release pattern of applied formulation.	The firm has stated that brand name of the product shall be revised to; **DESVEL 100mg XR Tablet.**
3.	3.2.S.4.1 & 3.2.S.4.2	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.	Copies are submitted
4.	3.2.S.4.3	Analytical method verification studies	The firm has submitted that drug

		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.	substance is of USP specifications. The firm has submitted method verification report that includes; system suitability, specificity, accuracy, precision and repeatability.
5.	3.2.S.7.3	The storage conditions under which stability study data of drug substance conducted is not as per Zone-IVA conditions.	Stability data of drug substance as per Zone IVa is submitted for following batches; DSVF20054. DSVF20055. DSVF20056.
6.	3.2.P.2.2.1	• Provide results of pharmaceutical equivalence data by performing all the quality tests of developed formulation and the innovator / reference / comparator product. • Justify why pharmaceutical equivalence and CDP studies were not performed against innovator product. • Justify why comparative dissolution profile was not conducted in three BCS media across the physiological pH range.	• Results of pharmaceutical equivalence with Lafaxine ER 100mg tablet batch No. 011T064 are submitted. • For not using innovator product frim has stated that it was not available at time of performance of CDP. • The firm vide letter No. nil dated 20.07.2023 has submitted CDP in 0.1N HCl, Acetate buffer and phosphate buffer at all-time points of dissolution profile. The results of CDP are similar to Lafaxime ER Tablet 100mg.
10.	3.2.P.5.1	Justify the sampling time points for dissolution test which are not as per recommendations of FDA.	As per provided data, samples were taken at time periods of 1h (25%). 2h (45%), 4h (71%), 8h (88%), 12h(90%), 16h (92%), 20h(96%), 24h(99%).
11.	3.2.P.6	Submit copy of COA of primary / secondary reference standard including source and lot number which is actually used in the testing of stability batches.	Submitted
12.	3.2.P.8	• Specify the batch size of stability batches in terms of number of units produced. • Justify the significant change in assay value of real time and accelerated stability study data of batch no. T003. • Reference of previous approval of applications with stability study data of the firm (if any).	• The firm vide letter No. nil dated 20.07.2023 has submitted revised stability sheets wherein size of each stability batch is mentioned as 1704 tablets • Difference of assay value are stated by the firm as a typographic error.

Decision: Registration Board approved the application of DESVEL 100mg XR Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product name as per SRO 496(I)/2023, before issuance of registration letter.

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

Export Facilitation

M/s Remington Pharmaceutical Industries:

Deputy Director PRV/EFD vide his letter dated 20th July 2023 informed that in pursuance of decision of 133rd meeting of the Authority wherein it was decided that for each 100,000 USD worth of export during a fiscal year one molecule will be considered on priority basis. In compliance to this M/s Remington Pharmaceutical

Industries (Pvt) Ltd., 18 Km Multan Road, Lahore has achieved the benchmark of more than 100,000 USD during the financial year 2021-2022. Accordingly, the firm has requested for priority consideration of the following molecule		
3.	Name, address of Applicant / Marketing Authorization Holder	M/s Remington Pharmaceutical Industries (Pvt) Ltd., 18 Km Multan Road, Lahore.
	Name, address of Manufacturing site.	M/s Remington Pharmaceutical Industries (Pvt) Ltd., 18 Km Multan Road, Lahore. DML No. 000061
	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. 1660 dated 04-07-2022.
	Details of fee submitted	PKR 30,000/- vide slip No.392742733 dated 26/05/2023.
	The proposed proprietary name / brand name	**ZOLOPAT 0.6% Nasal Spray**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 microlitre spray contains; Olopatadine HCl 665mcg equivalent to Olopatadine……..600mcg
	Pharmaceutical form of applied drug	Solution for Nasal Spray
	Pharmacotherapeutic Group of (API)	Histamine H1 receptor antagonist ATC Code: R01AC08
	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	15 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Patanase Nasal Spray USFDA Approved
	For generic drugs (me-too status)	Olonase Nasal Spray of M/s Sante (Pvt) Ltd, Karachi (Reg. No. 097084)
	GMP status of the Finished product manufacturer	M/s Remington Pharmaceutical Industries (Pvt) Ltd., 18 Km Multan Road, Lahore. Copy of GMP certificate No.80/2021-DRAP (AD-2040452-634) dated 12-10-2021 issued on the basis of inspection conducted on 30.09.2021 is submitted.
	Evidence of section approval.	The firm has submitted copy of letter of layout approval for regularization vide No. F-147/84-Lic (Vol-I) dated 05.11.2020 wherein Nasal Spray section is mentioned. Same is also mentioned in GMP certificate.
	Name and address of API manufacturer.	**M/s Medigraph Pharmaceuticals Pvt. Ltd**. Plot No. J-46/57, M. I. D. C. Taloja, Dist. Raigad, Maharashtra INDIA Copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/88548/2020/11/31596) dated 11-04-2020 issued by Food and Drug Administration, M.S. Bandra- Kurla Complex Bandra (E), Mumbai-400 051 Maharashtra, India valid till 10.04.2023 is submitted.

		The certificate specifies that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Tablet 1(attached)
	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 / 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 as submitted detail of nomenclature, structure, general properties (solubility & physical form), general properties of drug pellets., description of manufacturing process and controls, tests for related. Any other Individual unspecified impurity, 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	Stability study conditions: **Real time**: 30˚C ± 2˚C / 75% ± 5%RH for 48 months **Accelerated**: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **Batches**: PB/OLOH/001/05/10, PB/OLOH/002/05/10, PB/OLOH/001/04/17, PB/OLOH/002/05/17, PB/OLOH/001/01/18, PB/OLOH/002/01/18
	Module-III (Drug Product):	The firm has submitted detail of the description and composition of the drug product, manufacturers, description of manufacturing process and controls, Process validation, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has is performing tests for uniformity of delivered dose (within batch and within container)
	Pharmaceutical equivalence	**Test product: ZOLOPAT 0.6% Nasal Spray** Batch No. RND21075 Mfg 12.2021 Exp NA**.** **Reference Product:** Olonase Nasal Spray, Batch No. GE-013, Mfg date: 11.2021, Exp. Date: 11.2023. of M/s Sante (Pvt) Ltd. (Images of Pack are not provided) Pharmaceutical Equivalence is established against the comparator Olonase Nasal Spray, Batch No. GE-013, Mfg date: 11.2021, Exp. Date: 11.2023 of M/s Sante (Pvt) Ltd. by performing quality tests (Physical attributes, Identification, Assay, pH test and osmolarity). Results of both the products are comparable with each other.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, linearity& range, LOD, LOQ and robustness.
STABILITY STUDY DATA		
Manufacturer of API	M/s**.** Medigraph Pharmaceuticals Pvt. Ltd. Plot No. J-46/57, M. I. D. C. Taloja, Dist. Raigad, Maharashtra INDIA.	

API Lot No.	FP/OLOH/002/07/21		
Description of Pack (Container closure system)	5 ml clear colourless non-sterile aqueous solution in High density polyethylene (HDPE) bottle with meter dose manual pump and HDPE 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.	E22010	E22011	E22012
Batch Size	133 units	133 units	133 units
Manufacturing Date	05.07.2022	05.07.2022	05.07.2022
Date of Initiation	07.07.2022	07.07.2022	07.07.2022
No. of Batches	03		

Administrative Portion

55.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
56.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/88548/2020/11/31596) dated 11-04-2020 issued by Food and Drug Administration, M.S. Bandra- Kurla Complex Bandra (E), Mumbai-400 051 Maharashtra, India. The certificate specifies that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Tablet 1(attached).
57.	Documents for the procurement of API with approval from DRAP (in case of import).	**Drug Substance:** Olopatadine Hydrochloride USP **Quantity:** 1kg **Lot/ batch No.:** FP/OLOH/002/07/21 **Mfg date:** July 2021 **Invoice No.** MPPL/073/21-22 **Invoice date:** 25.01.2022 **Clearance date:** 09.02.2022
58.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
59.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
60.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Registration Board approved the application of ZOLOPAT 0.6% Nasal Spray.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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 of Form-5

4.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Axoff 40mg tablet
	Composition	Each film coated tablet contains: Febuxostat……..40mg
	Diary No. Date of R & I & fee	Dy.2685; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-Gout
	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	Approved by USFDA
	Me-too status	Febuxin by M/s AGP, Karachi (Reg. No. 081104)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	No official monograph is available for applied formulation in USP or BP.
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	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.	
5.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Axoff 80mg tablet
	Composition	Each film coated tablet contains: Febuxostat……..80mg
	Diary No. Date of R & I & fee	Dy.2690; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-Gout
	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	Approved by MHRA of UK
	Me-too status	Febuxin by M/s AGP, Karachi (Reg. No. 081105)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	No official monograph is available for applied formulation in USP or BP.
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.

	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	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.	
6.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Paradol tablets
	Composition	Each film coated tablet contains: Paracetamol……..325mg Tramadol hydrochloride……37.5mg
	Diary No. Date of R & I & fee	Dy. No 2691; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Analgesic/ Opioid Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ultracet by Janssen (USFDA)
	Me-too status	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	Decision: Approved	
7.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Levictam 500mg tablet
	Composition	Each film coated tablets Contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Dy. No 2687; 15-06-2016; Rs.20,000/- (15-06-2016)

	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Keppra Tablets 500mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045685)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	Decision: Approved	
8.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Levictam 250mg tablet
	Composition	Each film coated tablets Contains: Levetiracetam…….250mg
	Diary No. Date of R & I & fee	Dy. No 2689; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Keppra Tablets 250mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045684)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.

	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	Decision: Approved	
9.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Vamlodip-DS tablets
	Composition	Each film coated tablets Contains: Amlodipine as besylate……10mg Valsartan……..160mg
	Diary No. Date of R & I & fee	Dy. 2686; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Valpine Tablets 10/160mg by M/s Fassgen Pharmaceuticals, (Reg. No. 073303)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	Decision: Approved	
10.	Name and address of manufacturer/ Applicant	M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sertowan 50 mg tablet
	Composition	Each film coated tablets Contains: Sertraline (as hydrochloride) …… 50mg
	Diary No. Date of R & I & fee	Dy. No 2688; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Ertalin 50 mg Tablets of M/s Genome Pharma, (Reg.#076844)
	GMP status	Last inspection conducted on 21-12-2016.

	Remarks of the Evaluator	
	Previous decision(s)	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288th meeting of RB	Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. SW/Reg/188/03/23 dated 30.03.2023 has submitted inspection report for renewal of DML conducted on 13.12.2022. The panel has recommended renewal of DML.
	Decision: Approved	

Agenda of Evaluator PEC-X

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

a. New cases

11.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	N-Tox Powder
	Composition	Each gram contains: Methenamine ……700mg Sodium Citrate ……..…100mg Citric Acid ……100mg Vitamin B1 ……..…8mg Vitamin B6 ……..…9.2mg Vitamin K3 ……..…2mg
	Diary No. Date of R& I & fee	Dy. No 25608 dated 30-09-2020 Rs.20,000/- dated 29-09-2020
	Pharmacological Group	Antibacterial, diuretic, **antifungal**
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • Firm shall submit fee of Rs.7,500/- for correction in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings	
12.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.

