

**MINUTES OF 337<sup>TH</sup> MEETING OF REGISTRATION BOARD  
HELD ON 28<sup>TH</sup> JUNE, 2024**

<b>Item No.</b>	<b>Detail of Item</b>	<b>Page No.</b>
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DRUG REGULATORY AUTHORITY OF PAKISTAN  
PRIME MINISTER'S NATIONAL HEALTH COMPLEX.  
PARK ROAD, CHAK SHEHZAD  
ISLAMABAD.  
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337<sup>th</sup> meeting of Registration Board was held on 28<sup>th</sup> June, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex, Park Road, 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 Arif Ch, Director, Division of BE&R	Member
3.	Mr. Ajmal Sohail Asif, Director, Division of QA&LT	Member
4.	Ch. Zeeshan Nazir Bajar, Additional Director	Secretary
5.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad.	Member
6.	Mr. Ghulam Mujtaba, Deputy Director, Rep. of IPO, Islamabad. (Online)	Member
7.	Mr. Ali Jan, Director, DTL, Quetta. Govt. of Baluchistan	Member
8.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore (Online)	Co-opted Member
9.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert (Online)	Co-opted Member
10.	Mr. Saadat Ali Khan, Deputy Director, Rep. of Director, MD&MC Division	Member

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

**Pharmaceutical Evaluation Cell****Contract manufacturing cases**

DRAP Authority in its 184<sup>th</sup> meeting held on 26<sup>th</sup> June, 2024 decided as under:

*The Authority after thorough deliberations approved the proposal of PE&R Division to consider, out of queue, registration applications for contract manufacturing of those products, wherein product development and stability data of contract acceptor is already approved by the Registration Board and only cross reference is required.*

Accordingly, Contract manufacturing cases applied on Form 5-F from 1<sup>st</sup> August 2023 to 31<sup>st</sup> May 2024 in which product development and stability study data is already approved on Form 5F in previous meetings of Registration Board are placed before the Board for its consideration.

Registration Board was also apprised that for applications received online on eapp, the agenda has also been prepared automatically through eapp portal. The agenda of eapp applications is also presented before the Board. Registration Board appreciated the efforts of PE&R Division for timely evaluation of all cases and also appreciated the efforts of Pharmaceutical Evaluation Cell and Division of MIS DRAP for effective implementation of eapp and generation of agenda through eapp as well.

**Registration Board decided that for all cases of contract manufacturing considered in this meeting following points will be considered before issuance of Registration letter:**

- a) **Valid GMP inspection report / certificate of the contract manufacturer**
- b) **Capacity assessment of the contract manufacturer as per approved policy, as per decision of registration board in its 333<sup>rd</sup> and 336<sup>th</sup> meetings.**

**Agenda of Evaluator Dr. Haseeb Tariq**

<b>1.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22137: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 08-08-2023
	The proposed proprietary name / brand name	<b>ASPRIDE 50mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amisulpride...50mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	AMISULPRIDE TABLETS by Accord-UK Ltd (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets by Sami Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	AMPRID Tablets 50mg
Registration Board meeting	326

**Decision: Approved.**

<b>2.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22138: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 08-08-2023
	The proposed proprietary name / brand name	<b>ASPRIDE 100mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amisulpride...100mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	AMISULPRIDE TABLETS by Accord-UK Ltd (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets by Sami Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	AMPRID Tablets 100mg
Registration Board meeting	326

**Decision: Approved.**

<b>3.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22139: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 08-08-2023
	The proposed proprietary name / brand name	<b>ASPRIDE 200mg Tablet</b>

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amisulpride...200mg
Pharmacotherapeutic Group of (API)	Antipsychotics
Reference to Finished product specifications	BP
The status in reference regulatory authorities	AMISULPRIDE TABLETS by Accord-UK Ltd (MHRA Approved)
For generic drugs (me-too status)	Ampisol Tablets by Sami Pharma
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	AMPRID Tablets 200mg
Registration Board meeting	326

**Decision: Approved.**

<b>4.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22139: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 08-08-2023
	The proposed proprietary name / brand name	<b>ASPRIDE 400mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amisulpride...400mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	AMISULPRIDE TABLETS by Accord-UK Ltd (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets by Sami Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	AMPRID Tablets 400mg
Registration Board meeting	326

**Decision: Approved.**

5.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>								
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22135: 08-09-2023								
	Details of fee submitted	PKR 75,000/- : 08-08-2023								
	The proposed proprietary name / brand name	<b>ATOXET 4mg/ml Oral Solution</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Oral Solution Contains: Atomoxetine Hcl Eq. to Atomoxetine...4mg								
	Pharmacotherapeutic Group of (API)	Psychoanaleptic								
	Reference to Finished product specifications	Innovator specification								
	The status in reference regulatory authorities	STRATTERA 4mg/ml Oral solution by Eli Lilly and Company Limited, Austria Approved								
	For generic drugs (me-too status)	Not available								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi</td> </tr> <tr> <td>Brand Name</td> <td>MOXETIN Oral solution 4mg/ml</td> </tr> <tr> <td>Registration Board meeting</td> <td>324</td> </tr> </table>			Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	Brand Name	MOXETIN Oral solution 4mg/ml	Registration Board meeting	324
Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi									
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi									
Brand Name	MOXETIN Oral solution 4mg/ml									
Registration Board meeting	324									
<b>Decision: Approved.</b>										
6.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>								
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22134: 08-09-2023								
	Details of fee submitted	PKR 75,000/- : 08-08-2023								
	The proposed proprietary name / brand name	<b>TOLAC 10mg Tablet</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ketorolac Tromethamine...10mg								
	Pharmacotherapeutic Group of (API)	Analgesic								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	USFDA Approved								
	For generic drugs (me-too status)	Yukon Tablet 10mg CCL Pharma								
	Proposed Pack size