	Brand Name +Dosage Form + Strength	Try Tyl S Suspension
	Composition	Each ml contains: Trimethoprim…35mg Sulphadiazine…175mg Tylosin Tartrate…55mg
	Diary No. Date of R& I & fee	Dy.No 25609 dated 30-09-2020 Rs.20,000/- dated 29-09-2020
	Pharmacological Group	Antibiotic/ antibacterial/ **coccidiostat /antiprotozoal**
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 15000ml, 20000ml, 25000ml; Decontrolled
	Me-too status	Diatrim-T Oral Solution of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore. (Reg. No. 103836)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form) and pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form) and pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
13.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Para-20 Powder
	Composition	Each 100Gm Contains: **Paracetamol**…20Gm **Vitamin C**…5Gm Potassium Carbonate…12.5Gm Sodium Bicarbonate…12.5Gm Vitamin E…12.5Gm
	Diary No. Date of R& I & fee	Dy. No 24961 dated 24-09-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	Para CE Oral Powder of M/s Biogen Pharma, Rawat. (Reg. No. 063812)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. The firm had already applied for same formulation with same brand name **(vide Dy. No. 23816 dated 10-07-2018; Rs. 20,000/- 06-07-2018)** which was considered by the

		Registration Board in its **291st, 316th meetings** and the board referred the applied formulation to EWG on Veterinary Drugs for review. In **320th** meeting, Registration Board endorsed the following decision of EWG on Veterinary Drugs. ***"The EWGVD deliberated the cases of paracetamol with Vit C and similar combinations with their dosage form at length and decided to obtain scientific rationale of combination and pharmacokinetics with examples of such products registered at scientifically developed countries for use in variety of animal species as applied by the firms in their applications for product registration".***
	Decision: The board directed the PEC to deliberate the matter with scientific rationale keeping in view the International Practices .	
14.	**Deleted.**	

b. Deferred Cases.

15.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Enrocol B Solution
	Composition	Each 100ml contains: Enrofloxacin HCl…10gm Colistin Sulphate…5 MIU Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 11126 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 2060509181. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg **Shortcomings:** • 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 323rd meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: The firm has now provided the following evidence of generic/metoo status. ➢ **Me too status:** Enrocoli Liquid of M/s Symans Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 059167) Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt	

	form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
16.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Doxy Plus Powder
	Composition	Each 1000gm 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 24870 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antibacterial, Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Could not be confirmed in the applied strength and combination
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Colistin Sulphate from MIU to grams.
	Decision of 326th 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. • Conversion of Colistin Sulphate from MIU to grams	
	Updated status: The firm has now provided the following. ➢ **Metoo status:** Pulmodox-S Powder of M/s Attabak Pharmaceutical Islamabad. (Reg. No. 071069) ➢ Conversion of Colistin Sulphate (1mg of Colistin Sulphate = 19000IU) Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
17.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	S Pro C Powder
	Composition	Each 100gm contains: **Acetylsalicyclic Acid**…20gm **Ascorbic Acid**…20gm Vitamin-K3…2.5gm
	Diary No. Date of R& I & fee	Dy.No 24872 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Could not be confirmed in the applied strength and

		combination
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report 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.
	Decision of 326th 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.	
	Updated status: The firm has now provided the following. ➢ **Metoo status:** C-Plus Powder of M/s Intervac (Pvt) Ltd., Lahore. (Reg. No. 046598)	
	Decision: The board directed the PEC to deliberate the matter with scientific rationale keeping in view the International Practices .	
18.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bonaid Minerals Granular Powder
	Composition	Each Kg Contains: Calcium…155gm Phosphorus…135gm Magnesium…55gm Sodium…45gm Iron as Ferrous…1gm Zinc…..3gm Manganese…2gm Copper…0.6gm Cobalt…0.01gm Iodine…0.04gm
	Diary No. Date of R& I & fee	Dy.No 6160 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Macro and mineral mixture
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg and 25Kg; Decontrolled
	Me-too status	L.S. Minerals Powder of M/s Nawan Labs Karachi (Reg. No. 021306)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 0329580112.
	Decision of 323rd meeting: Deferred for complete salt form, requisite fee and generic status	
	Updated status: The firm has now revised the formulation as mentioned below: **Each gram contains:** **Calcium as Dicalcium Phosphate…155mg** **Phosphorus as Calcium Phosphate…135mg** **Magnesium as Magnesium Oxide…55mg** **Sodium as Sodium Chloride…45mg** **Iron as Ferrous Sulphate…1mg** **Zinc as Zinc Sulfate….3mg**	

	Manganese as Manganese Sulfate…2mg **Copper as Copper Sulfate …0.6mg** **Cobalt as Cobalt Sulfate…0.01mg** **Iodine as Potassium Iodide…0.04mg** ➢ **Metoo status:** Nittafos-BP Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 093617) Firm shall submit differential fee of Rs.22,500/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Approved as per following composition: **"Each gram contains:** **Calcium as Dicalcium Phosphate…155mg** **Phosphorus as Calcium Phosphate…135mg** **Magnesium as Magnesium Oxide…55mg** **Sodium as Sodium Chloride…45mg** **Iron as Ferrous Sulphate…1mg** **Zinc as Zinc Sulfate….3mg** **Manganese as Manganese Sulfate…2mg** **Copper as Copper Sulfate …0.6mg** **Cobalt as Cobalt Sulfate…0.01mg** **Iodine as Potassium Iodide…0.04mg"** **Registration letter will be issued upon submission of following:** • **Differential fee of Rs.22,500/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Verification of availability of testing facility required for applied formulation by the QA division.**	
19.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Anical Injection
	Composition	Each ml Contains: Calcium Gluconate…38.71gm Boric Acid…7.29gm Calcium Hydroxide…1.32gm Magnesium Chloride…6.50gm
	Diary No. Date of R& I & fee	Dy.No 31451 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Calcium and Magnesium supplementary source for energy
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 450ml, 500ml: Decontrolled
	Me-too status	Could not be confirmed in the applied strength and combination
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and accordingly provide evidence of applied formulation/drug already approved by DRAP (generic /

		me-too status) 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) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has now revised the formulation as mentioned below: **Each ml contains:** **Calcium Gluconate…….208.30mg.** **Magnesium Hypophosphite…… 53.30mg** **Magnesium Chloride ……. 20mg** **Calcium D Saccharate ……10mg** **Boric Acid……. 43.30mg** **Dextrose…….200mg** ➢ **Metoo status:** Calpho-M Injection (300ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043146) ➢ Demanded pack size: **300ml** ➢ **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. The firm has submitted registration letter dated 18-08-2017 of **Suldin Injection (500ml)** Reg. No.084931, as an evidence of required manufacturing facility **Remarks of the evaluator:** ➢ Firm shall submit fee of Rs. 30,000/- for pre-approval correction/revision of formulation and change of pack size, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. ➢ Firm shall submit documentary evidence (inspection report, commercial invoice, installation qualification, operational qualification reports) of the required manufacturing facility	
	Decision: Deferred for following • **Submission for evidence of manufacturing facility of LVP** • **Fee of Rs. 30,000/- for pre-approval correction/revision of formulation and change of pack size, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	

Case no. 02 Registration applications of New DML (Veterinary)

a. New DML

I. M/s Poulvet Pharmaceuticals (Pvt) Ltd, Multan.

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 (General) I (Veterinary)
2. Oral Powder (General) II (Veterinary)
3. Oral Liquid/ Drench (General) (Veterinary)

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

Section	No. of Products applied	No. of Molecules applied
Oral Powder (General) II (Veterinary)	17	10

Oral Powder (General) II (Veterinary)
(17 Products/ 10 Molecules)

20.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tylo Rate-50 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…500mg
	Diary No. Date of R& I & fee	Dy. No 14664 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 8825382048)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Tylo-50 Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063847)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
21.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tylo Rate-98 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…980mg
	Diary No. Date of R& I & fee	Dy. No 14655 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 93377392011)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Tylo Tartrate-98 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113431)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
22.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	P-Tylox 10 Premix
	Composition	Each gram contains: Tylosin Phosphate…100mg
	Diary No. Date of R& I & fee	Dy. No 14639 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 830832862252)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Lincomiks 10 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113518)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
23.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	P-Tylox 25 Premix
	Composition	Each gram contains: Tylosin Phosphate…250mg
	Diary No. Date of R& I & fee	Dy.No 14638 dated 12-06-2023 Rs.30,000/- dated 07-

		06-2023 (slip No. 355524265)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Mylosin Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 097930)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
24.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Oxy Poul-50 Water Soluble Powder
	Composition	Each gram Contains: Oxytetracycline HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 14657 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 8983345665)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Nobitet 50% Powder of M/s Noble Pharma, Industrial Area, Mirpur Azad Kashmir. (Reg. No. 063643)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
25.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Oxy Poul-95 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…950mg
	Diary No. Date of R& I & fee	Dy.No 14662 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 429518509)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Oxybar Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore (Reg. No.079818)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
26.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Spira Prim Powder
	Composition	Each gram contains: Spiramycin…5,00,000 IU Trimethoprim…50mg
	Diary No. Date of R& I & fee	Dy.No 14642 dated 12-06-2023 Rs.30,000/- dated 07-06-2023(slip No. 31662105685)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm,

		5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Sirova Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No.074011)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
27.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Paramol CE Oral Powder
	Composition	Each gram contains: **Paracetamol**…200mg Vitamin C…50mg Potassium Carbonate…125mg Sodium Bicarbonate…125mg Vitamin E…125mg
	Diary No. Date of R& I & fee	Dy.No 14649 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 737034728)
	Pharmacological Group	Analgesic, Antipyretic with Vitamin C, E & Electrolytes
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Para CE Oral Powder of M/s Biogen Pharma, Rawat. (Reg. No.063812)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Sub-committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
28.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Diuri Tox Powder
	Composition	Each gram contains: Sodium Benzoate…500mg Ethanol Beta Amino Phosphoric Acid…100mg Vitamin A…10,000 IU Vitamin E…2.5mg Vitamin K3…1mg Vitamin C…2.5mg
	Diary No. Date of R& I & fee	Dy.No 14643 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 31604924)
	Pharmacological Group	Multivitamin/ growth promoter
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Diurizone Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 073908)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
29.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Fartylo Fos Oral Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Fosfomycin Calcium…200mg Fructose…180mg Magnesium Sulphate…100mg Sodium Phosphate…150mg
	Diary No. Date of R& I & fee	Dy.No 14646 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 150157930)
	Pharmacological Group	Antibiotic/ Antibacterial/ Minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Role of sodium chloride in instant formulation • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following: • **Role of sodium chloride in instant formulation** • **Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
30.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Neof-55 Oral Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 14644 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 70568667175)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Neoxflor Oral Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No.088638)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved.	
31.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tydo Hale-60 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…200mg Doxycycline Hyclate…400mg
	Diary No. Date of R& I & fee	Dy.No 14666 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 242482872337)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled

	Me-too status	Wimsdox-60 Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No.102047)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
32.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tydo Hale-45 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…200mg Doxycycline Hyclate…250mg
	Diary No. Date of R& I & fee	Dy.No 14665 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No.324169221)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Macrodox Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No.043291)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
33.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Tydo Hale-30 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Doxycycline Hyclate…200mg
	Diary No. Date of R& I & fee	Dy.No 14668 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No.2973926569)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Doxysin Water Soluble Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 033256)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
34.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Dox T-40 Water Soluble Powder

	Composition	Each gram Contains: Tylosin Tartrate…200mg Doxycycline Hyclate…400mg Colistin Sulphate…100mg Bromhexine HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 14675 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 305528912)
	Pharmacological Group	Antibiotic/ Antibacterial/Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Brocotyd Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 058962)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
35.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Dox T-20 Water Soluble Powder
	Composition	Each gram Contains: Tylosin Tartrate…100mg Doxycycline Hyclate…200mg Colistin Sulphate…50mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 14676 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 8201303094)
	Pharmacological Group	Antibiotic/ Antibacterial/Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	CD RAAS Powder of M/s Zakfas Pharmaceutical (Pvt) Ltd Multan (Reg. No.057072)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
36.	Name and address of manufacturer / Applicant	M/s Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Poul Dox T-36 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Doxycycline Hyclate…200mg Colistin Sulphate…50mg Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 14661 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 6327027208)
	Pharmacological Group	Antibiotic/ Antibacterial/Expectorant
	Type of Form	Form 5

	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Tycodox-Plus Powder of M/s M/s Univet Pharmaceuticals, Rawalpindi (Reg. No.058963)
	GMP status	New DML
	Remarks of the Evaluator [X]	Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

Case no. 03 Registration applications of categories to be considered on priority

c. Export facilitation

i. Veterinary

Deputy Director PRV/EFD vide letter No.1-6/2019-PR-I (EFD) dated 26-05-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision, **M/s International Pharma Lab. Lahore** has submitted following application(s) for priority consideration/ evaluation in lieu of export facilitation, submitted before the Board for its consideration please:

37.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Power Drench
	Composition	Each ml Contains: Triclabendazole…12gm Ivermectin…0.2gm Albendazole…10gm
	Diary No. Date of R& I & fee	Dy. No 8508 dated 01-04-2022 Rs.30,000/- dated 28-03-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 1000ml, and 5000ml; As per DPC
	Me-too status	Thunder Drench of M/s Star Laboratories (Pvt) Ltd, Lahore. (Reg. No. 058941)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Upon clarification regarding the applied formulation since same quantities of APIs are mentioned **per ml** in covering letter while **per 100ml** in Form-5 and throughout the dossier, the firm has submitted the correct formulation in line with above stated generic formulation as follows: **Each 100ml contains:** **Triclabendazole…12gm**

		Ivermectin…0.2gm **Albendazole…10gm**
	Decision: Approved with following label claim: **Each ml contains:** **Triclabendazole…120mg** **Ivermectin…2mg** **Albendazole…100mg** **Firm shall submit fee of Rs.30000/- 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.**	

Case no. 04 Registration applications of import cases

a. Deferred cases (Veterinary)

38.	Name and address of Applicant	M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan
	Detail of Drug Sale License	Name: M/s Prix Pharmaceutica, Address: 26 Abbot Road, Lahore Validity: 12-06-2027. Status: License to sell drugs as Distributor (Form No.11).
	Name and address of manufacturer	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands
	Name and address of marketing authorization holder	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands
	Name of exporting country	The Netherlands
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33720 Dated 18-12-2020
	Fee including differential fee	Rs : 50,000 Dated 18-12-2020
	Brand Name +Dosage Form + Strength	Revozyn RTU 400mg/ml Suspension for Injection
	Composition	Each ml Contains: Penethamate Hydroiodide…400mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Penicillin Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	**Netherlands approved**
	Me-too status	N/A
	Detail of certificates attached	➢ Photocopy of Legalized COPP No. 253161 dated 09-03-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➢ Copy of distribution agreement/ letter of authorization **not provided**
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The already submitted COPP is **photocopy,** Provide legalized valid original COPP.

		• Provide legalized valid original letter of Authorization (LOA) • Confirmation of dedicated penicillin injectable section. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following • legalized valid original COPP • legalized valid original letter of Authorization (LOA) • Confirmation of dedicated penicillin injectable section • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	The firm has submitted the following: ➢ Scanned copy of legalized COPP No. 259737 dated 16-06-2023 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➢ copy of LOA dated 30-09-2020 **(not notarized/ legalized**). ➢ label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Decision: Deferred for following: • **Consideration of case after the decision of the Authority regarding the manufacturing of Beta-lactum antibiotics and general products as per the International practices** • **Notarized Valid copy of Letter of Authorization.**	

Evaluator PEC-II

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

c. **New DML**

CLB in its 253rd meeting held on 25th May, 2017 has approved grant of DML by way of formulation for M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore including section of Dry powder injection (Cephalosporin). Now the firm has applied for priority consideration of following two molecules against their available quota of priority consideration for 10 molecules per section.
Previously 6 molecules have been considered by Registration Board for Dry powder injection (Cephalosporin) section of M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore.

39.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-07-2019 based on inspection conducted on 24-05-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-06-2017 specifying Dry Powder Injection (Cephalosporin) section, Dry Powder Suspension (Cephalosporin) section & 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 22725 dated 11-08-2022
	Details of fee submitted	Rs.50,000/- dated 02-08-2022 & Rs.25,000/- dated 06-07-2022
	The proposed proprietary name / brand name	**Ceflaro 600mg Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil monoacetate monohydrate eq. to Ceftaroline Fosamil……. 600mg (With L-Arginine)
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use. Fifth-generation cephalosporin
	Pharmaceutical form of applied drug	Yellow-white to light yellow dry Powder for Injection
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1's & 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 600mg Injection (US-FDA Approved) by M/s ALLERGAN Pharma
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, Jinan, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	Monograph of Ceftaroline Fosamil is not present in any Pharmacopoeia. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of 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 with Innovator Brand Teflaro Injection 600mg IV has been 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 Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, Jinan, Shandong Province, China		
API Lot No.	1003DJ87ZA		
Description of Pack (Container closure system)	1's (Blister of 1 filled vial & 1 WFI 20mL, LDPE ampoule), securely packed in 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	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	RD-CH-22004	RD-CH-22005	RD-CH-22006
Batch Size	180 Vials	180 Vials	180 Vials
Manufacturing Date	Feb-2022	Feb-2022	Feb-2022
Date of Initiation	08-Feb-2022	08-Feb-2022	08-Feb-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. SD20170569 issued by CFDA & Copy of DML certificate No. Lu 20160006 issued by CFDA valid till 25/06/2022 & 03/11/2025 respectively has been provided.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. A21229J dated 14/10/2021 (DRAP Approval Ref. No. 17934/2021-DRAP dated 24-11-2021) (Approval letter No. F.08-10/2021-I&E (QA&LT) from AD (I&E) Islamabad is also 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	Firm's response

1.3.5	Latest GMP inspection reports of drug product manufacturer, conducted within last three years, shall be submitted.	Copy of GMP certificate dated 11-07-2019 based on inspection conducted on 24-05-2019 is submitted
3.2.P.2.5	Compatibility study report mentions 0.9% NaCl solution and water for injection as reconstitution diluents, whereas innovator drug product literature only recommends water for injection as reconstitution diluent. Clarification shall be submitted in this regard.	Firm has referred to the unit carton label of the innovator pack wherein 0.9%NaCl is also recommended as reconstitution diluent.
3.2.P.5.1	• Firm has proposed limits for pH test as "4.8 - 6.5", whereas innovator drug product literature declares the pH of the reconstituted solution as "5.0 - 7.0" Justification shall be submitted for this variation. • Limits of water content declared in the drug product specifications are different from that declared in process validation protocol.	Firm has referred to the unit carton label of the innovator pack wherein pH range of 4.8-6.5 is declared. The in-process limits are kept tighter than the finish drug product specifications.

- Submitted trial mentions theoretical weight of 400mg as label claim for the calculation of dispensed quantity of drug substance per unit vial.

  Response: It is a typographical error. 400mg is mistakenly written instead of 600mg.

  Calculation of dispensed quantity of drug substance per unit vial of Ceflaro 600mg is as follows;

  Ceftaroline fosamil with arginine lot No: 2201000020

  Potency (on as is basis) = 56.8416%

  Formula for fill weight:

  Theoretical weight (mg) x Std. Assay % / Actual Assay %

  600 x 100 / 56.8416 = 1056mg per unit vial

- Value of as is potency of "56.8416%", used for the calculation of dispensed quantity of drug substance per unit vial, shall be justified against the results of drug substance analysis performed by M/s Curexa.

  Response:

  Potency from Manufacturer CoA calculated and used for target filled weight as follows:

  Assay = 99.2 %

  (Anhydrous, acetic acid and arginine free basis)

  Water = 0.5 %

  Acetic Acid = 5.3 %

  Arginine = 36.9 %

  Potency = (100 – 0.5 – 5.3 – 36.9)/100 x 99.2

  = 56.8416 % (as is basis)

Same Test Method with formula used for testing of RM as provided by manufacturer.

Ceftaroline Fosamil for Injection is supplied with L-Arginine as pre-mix blend. The value 56.8416% refers to API contents in portion of sample under analysis i.e., blend uniformity, not the potency which applies to pure API, the reason why Uniformity of Dosage Units by Weight Variation is performed for drug product. Further the value is not used to calculate the API required to prepare a bulk but used to calculate the target fill wight to ensure that Ceftaroline fosamil for injection meets the requirements of Uniformity of Dosage Units by Weight Variation.

- Justify the imported quantity of 1 kg of drug substance against the quantity required for the drug substance analysis and manufacturing of three trial batches of each strength i.e., 400mg & 600mg of applied formulation.

Response: Ceflaro 400mg Injection IV:

Quantity of API used per batch x Total No. of batches:

0.141 Kg x 3 = 0.423 Kg

Ceflaro 600mg Injection IV

Quantity of API used per batch x Total No. of batches

0.190 Kg x 3 = 0.57 Kg API

Total Quantity of Used = 0.57 Kg + 0.423 Kg = 0.993 Kg

- Justification shall be submitted for the manufacturing of trial batches before the sterility testing of drug substance.
  Response:
  Prior to procurement of trial material, source approval samples from three different batches evaluated for physical, chemical & microbiological attributes were found compliant. Keeping in view the risk associated with sampling, the sterile materials are supplied with separate sample portions for evaluation in routine but because of the high cost of material, the trial material was supplied without sample portion and the sterility test is performed on filled vials to mitigate the risk associated with sampling. The material is directly processed in sterile area and the sterility is evaluated in initial testing of drug product.

- Justification shall be submitted for initiating stability studies prior to the batch release of trial batches by QC.
  Response:
  Initial testing includes sterility testing which delayed batch release, all other applicable quality tests were conducted prior to initiating stability studies.

Curexa received the drug substance with manufacturing date of 29-Apr-2021. Material when received (25-Jan-2022) almost 9 months passed. So, drug product placed for stability study on same day of filling to avoid any further delay due to initial evaluation.

Decision: Deferred for submission of justification for:

- **Non-performance of drug substance analysis of the relevant batch used for manufacturing of drug product stability batches, by M/s Curexa Health (Pvt.) Ltd.**
- **Rationale of quantity of drug substance imported against the proposed batch size, considering the quantity required for the drug substance analysis and process loss during manufacturing for trial batches.**

40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 11-07-2019 based on inspection conducted on 24-05-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-06-2017 specifying Dry Powder Injection (Cephalosporin) section, Dry Powder Suspension (Cephalosporin) section & 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 9444 dated 13-04-2022
	Details of fee submitted	PKR 75,000/- dated 14-03-2022
	The proposed proprietary name / brand name	**Ceftavi 2.5g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Sterile Ceftazidime pentahydrate/sodium carbonate

		equivalent to Ceftazidime ……. 2 g Sterile Avibactam sodium equivalent to Avibactam .....… 0.5 g
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use.
	Pharmaceutical form of applied drug	White to pale yellow dry Powder for Injection
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1's & 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	AVYCAZ (ceftazidime and avibactam) for injection, for intravenous use (USFDA Approved)
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Name of Manufacturer: Chifeng Addisun Pharmaceutical Co., Ltd. Site address: 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, 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 details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of 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 intermediate stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. The long term 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 with Innovator Brand Avycaz 2.5g Injection IV has been submitted

		Comparative Dissolution Profile - NA
	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 of Manufacturer: Chifeng Addisun Pharmaceutical Co., Ltd. Site address: No.3 Minsheng Street, Economic Development Zone of Hongshan District, Chifeng, Inner Mongolia, China		
API Lot No.	2105001		
Description of Pack (Container closure system)	1's (Blister of 1 filled vial & 1 WFI 10mL, LDPE ampoule), securely packed in 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	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	RD-CH-21002	RD-CH-21003	RD-CH-21004
Batch Size	158 Vials	158 Vials	158 Vials
Manufacturing Date	July-2021	July-2021	July-2021
Date of Initiation	16-Aug-2021	16-Aug-2021	16-Aug-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)	• Fortez Injection 2g IV CTD Dossier approved in 317th DRB Meeting held on 16th-17th May-2022 • Ceflaro 400mg Injection CTD Dossier approved in 329th DRB 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 valid till Dec-2022 & Copy of DML No. Inner 20160028 of Chifeng Addisun Pharmaceutical Co., Ltd. Valid till 27-12-2025 issued by Inner magnolia autonomous region drug administration is provided. 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 No. IV21S002 dated 9th June, 2021 attested by DRAP dated 22-06-2021. 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:

Section#	Observations	Firm's response

1.3.5	The production scope mentioned in the submitted DML of drug substance manufacturer does not include "Ceftazidime/Aviabactam"	Firm has submitted GMP certificate and DML issued by CFDA, wherein scope of manufacturing does not include "Ceftazidime/Avibactam".
3.2.S.4.4	Analytical record for the drug substance analysis performed by M/s Curexa shall be submitted. Submitted batch COAs of drug substance does not elaborate about the declared Assay results, whether it is "on dried basis" or " as is basis".	Assay in the submitted batch CoAs of the drug substance is calculated on "as is basis"
3.2.P.5.1	• Justification shall be submitted for the proposed limits for pH test of drug product..	The proposed limits for pH test of drug product are as per API Manufacturer's CoA.

- Proposed weight of 3.15gm per unit vial shall be justified against the label claim of applied product and contents of sodium bicarbonate.

  Response:

  Firm has submitted justification for the filled weight per unit vial against the potency of Ceftazidime declared in drug substance batch analysis.

- Use of value of potency "64.8%" of Ceftazidime, for the calculation of dispensed quantity of drug substance per unit vial, shall be justified against the results of drug substance analysis performed by M/s Curexa wherein Assay results have been declared as 64.5% for Ceftazidime.

  Response:

  The value 64.8% refers to API contents in portion of sample under analysis (blend uniformity) not the potency which applies to pure API, the reason why Uniformity of Dosage Units by Content Uniformity is performed for drug substance to ensure blend uniformity

- Justify the imported quantity of 1.5 kg of drug substance against the quantity required for the drug substance analysis and manufacturing of three trial batches.

  Response:

  1.5 kg of drug substance (Ceftazidime and Avibactam sterile powder) was imported for manufacturing of trial batches. **(ADC Attested invoice is enclosed in Annexure-3)** Justification is as follows;

No. of Batches	3
Batch No.	RD-CH-21002, RD-CH-21003, RD-CH-21004
Batch size	0.500 Kg
No. of units (Vials) per batch	158 vials
Total No. of vials in 3 batches	158 x 3 = 474 vials
Quantity of API used per vial	3.15g = 0.00315kg
Total Quantity of API used in Ceftavi 2.5g Injection IV	Quantity of API used per vial x Total No. of vials = 0.00315 Kg x 474 = 1.49 Kg ≈ 1.50 Kg

- Justification shall be submitted for the manufacturing of trial batches before on 17-07-2021 whereas drug substance release was issued on 16-8-2021 by M/s Curexa.

  Response:

  The material is directly processed in sterile area and the Physical/Chemical/Microbial test are evaluated in initial testing of drug product.

  Details are as follows:

  RM received on 08-Jul-2021

RM and FP tests started on 31-Jul-2021. Physical/Chemical tests completed on 10-Aug-2021 and sterility test results reported on 16-Aug-2021. Product placed for stability study on same date i.e., 16-Aug-2021.

Decision: Deferred for submission of justification for:

- **Non-performance of drug substance analysis of the relevant batch used for manufacturing of drug product stability batches, by M/s Curexa Health (Pvt.) Ltd.**
- **Rationale of quantity of drug substance imported against the proposed batch size, considering the quantity required for the drug substance analysis and process loss during manufacturing for trial batches.**

Agenda of Evaluator (PEC-XI)

Case No. 01: Registration applications of Human Drugs on form 5F (New sections):
M/s Curatech Pharma Pvt. Ltd., 35-Km, Multan Road, Lahore

The Central Licensing Board in its 278th meeting held on 10th-11th December, 2020 has considered and approved the grant of following four additional sections to **M/s Curatech Pharma Pvt. Ltd.,** 35-Km, Multan Road, Lahore under Drug Manufacturing License No. 000619 (Formulation) vide approval letter No. F. 1-4/2002-Lic (Vol-I) dated 22nd December 2020.

S No.	Section
5.	Syrup/Suspension (General) Section (Revised New)
6.	Capsule (Cephalosporin) Section (New)
7.	Dry Powder for Suspension (Cephalosporin) Section (New)
8.	Dry Powder for Injection (Cephalosporin) Section (New)

Following applications have been submitted for registration by the firm.

41.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10844 dated 02-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#769650711)
	The proposed proprietary name / brand name	Combozon 1g Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperazone Sodium……..…...500mg Sulbactam Sodium…….……..…...500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics

	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 1g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sephon for intravenous injection 1g PMDA Japan Approved
	For generic drugs (me-too status)	Sulcef Injection 1gm IV/IM of M/s Lowitt Pharma (Reg#50990)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & 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, 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	Firm has submitted stability study 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; 1706405122, 1706405123, 1706405124)
	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 2Sum Injection 1g by M/s Healthtek (Pvt.) Ltd (Sami Pharma) by performing quality tests (Description, identification, clarity of solution, pH, water content, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including Accuracy, precision (repeatability), linearity, specificity, robustness, LOD and LOQ.
STABILITY STUDY DATA		
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic &	

	Technological Development Zone, Datong, Shanxi, China		
API Lot No.	2104405118		
Description of Pack (Container closure system)	A white to almost white slightly powder, filled in clear glass vial with rubber stopper and aluminium 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 , 9, 12 (Months)		
Batch No.	TR-CEP-57	TR-CEP-58	TR-CEP-59
Batch Size	1027 vials	1027 vials	1027 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	07-09-2021	07-09-2021	07-09-2021
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 Suzhou Dawnrays Pharmaceuticals Co., Ltd., No. 22 Tianling Road, Wuzhong Economic Development District, Suzhou, Jiangsu Province People's Republic of China issued by Jiangsu Drug Administration China valid upto 22-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. DRSZ21054 dated 17-06-2021 for import of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 10kg (Batch#2104405118). *However, the invoice is not attested by AD (I&E) field office*
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 chromatograms, Raw data sheets, COA, 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) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years shall be submitted	•
1.5.2	• Submit your label claim as per reference formulation considering the salt factor along with submission of applicable fee	•
1.5.6	• You have claimed for USP specifications while the applied product monograph is not available in USP, clarify	•
1.6.5	• Name & Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify	•

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for particulate matter by drug product manufacturer as recommended by drug substance manufacturer	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product • Justification shall be submitted for not performing the test for uniformity of dosage units and particulate matter in pharmaceutical equivalence studies as recommended by JP monograph • Compatibility studies of the applied drug product with re constitution diluent shall be submitted.	•
3.2.P.5	• Justification is required since limit of pH (3.5-6.5) mentioned in finished product specifications is different than that recommended by JP monograph (4.5-6.5) • Justification is required since limit of water content (NMT 4%) mentioned in finished product specifications is different than that recommended by JP monograph (1%) • Justification is required since limit of sulbactam (90-110%) in assay test mentioned in finished product specifications is different than that recommended by JP monograph (95-110%) • The chromatographic conditions (Column dimensions; length 15cmx4.6mm, mobile phase ratio tetrabutyl ammonium hydroxide:Acetonitrile 500:180) mentioned in analytical procedure is different than that recommended by JP monograph (Column dimensions; length 30cmx3.9mm, mobile phase ratio tetrabutyl ammonium hydroxide:Acetonitrile 3:1) • JP monograph recommends the use of internal standard in chromatographic method while you have not used internal standard in chromatographic method, clarify	•
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials of cefoperazone and sulbactam was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials was May 22, 2019 and June 3, 2019 while drug product stability testing has been performed subsequent to this date.	•
3.2.P.8	• Documents for procurement of API with approval from DRAP shall be submitted • Justification shall be submitted for the dispensed quantity (1.110kg) of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 against the label claim with reference to the potency (determined 46.235%...batch size 1027vial) of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 determined during drug substance analysis by M/s Curatech Pharma	•

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

42.	Name, address of Applicant / Marketing Authorization Holder	M/s Curatech Pharma (Pvt.) Ltd., 12 Baqir Lane, Canal View Society Canal Road, Lahore
	Name, address of Manufacturing site.	M/s Curatech Pharma (Pvt.) Ltd., 35-Km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 08-04-2020 based on inspection conducted on 19-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 22-12-2020 specifying dry powder for injection (Cephalosporin) New section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10845 dated 02-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023 (Deposit slip#4590288265)
	The proposed proprietary name / brand name	Combozon 2g Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperazone Sodium……..…...1000mg Sulbactam Sodium…….……..…...1000mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin-Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's vial of 2g
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by 3 European countries: Czech republic, Slovakia, Poland
	For generic drugs (me-too status)	Sulcef Injection 2gm IV/IM of M/s Lowitt Pharma (Reg#50996)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & 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, 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	Firm has submitted stability study 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; 1706405122, 1706405123, 1706405124)
	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 2Sum Injection 2g by M/s Healthtek (Pvt.) Ltd (Sami Pharma) by performing quality tests (Description, identification, clarity of solution, pH, water content, B.E.T., Sterility, assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including Accuracy, precision (repeatability), linearity, specificity, robustness, LOD and LOQ.

STABILITY STUDY DATA			
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & Technological Development Zone, Datong, Shanxi, China		
API Lot No.	2104405118		
Description of Pack (Container closure system)	A white to almost white slightly powder, filled in clear glass vial with rubber stopper and aluminium 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: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 , 9, 12 (Months)		
Batch No.	TR-CEP-60	TR-CEP-61	TR-CEP-62
Batch Size	1027 vials	1027 vials	1027 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	07-09-2021	07-09-2021	07-09-2021
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 Suzhou Dawnrays Pharmaceuticals Co., Ltd., No. 22 Tianling Road, Wuzhong Economic Development District, Suzhou, Jiangsu Province People's Republic of China issued by Jiangsu Drug Administration China valid upto 22-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. DRSZ21054 dated 17-06-2021 for import of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 10kg (Batch#2104405118). *However, the invoice is not attested by AD (I&E) field office*
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 chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

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

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years shall be submitted	•
1.5.2	• Submit your label claim as per reference formulation considering the salt factor along with submission of applicable fee	•
1.5.6	• You have claimed for USP specifications while the applied product monograph is not available in USP, clarify	•
1.6.5	• Name & Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify	•
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for particulate matter by drug product manufacturer as recommended by drug substance manufacturer	•
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product • Justification shall be submitted for not performing the test for uniformity of dosage units and particulate matter in pharmaceutical equivalence studies as recommended by JP monograph • Compatibility studies of the applied drug product with re constitution diluent shall be submitted.	•
3.2.P.5	• Justification is required since limit of pH (3.5-6.5) mentioned in finished product specifications is different than that recommended by JP monograph (4.5-6.5) • Justification is required since limit of water content (NMT 4%) mentioned in finished product specifications is different than that recommended by JP monograph (1%) • Justification is required since limit of sulbactam (90-110%) in assay test mentioned in finished product specifications is different than that recommended by JP monograph (95-110%) • The chromatographic conditions (Column dimensions; length 15cmx4.6mm, mobile phase ratio tetrabutyl ammonium hydroxide:Acetonitrile 500:180) mentioned in analytical procedure is different than that recommended by JP monograph (Column dimensions; length 30cmx3.9mm, mobile phase ratio tetrabutyl ammonium hydroxide:Acetonitrile 3:1) • JP monograph recommends the use of internal standard in chromatographic method while you have not used internal standard in chromatographic method, clarify	•
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials of cefoperazone and sulbactam was used for test and analysis of drug product as the expiry date mentioned on the COA of Reference Standards or Materials was May 22, 2019 and June 3, 2019 while drug product stability testing has been performed subsequent to this date.	•
3.2.P.8	• Documents for procurement of API with approval from DRAP shall be submitted • Justification shall be submitted for the dispensed quantity (2.220kg) of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 against the label claim with reference to the potency (determined 46.235%...batch size 1027vial) of Cefoperazone Sodium and Sulbactam Sodium Sterile 1:1 determined during drug substance analysis by M/s Curatech Pharma	•

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

Evaluator PEC XXI

Case No. 01: M/s Biogen Life Sciences, Rawalpindi was granted New DML w.e.f. 13-02-2020 for the following Sections: -

i. Dry Suspension (Cephalosporin) Dedicated Facility
ii. Capsule Section (Cephalosporin) Dedicated Facility
iii. Dry Vial Section (Cephalosporin) Dedicated Facility
iv. Penem Injection Section (Cephalosporin) Dedicated Facility
v. Tablet Section (General)
vi. Capsule Section (General)
vii. Sachet Section (General)
viii. Cream Section (General)
ix. Ointment Section (General)
x. Lotion Section (General)
xi. Dry Vial Section (General)
xii. Ampule Section SVP (General)
xiii. Infusion Section (General)
xiv. Hydrocortisone Injection (Steroid)
xv. Soft Gel Capsule General

43.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences.** 8-KM Chakbeli Road ,Rawat, Rawalpindi
	Name, address of Manufacturing site.	**M/s Biogen Life Sciences.** 8-KM Chakbeli Road ,Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000911) granted w.e.f. 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14th February 2020 specifying Ampoule Section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13634 dated 01 JUN 2023
	Details of fee submitted	PKR 30,000/- dated 16-02-2023 (Fee Challan / Receipt # 15380526027).
	The proposed proprietary name / brand name	**Tygagen 50mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Tigecycline … 50mg (JP Specifications)
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Tetracycline.
	Pharmaceutical form of applied drug	Powder for Infusion
	Reference to Finished product specifications	USP specs
	Proposed Pack size	5ml x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil 50mg powder for solution for infusion of M/s Pfizer Limited, UK (MHRA Approved).

	For generic drugs (me-too status)	Tygacil 50mg Injection (Reg. No. 045642) by M/s Pfizer Pharma.
	Name and address of API manufacturer.	Fuan pharmaceutical group chomming Bosen Pharmaceuticals Co. Ltd. No. 01 Huanan Road, changshou distric Chongqing, 401254 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 12 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 Tygacil 50mg Injection manufactured by Pfizer Pakistan.
	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	Fuan pharmaceutical group chomming Bosen Pharmaceuticals Co. Ltd. No. 01 Huanan Road, changshou distric Chongqing, 401254 China.		
API Lot No.	TI210402		
Description of Pack (Container closure system)	USP 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	500 vial	500 vial	500 vial
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	10-04-2022	10-04-2022	10-04-2022
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)	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. CQ20180031 issued by CFDA, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Firm has not provided documents for the procurement of API having approval from 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	**Not Submitted. The Firm have mentioned 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: -

i. Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as "M/s Biogen Life Sciences" whereas the name mentioned on submitted copy of DML is "M/s Biogen Pharmaceuticals".

ii. Please provide label claim as per the innovator's product. The mentioned label claim is not as per innovator's product.

iii. Please provide details of Column used for Analysis of Finished Pharmaceutical Product. Furthermore, the chromatographic conditions (specifically Injection volume and System Suitability) are not as per USP. Please justify.

iv. In Section 2.3.S.7.1, Please justify the stability studies of the drug substance conducted as per zone IV-A conditions, since as per API manufacturer as well as USP the storage conditions is to store the drug substance from 2℃ to 8℃.

v. In Section 2.3.S.7.1 (b), the proposed storage condition of API is mentioned as *"Store below 30℃"* and Expiry period as *"3 years"*, however the same has been mentioned as *"Store between 2℃ to 8℃"*and *"02 years"* by API Manufacturer in Section 3.2.S.7.1. Please justify.

vi. In Section 3.2.P.1, composition has been mentioned as Tigecycline only whereas list of excipients as per innovator include Lactose monohydrate, Hydrochloric acid and Sodium hydroxide (for pH adjustment) as well. Please justify the reason for not using the same in your formulation.

vii. Please provide details (along with supporting evidence) of Reference / Innovator's pack used for Pharmaceutical Equivalence.

viii. Section 3.2.P.8, please justify, with supporting evidence, the reason for not conducting Bacterial Endotoxin Test and Sterility Test at the end of 6th Month Accelerated & Real Time Stability Study Testing.

ix. Please provide documents for the procurement of API having approval from DRAP (for submitted copy of Invoice KSDS20210411 dated 10th September 2021).

x. Section 2.3.R.1.1 Please 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.

xi. Please provide details of the lyophilizer installed in your premises including details of the minimum and maximum capacity of the equipment.

xii. Please provide evidence of availability of Auto sampler in HPLC, wherein 10℃ temperature conditions could be maintained.

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

Evaluator PEC-XX

A) Priority consideration on account of Export Facilitation:

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements

Following registration application of firm may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 20.07.2023:

44.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Abbott Laboratories Pakistan Ltd, opposite Radio Pakistan Transmission centre Hyderabad Road Karachi**
	Name, address of Manufacturing site.	**M/s Abbott Laboratories Pakistan Ltd, opposite Radio Pakistan Transmission centre Hyderabad Road Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate based on Inspection dated 09.03.2023 valid till two years.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 15-06-2021 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 13177 dated 29-05-2023
	Details of fee submitted	PKR 30,000/- Dated 31/01/2023
	The proposed proprietary name / brand name	**Equasis Tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Vildagliptin……..50mg
	Pharmacotherapeutic Group of (API)	Anti hyperglycemic agent
	Pharmaceutical form of applied drug	Oral tablet
	Reference to Finished product specifications	Not provided
	Proposed Pack size	10’s , 28’s
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Galvus 50mg tablet by M/s Novartis Pharmaceutical UK Ltd MHRA Approved
	For generic drugs (me-too status)	Galvus 50mg tablet by M/s Novartis, Reg No 059038
	Name and address of API manufacturer.	M/s Lee Pharma Limited Survey No 30P, 31P,32P, 34P & 35P, Plot No 22A and 22B Denotified area-APSEZ, Lalam Koduru Village, Rambilli Mandal, Visakhapatnam District, Andhra Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (VNFP17001, VNFP17002 and VNFP17003) 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 / 75% ± 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 was determined against Galvus 50mg tablet by M/s Novartis Farmaceutica S.A Spain M.A Holder in Pakistan: Novartis Pharma Pakistan Limited Batch No BWY 84 Quality parameters such as Appearance, uniformity of dosage, water by KF, identification, disintegration time, dissolution assay, and related substances against Test product (Batch No 422004XZ) Firm has submitted CDP results of their product against the same innovator product Galvus 50mg tablet by M/s Novartis Farmaceutica S.A Spain in Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 value was not required since more than 85% drug release within 15 min.
	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 Lee Pharma Limited Survey No 30P, 31P,32P, 34P & 35P, Plot No 22A and 22B Denotified area-APSEZ, Lalam Koduru Village, Rambilli Mandal, Visakhapatnam District, Andhra Pradesh, India		
API Lot No..Batch number	VNFP22013U4		
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: 3months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	422004XV	422005XV	422006XV
Batch Size	---	---	----
Manufacturing Date	06/22	06/22	06/22
Date of Initiation	18.07.2022	18.07.2022	18.07.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	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
1.	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.	**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. Moreover, clarify stability batch size.
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.P.4** Finished product specification to be mentioned on Form5F along with prescribed fee.
5.	**3.2.P.4** Analytical Method Validation studies was performed by Abbott HealthCare Pvt Ltd, Mumbai, although method has been test method has been transferred from Abbott HealthCare Pvt Ltd, Mumbai to Abbott Karachi Pakistan yet validation studies to be performed at manufacturing site.
6.	**3.2.P.8** Provide document for procurement of API with Clearance from DRAP.

7.	**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.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		

Evaluator PEC-III

M/s Pearl Pharmaceuticals, Islamabad.

M/s Pearl Pharmaceuticals Islamabad has informed that their following case was approved by the Board in its 324th meeting.

45.	**Name and address of manufacturer / Applicant**	**M/s Pearl Pharmaceuticals Plot No. 204, Street No.1, I-10/3, Islamabad**
	Brand Name +Dosage Form + Strength	Vildomin 50/500mg Tablets
	Composition	Each Tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…500mg
	Diary No. Date of R& I & fee	Dy No. 16178: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	The last inspection conducted on 03-11-2022, the panel recommended renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision of 324th meeting: Approved with Innovator's specifcations. 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.	

However, the firm informed that they have applied for 50/850mg strength while in agenda 50/500mg was mentioned. Upon verification from original dossier it is verified that the firm has applied for following brand name and label claim:

Brand Name +Dosage Form + Strength	Vildomin 50/800mg Tablets
Composition	Each Tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…500mg
Diary No. Date of R& I & fee	Dy No. 16178: 07-03-2019 PKR 20,000/-: 06-03-2019

It is evident that 50/850mg strength was mentioned on fee challan as well as brand name, while the label claim is submitted for 50/500mg.

Submitted for consideration by the Board.

Decision of 330th meeting: Registration Board approved the application with following composition:
Vildomin 50/850mg Tablets
Each Tablet Contains:
Vildagliptin…50mg
Metformin Hydrochloride…850mg

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.

Evaluator PEC-XV

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD) "M/s.Global Pharmaceuticals (Pvt.) Ltd Islamabad have achieved benchmark of USD 221638.39 as defined in the Board's decision during fiscal year 2022-2023. In this regard, please find the (1 molecule) 02 products applications submitted by the firm."		
46.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 15015 dated 14-06-2023
	Details of fee submitted	PKR 30,000/-: dated 07-06-2023(**4465869119**)
	The proposed proprietary name / brand name	**Vonoglob 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Vonoprazan Fumarate 13.36mg eq to 10mg Vonoprazan
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	potassium-competitive acid blocker
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack Size: 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab tablet 10mg Takeda Pharmaceutical Company Limited Approved by PMDA
	For generic drugs (me-too status)	Vonov 10mg Tablets Pharmedic Laboratories Pvt. Ltd Lahore Reg No: 115291
	GMP status of the Finished product manufacturer	New license granted on 04/01/2022 Tablet Section Approved.
	Name and address of API manufacturer.	**Manufacturer:** AMI LIFESCIENCES PRIVATE LIMITED **Manufacturing Site:** Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara 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, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months, while the claimed re-test period is till 60month Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (VPF/30021020**,** VPF/30031020 **,** VPF/30041020)
	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 Vonozan 10mg Tablet by Getz Pharma Pvt. Limited, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP was performed against same brand 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Manufacturer:** AMI LIFESCIENCES PRIVATE LIMITED **Manufacturing Site:** Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara Gujrat, INDIA		
API Lot No.	30040821		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 36 months (submitted only 3-month data) Accelerated: 6 months(submitted only 3 month data)		
Frequency	Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	ST23A003	ST23A004	ST23A005
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	23-01-2023	23-01-2023	23-01-2023

No. of Batches		03
Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289 meeting of Registration Board decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: • The HPLC software is 21 CFR compliant. • The firm has provided data loggers with stability chambers.
8.	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 FOOD AND DRUGS CONTROL ADMINISTRATION GANDHINAGAR, GUJRAT STATE INDIA. The certificate is valid till 17-04-2025 & License No: 22043267
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by DRAP for Vonoprazan Fumarate dated on 30-09-2021 with Invoice No: EXP/1/21-22/0366
10.	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.
11.	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.
12.	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.
47.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.15016 dated 14-06-2023
	Details of fee submitted	PKR 30,000/-: dated 07-06-2023(**4465869119**)
	The proposed proprietary name / brand name	**Vonoglob 20mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Vonoprazan Fumarate 26.72mg eq to 20mg Vonoprazan.
	Pharmaceutical form of applied drug	Film coated Tablet

	Pharmacotherapeutic Group of (API)	potassium-competitive acid blocker
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	Pack Size: 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab tablet 20mg Takeda Pharmaceutical Company Limited Approved by PMDA
	For generic drugs (me-too status)	Vonov 20mg Tablets Pharmedic Laboratories Pvt. Ltd Lahore Reg No: 115292
	GMP status of the Finished product manufacturer	New license granted on 04/01/2022 Tablet Section Approved.
	Name and address of API manufacturer.	**Manufacturer:** AMI LIFESCIENCES PRIVATE LIMITED **Manufacturing Site:** Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara 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, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months (Claimed re-test period is 60month) Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (VPF/30021020**,** VPF/30031020 **,** VPF/30041020)
	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 Vonozan 20mg Tablet by Getz Pharma Pvt. Limited, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP was performed against same brand 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 linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		**Manufacturer:** AMI LIFESCIENCES PRIVATE LIMITED **Manufacturing Site:** Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara Gujrat, INDIA		
API Lot No.		30040821		
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: 36 months (Data of only 3 month has submitted) Accelerated: 6 months (Data of only 3 month has submitted)		
Frequency		Accelerated: 0, 1, 2, 3, 4, 5, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.		ST23A006	ST23A007	ST23A008
Batch Size		2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date		01-2023	01-2023	01-2023
Date of Initiation		01-2023	01-2023	01-2023
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 referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289 meeting of Registration Board decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: • The HPLC software is 21 CFR compliant. • The firm has provided data loggers with stability chambers.		
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 FOOD AND DRUGS CONTROL ADMINISTRATION GANDHINAGAR, GUJRAT INDIA. The certificate is valid till 17-04-2025 & License No: 22043267		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by DRAP for Vonoprazan Fumarate dated on 30-09-2021 with Invoice No: EXP/1/21-22/0366		
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	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability		

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

Remarks OF Evaluator:

Sections	Observations/Deficiencies/ Short-comings	Response
3.2.S.4.3	Justify for performing the validation studies of drug substance on assay method different from that given in section 3.2.S.4.2.	Firm has submitted revised analytical method verification studies.
3.2.S.7	Provide the stability data of long term till the claimed re-test date i.e. 60 month as per the submitted stability data sheet.	Submitted
3.2.P.5.3	Justify for submitting the same validation report for drug substance and drug product as well as the same report has been in the dossier of both strength.	Firm submitted analytical method validation report for drug product.
3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm has submitted stability data of 6thmonth time point

Decision: Registration Board approved the applications of "Vonoglob 10mg tablet" & "Vonoglob 20mg 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.**

Mr. Salateen Waseem Philip

Case No. 01: <u>Export facilitation cases:</u>

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 20th July 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s wnsfield Pharmaceuticals Plot # 122, Block –A, Phase V, Industrial Estate, Hattar. (DML # 000610)** has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2020-2021** and requested for priority consideration of following molecule.

48.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfield Pharmaceuticals Plot # 122, Block –A, Phase V, Industrial Estate, Hattar. **(DML # 000610)**
	Name, address of Manufacturing site.	M/s wnsfield Pharmaceuticals Plot # 122, Block –A, Phase V, Industrial Estate, Hattar. **(DML # 000610)**
	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. 34956 (dated: 02-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 10-11-2022 (Invoice # 953987044)
	The proposed proprietary name / brand name	**Tablet Pruco 1 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride (as Succinate)……. 1 mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Selective, high affinity serotonin (5-HT4) receptor agonist. (for constipation)
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*EMAE* approved **Resolor®** by Takeda
	For generic drugs (me-too status)	**Not applicable**
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 02-04-2025
	Name and address of API manufacturer.	**Prucalopride Succinate** M/s Kimia Biosciences Limited. *Formerly (M/s Laurel Organics Limited)* Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India. **GMP Certificate valid till 06/04/2027**
	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	**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 Resolor Tablet by M/s**

		Fabricado Pharmaceuticals Italy performing quality tests (appearance, identification, average weight, Assay, Dissolution).
	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	**Prucalopride Succinate** M/s Kimia Biosciences Limited. *Formerly (M/s Laurel Organics Limited)* Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India.		
API Lot No.	WS-PPD002/21		
Description of Pack (Container closure system)	Strips of ALU-ALU blister further packed in a 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**PR-01**	**PR-02**	**PR-03**
Batch Size	1200 Tablets	1200 tablets	1200 tablets
Manufacturing Date	07/2021	07/2021	07/2021
Date of Initiation	03/08/2021	03/08/2021	03/08/2021
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:** 0.020 kg Form 6 – 00697/2021-DRA dated 05-07-2021
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.
49.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s wnsfield Pharmaceuticals** **Plot # 122, Block –A, Phase V, Industrial Estate, Hattar.** **(DML # 000610)**

	Name, address of Manufacturing site.	M/s wnsfield Pharmaceuticals Plot # 122, Block –A, Phase V, Industrial Estate, Hattar. **(DML # 000610)**
	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. 34957 (dated: 02-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 10-11-2022 (Invoice # 3626275852)
	The proposed proprietary name / brand name	**Tablet Pruco 2 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride (as Succinate)……. 2 mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	selective, high affinity serotonin (5-HT4) receptor agonist. (for constipation)
	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	*EMAE* approved **Resolor®** by Takeda
	For generic drugs (me-too status)	**Not applicable**
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 02-04-2025
	Name and address of API manufacturer.	**Prucalopride Succinate** M/s Kimia Biosciences Limited. *Formerly (M/s Laurel Organics Limited)* Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India. **GMP Certificate valid till 06/04/2027**
	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	**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 Resolor Tablet by M/s Fabricado Pharmaceuticals Italy** performing quality tests (appearance, identification, average weight, Assay, Dissolution).
	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	**Prucalopride Succinate** M/s Kimia Biosciences Limited. *Formerly (M/s Laurel Organics Limited)* Village Bhondsi, Tehsil Sohna, District-Gurgaon 122102 Haryana, India.		
API Lot No.	WS-PPD002/21		
Description of Pack (Container closure system)	Strips of ALU-ALU blister further packed in a 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**PR-04**	**PR-05**	**PR-06**
Batch Size	1200 Tablets	1200 tablets	1200 tablets
Manufacturing Date	07/2021	07/2021	07/2021
Date of Initiation	07/08/2021	07/08/2021	07/08/2021
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:** 0.020 kg Form 6 – 00697/2021-DRA dated 05-07-2021

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 the Evaluator:

Observations	Reply of the firm
3.2.S.4 Please submit validation report of analytical method on HPLC, for **chemical assay of drug Substance /API**. Please submit complete analytical method for chemical assay with details of *Composition of mobile phase, standard / sample preparation, details of column used, wavelength of UV/PDA detector, flow rate, system suitability parameters,* ***complete calculation formula*** etc.	Validation report at **Annex – I** Complete analytical method submitted.
3.2.P.1 In the composition of film coating of tablets, applicant has used **isopropyl alcohol (solvent) with Colorcoat FC4S** *(Hydroxypropyl Methylcellulose, Polydextrose Sugar, Polyvinyl Alcohol)***.** While innovator product **(Resolor)** used **Water** as a solvent for film coating of the tablets including Hypromellose Lactose monohydrate Triacetin Titanium dioxide (E171) Macrogol. Please justify the difference in coating materials and use of IPA instead of water as solvent for coating?	Immediate release core tablet of Prucalopride is sensitive to moisture. Due to sensitivity of moisture, we have selected IPA as a solvent for coating instead of water. The relative humidity in Zone IV-A is much greater than the Relative humidity at Zone II where this innovator brand got approval. For the environmental condition of Zone IV – A, IPA is much better solvent for moisture sensitive formulation as compared to water. Furthermore, the coating compound **Colorcoat FC4S** has same physiochemical properties as the coating ingredients selected by innovator brand. The taste masking of tablet with **polydextrose** give it a pleasant smell and taste which is good for patient compliance. It is to also bring in knowledge that Innovator also allowed different coating powders commercially available mixtures mentioned in assessment report of European medicine agency.
3.2.P.2.3 In the assessment report of Committee for Medicinal product for human use **(CHMP)** of European Medicine Agency **(EMA)** for **Resolor Tablets**, during pharmaceutical development, it was observed that **wet granulation process** was replaced by **direct compression** due to the **formation of a lactose adduct induced by exposure to moisture**. Moisture was shown to induce the formation of a lactose adduct in the finished	We have also adopted the direct compression method for manufacturing of core tablet. It was by mistake that we have submitted manufacturing protocol with wet granulation method. We apologize for submission of protocol of manufacturing by wet granulation. Moreover, the tablet manufacturing by direct compression is more economical & time saving

product, which was confirmed in the stability studies. Please justify that i. why applicant is still following process of **wet granulation** process for manufacturing of core tablets instead of **Direct Compression** method? ii. Why are you declaring in **Section 3.2.P.2.2.1 (b)** that qualitative composition of your applied formulation is same as innovator product when both are using different method for manufacturing of core tablet? iii. Please submit report of Pharmaceutical equivalence in tabulated form, mentioning results of all the tests performed *(Identification, Description, Dissolution in 10 minutes, Assay, Content uniformity, microbial purity)* of your applied formulation vs **Resolor Tablet by M/s Fabricado Pharmaceuticals Italy**. iv. Submit Batch #, date of purchase for **Resolor Tablet by M/s Fabricado Pharmaceuticals Italy**.	than wet granulation. We hereby declare that we are using direct compression method for tablet manufacturing as per active and inactive ingredient mentioned in composition of our formulation. **It is also obvious from inactive ingredient of our formulation that we are not using wet granulation process but Direct compression method.** We are submitting our batch manufacturing record **(Annex-VIII)**, as an evidence for use of direct compression method for manufacturing of core tablet. **Reply for point (i),** We are also using Direct compression method for manufacturing of core tablet as per innovator brand. It was by mistake that we have submitted wrong manufacturing protocol. Now we have submitted manufacturing protocol of direct compression method along with BMR as an evidence of direct compression. **Reply for point (ii) & (iii),** We are submitting complete pharmaceutical equivalence report as **Annex – II** **Reply for point (iv) Annex-III**
3.2.P.5.3 Please submit validation report of analytical method on HPLC, for **chemical assay of drug product** containing Prucalopride. Please submit complete analytical method for chemical assay with details of *Composition of mobile phase, standard / sample preparation, details of column used, wavelength, flow rate, system suitability parameters, **complete calculation formula*** etc. The analytical method for testing dissolution samples of Innovator product is on **HPLC.** Submit complete testing method on HPLC with details of *Composition of mobile phase, standard / sample preparation, details of column used, wavelength of UV detector / PDA, flow rate, system suitability parameters **complete calculation formula for dissolution samples*** etc.	**Annex – IV** **Annex-V** **Annex-VI**
3.2.P.8 In the calculation sheets of dissolution test in the stability data (**R.T 06 month, B # PR-02**) The area of the peaks in calculation sheet are not matching with the areas mentioned on chromatograms.	All stability data sheets have been again submitted for accelerated and real time stability.

Please re-check your stability data for the three batches and submit calculation sheets for all three stability batches for both chemical assay and dissolution, mentioning the **Calculation formulas on the calculation sheets, potency of ref. std., weight of std / spl taken in mg or grams and its dilution in ml.** Make sure that data entered in the calculation sheet should match with the chromatograms.	
Please submit the COA for the API Lot # used in Pharmaceutical development and manufacturing of Stability batches. Also submit the approval documents from DRAP for procurement of API.	COA submitted **Annex-VII**
Submit BMR of stability batches.	BMR – **Annex-VIII**

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

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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: <u>Export facilitation cases:</u>

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 20th July 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. (DML # 000019)Kalawala Stop, 20km Lahore – Jaranwala Road, District Sheikhupura, Pakistan** has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2022-2023** and requested for priority consideration of following molecule.

50.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. (DML # 000019)** **Kalawala Stop, 20km Lahore – Jaranwala Road, District Sheikhupura, Pakistan.**
	Name, address of Manufacturing site.	M/s Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. (DML # 000019) Kalawala Stop, 20km Lahore – Jaranwala Road, District Sheikhupura, 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. 30337 (dated: 26-10-2022)

	Details of fee submitted	PKR 75,000/-: dated: 13-09-2022 (Invoice # 79446820)
	The proposed proprietary name / brand name	**Optine Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Olopatadine (as HCl) USP……. 7 mg
	Pharmaceutical form of applied drug	Sterile Eye Drops (Ophthalmic)
	Pharmacotherapeutic Group of (API)	Selective Histamine H1-Receptor Antagonist
	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 **Pazeo®** by Alcon
	For generic drugs (me-too status)	**Not applicable**
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 29-05-2022
	Name and address of API manufacturer.	**Olopatadine HCl** M/s Medigraph Pharmaceuticals Pvt. Ltd. Plot # J-46/57, M.I.D.C. Taloja, Dist. Raigad, Maharashtra, India. **GMP Certificate valid till 03-11-2023**
	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	**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 Pazeo Eye Drops by M/s Alcon** performing quality tests (appearance,

		identification, sealing of caps, Deliverable volume, pH, Clarity test, Osmolality & Osmolarity, Specific gravity, Assay, Sterility test, impurity testing).
	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	**Olopatadine HCl** M/s Medigraph Pharmaceuticals Pvt. Ltd. Plot # J-46/57, M.I.D.C. Taloja, Dist. Raigad, Maharashtra, India.		
API Lot No.	FP/OLOH/002/07/21		
Description of Pack (Container closure system)	White opaque plastic bottles with yellowish green color plastic caps, and finally packed in bleach board carton along with 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**OPD/T1/22**	**OPD/T2/22**	**OPD/T3/22**
Batch Size	3.0 Litre	3.0 Litre	3.0 Litre
Manufacturing Date	04/2022	04/2022	04/2022
Date of Initiation	30/04/2022	30/04/2022	30/04/2022
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).	**Quantity:** 0.130 kg Form 6 – 1314/2022-DRAP dated 25-01-2022 Invoice # MPPL/072/21-22 dated 13-01-2022
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:

Observations	Reply o the firm
1.3.5 Please submit fresh / valid GMP certificate of Drug Product Manufacturer **(Schazoo) OR** inspection report conducted within last three years.	Firm again submitted **GMP Certificate:** valid till 29-05-2022. **Last inspection report:** conducted on 13-05-2019 **Remarks of Evaluator:** Firm also submitted unclear and zoomed photocopy of request for inspection for renewal cGMP certificate however, dates are not visible.
1.6.5 Please submit fresh / valid GMP certificate of API supplier which should be in force till date.	Firm has submitted GMP certificate valid till 03-11-2023.
3.2.2.7. Please submit the details about the site where sterilization of the empty primary container of drug product takes place and also provide information if the facility of sterilization got certificate of compliance with **ISO 11137-1:2006/Amd 1:2013.**	Firm has submitted source of sterilization of primary container as under: - **Name of source:** PARAS FOODS PVT. LTD 18-km Multan Road LAHORE. **Radiation by:** M/s Pakistan Radiation Services **Certification: ISO9001:2008**
3.2.P.8 In the calculation sheet for the long term stability Raw data sheet at zero month for **Batch # OPD-T1-22**, The Q.C Laboratory of your firm submitted result for the assay of olopatadine, calculated as **100.84%** but as per the calculation formula and values mentioned on the calculation sheet, the result of assay is app. **104.41%.** please re-check the calculation sheet of **B# OPD-T2-22 (Accelerated – 03 month)** and for all three stability batches and clarify the difference in assay value mentioned by Q.C Laboratory vs actual assay values as per formula mentioned and values given in calculation sheet?	Raw data sheets and calculation sheets are thoroughly re-checked. Some errors in assay values in raw data sheets ***(transferred from excel calculation sheet)*** were observed due to typo mistakes. These mistakes have been removed now. Revised raw data sheets are attached for kind reference.
Please submit stability data along with raw data sheet and chromatograms for the **06th month accelerated and long term conditions.**	**Remarks:** Submitted, however stability conditions followed are not matching with the conditions mentioned for stability conditions of semi permeable containers as under: - **Long-term:** 25 °C ± 2 °C/40% RH ± 5% RH **OR** 30 °C ± 2 °C/35% RH ± 5% RH **Accelerated:** 25 °C ± 2 °C/40% RH ± 5% RH **OR** 30 °C ± 2 °C/35% RH ± 5% RH
Please also submit Stability studies conducted for potential water loss of your primary container **(semipermeable container)** as per ICH guidelines (ICH Q1A(R2).	**Remarks:** Submitted **on a single sheet without raw data and calculation sheets**, however stability conditions followed are not matching with the conditions mentioned for stability conditions of semi permeable containers as under: - **Long-term:** 25 °C ± 2 °C/40% RH ± 5% RH **OR**

	30 °C ± 2 °C/35% RH ± 5% RH **Accelerated:** 40 °C ± 2 °C/25 RH ± 25% RH

Decision: Deferred for following:

- **Justification of applying temperature and humidity conditions of accelerated and long term stability studies, other than those recommended by ICH guidelines, for semi permeable containers.**
- **Justification for not performing water loss studies during stability studies.**
- **Submission of raw data sheets aligned with the submitted analytical record for stability studies.**

Case No. 03: <u>Export facilitation cases:</u>

Deputy Director (PRV/EFD) vide letter No. F.1-6/2019-PR-I (EFD) dated 26th May 2023 informed that, in compliance to the decision of 133rd meeting of the authority held on 13th April 2022, **M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837) Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.** has achieved the benchmark of more than **100,000 USD** worth of export of medicines during the **fiscal year 2020-2021** and requested for priority consideration of following molecule.

51.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837) Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd. **(DML # 000837)** Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP), 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. 33022 (dated: 17-11-2022)
	Details of fee submitted	PKR 30,000/-: dated: 02-11-2022 (Invoice # 251431133725)
	The proposed proprietary name / brand name	**Tablet Pranz 10 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan fumarate eq. to Vonoprazan ……...…….…….…. 10 mg

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	**Potassium competitive acid blocker (P-CAB)**
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 14's, 28's & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*PMDA* Japan approved **Takecab®** by Takeda
	For generic drugs (me-too status)	Vonozan by M/s Getz
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 01-03-2023
	Name and address of API manufacturer.	**Vonoprazan Fumarate** M/s AMI Lifesciences (Pvt.) Ltd. Block # 82/B, ECP Road, AT & Post, Karakhad, TAL-PADRA, Karakhadi, Dist. Vadodara, India. **GMP Certificate valid till 04/03/2023**
	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	**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. Tablet Voniza 10 mg by M/s Alcon** performing quality tests (appearance, identification, purity, Uniformity of dosage form, Assay, dissolution 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		**Vonoprazan Fumarate** M/s AMI Lifesciences (Pvt.) Ltd. Block # 82/B, ECP Road, AT & Post, Karakhad, TAL-PADRA, Karakhadi, Dist. Vadodara, India.	
API Lot No.		VPF/30100921	
Description of Pack (Container closure system)		White opaque plastic bottles with yellowish green color plastic caps, and finally packed in bleach board carton along with 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: 24 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)	
Batch No.		**015B22**	**016B22**	**017B22**
Batch Size		5000 tablets	5000 tablets	5000 tablets
Manufacturing Date		01/2022	01/2022	01/2022
Date of Initiation		16/03/2022	16/03/2022	16/03/2022
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).	**Quantity:** 0.6 kg Form 6 – 3835/2022-DRAP dated 02-12-2021	
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:			
52.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. (DML # 000837) Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**	

	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd. **(DML # 000837)** Plot # FD-57/58-A2, Korangi Creek Industrial Park (KCIP), 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. 33023 (dated: 17-11-2022)
	Details of fee submitted	PKR 30,000/-: dated: 02-11-2022 (Invoice # 190665994)
	The proposed proprietary name / brand name	**Tablet Pranz 20 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan fumarate eq. to Vonoprazan ……...…….…….…. 20 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker (P-CAB)
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 14's, 28's & 30s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*PMDA* Japan approved **Takecab®** by Takeda
	For generic drugs (me-too status)	Vonozan by M/s Getz
	GMP status of the Finished product manufacturer	GMP Certificate valid up to 01-03-2023
	Name and address of API manufacturer.	**Vonoprazan Fumarate** M/s AMI Lifesciences (Pvt.) Ltd. Block # 82/B, ECP Road, AT & Post, Karakhad, TAL-PADRA, Karakhadi, Dist. Vadodara, India. **GMP Certificate valid till 04/03/2023**
	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	**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. Tablet Voniza 20 mg by M/s Alcon** performing quality tests (appearance, identification, purity, Uniformity of dosage form, Assay, dissolution 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	**Vonoprazan Fumarate** M/s AMI Lifesciences (Pvt.) Ltd. Block # 82/B, ECP Road, AT & Post, Karakhad, TAL-PADRA, Karakhadi, Dist. Vadodara, India.		
API Lot No.	VPF/30100921		
Description of Pack (Container closure system)	White opaque plastic bottles with yellowish green color plastic caps, and finally packed in bleach board carton along with 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**018B22**	**019B22**	**020B22**
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	01/2022	01/2022	01/2022
Date of Initiation	16/03/2022	16/03/2022	16/03/2022
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).	**Quantity:** 0.6 kg Form 6 – 3835/2022-DRAP dated 02-12-2021
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:

Decision: Registration Board approved the applications of Tablet Pranz 10 mg & Tablet Pranz 20 mg.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the 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. V Miscellaneous Cases

Case No. 1:- Sub-committee on Veterinary Drugs

Registration Board in its 281st meeting held on 11-13th April, 2018 has constituted expert working group on veterinary drugs regarding matters related to veterinary drugs.

Decision of 281st meeting of RB: -

The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised for inclusion of relevant expert(s) member(s) of the Board etc. However, since process of revision of constitution may take some time as the approval of Federal Government and other relevant organizations are required before revised Gazette notification, so, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -

1.	*Dr. Qurban Ali, Ex-Director General* *National Veterinary Laboratory, Islamabad.* *Expert Member Veterinary Drugs*	*Chairman*
2.	*Animal Husbandry Commissioner or his representative,* *M/o National Food Security & Research, Islamabad.*	*Member*
3.	*Dr.Mazhar-ul-Haq* *Veterinary Pharmacologist* *Arid Agriculture University, Rawalpindi.*	*Member*
4.	*Any other relevant expert(s)*	*As Co-opted member(s)*
5.	*Deputy Director (Reg-I), DRAP*	*Member, Secretary*

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).

The Board further advised that in order to avoid any pendency, the "expert working

group" needs be notified immediately without waiting till formal approval of the minutes of 281st meeting so that the meeting of the expert working group may be called earlier.

Accordingly, notification of expert working group was issued on 08th May 2018. Chairman of Expert working Group co-opted Dr. Shabnum Firdous, Secretary PVMC as a co-opted member, and letter for in this regard was issued on 16th June 2022.

After completion of 2nd term Dr. Qurban Ali, (Chairman EWG) was retired as member registration board [under Rule 24 (f) of Drugs (LR&A) Rules, 1976 (Expert Member for Veterinary Drugs)]. Accordingly, de-notification letter of EWG, after approval from Chairman, Registration Board, was issued on 24th February, 2023 vide letter No. 7-4/2018 (M-281) and endorsed in 325th meeting of Registration Board.

Decision of M-326: - *The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised in order to avoid pendency/delay in processing of issues relating to veterinary drugs which require input/recommendation of pertinent veterinary expert, hence Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -*

1.	*Dr. Qurban Ali,* *Ex-Director General,* *National Veterinary Laboratory, Islamabad.*	*Chairman*
2.	*Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.*	*Member*
3.	*Mst. Najia Saleem, Deputy Director (PE&R), DRAP*	*Member*
4.	*Any other relevant expert(s)*	*As Co-opted member(s)*
5.	*Assistant Director (I&V-I), DRAP*	*Member, Secretary*

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).
The Board further advised that in order to avoid any pendency, the "expert working group "needs be notified immediately without waiting till formal approval of the minutes of 281st meeting so that the meeting of the expert working group may be called earlier.

Decision 329th: - *The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised in order to avoid pendency/delay in processing of issues relating to veterinary drugs which require input/recommendation of pertinent veterinary expert, hence Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -*

1.	*Dr. Qurban Ali,* *Ex-Director General,* *National Veterinary Laboratory, Islamabad.*	*Chairman*
2.	*Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.*	*Member*
3.	*Mst. Najia Saleem, Deputy Director (PE&R), DRAP*	*Member*
4.	*Dr. Irfan Yousaf* *Dean Faculty of Veterinary and Animal Sciences Pir Meher Ali Shah Arid Agriculture University, Rawalpindi*	*Member*
5.	*Any other relevant expert(s)*	*As Co-opted member(s)*
6.	*Assistant Director (I&V-I), DRAP*	*Member, Secretary*

Correction in decision of 329th meeting regarding EWG are as under:

The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised for inclusion of relevant expert(s) member(s) of the Board etc. However, since process of revision of constitution may take some time as the approval of Federal Government. So, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board under Rule 24 (4) of the Drugs (L,R&A) Rules, 1976 decided to constitute sub-committee on Veterinary Drugs having

following composition: -

1.	*Dr. Qurban Ali,* *Co-opted Member* *Ex-Director General,* *National Veterinary Laboratory, Islamabad.*	*Chairman*
2.	*Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.*	*Member*
3.	*Mst. Najia Saleem, Deputy Director (PE&R), DRAP*	*Evaluator*
4.	*Assistant Director (I&V-I), DRAP*	*Secretary*

The sub-committee on Veterinary Drugs will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations.

Decision of 330th meeting:
The Board acceded to the request of correction in minutes as under;
The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised for inclusion of relevant expert(s) member(s) of the Board etc. However, since process of revision of constitution may take some time for approval by Federal Government. So, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board under Rule 24 (4) of the Drugs (L, R&A) Rules, 1976 decided to constitute sub-committee on Veterinary Drugs having following composition: -

1.	Dr. Qurban Ali, Co-opted Member Ex-Director General, National Veterinary Laboratory, Islamabad.	Chairman
2.	Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.	Member
3.	Mst. Najia Saleem, Deputy Director (PE&R), DRAP	Evaluator
4.	Assistant Director (I&V-I), DRAP	Secretary
5.	Any Co-opt member with the consent of Chairman/Secretary Registration Board	Member

In order to in time disposal of applied dossiers, the sub-committee on Veterinary Drugs will place its input/recommendations on the registration applications of veterinary drugs, including review of existing/new veterinary drug formulations for consideration/decision by the Registration Board.

Case No. 2:- Storage Facility Verification.

Verification of the cold storage facility/ room temperature storage facility is one of the prerequisites for grant of registration to imported products. As per decision of 278th meeting of Registration Board:

a. For imported Biological products stored at 2-8^{0}C, cold storage facility verification report shall be valid for 5 years provided that the address of Drug Sale License remains the same.
b. For imported biological products stored at room temperature, storage facility verification shall be conducted once provided that the address of Drug Sale License remains the same.

Decision of 330th meeting:

The Board after deliberation on the matter that registrations for import of products are granted to only those importers who have a valid DSL duly issued by the respective Provincial Health Department / Licensing Authority. The Board after detailed deliberation decided that storage facility verification shall be only conducted for those products, which requires storage at 2-8^{0}C or which requires special storage conditions. The inspection report in this case shall be valid for a period of (05) years, provided that the address of Drug Sale License shall remain same.

Case No. 3:- Correction of minutes of 329th meeting of Registration Board:

Following case of M/s Pinnacle Biotech (Pvt.) Ltd. was presented in 329th meeting of Registration Board, held on 6th – 8th June, 2023, wherein the Board had approved the case. However, during subsequent processing it has been identified that the decision of the case was not included in the minutes, hence the case is re produced here for recording of the decision and information of Board.

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 369; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 22232543805 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 75mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ……75mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Analgesics and *Anticonvulsant drug.*
	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 (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 75mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 047365
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.

	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana-502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri 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)	The official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the 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 (KBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. 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. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, 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 is established against the innovator brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable.

		CDP is also performed against the same brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.	KBF/K/21/0014		
Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules 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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T071	T074	T075
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	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. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 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	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	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 306443220047 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana-502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.
5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer.*
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Evidence of the pack of the innovator product shall be submitted.	Firm has submitted evidence of the innovator product with same batch number and manufacturing date as

			mentioned in CDP and PE.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data 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.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision of 326th meeting of Registration Board: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.

Reply submitted by the firm:

Firm has submitted that it was a typo error and they also provided corrected COA with same batch number as that of the drug substance manufacturer.

Proceeding & Decision: Registration Board noted the information and acknowledged the following decision for above application:

"**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."**

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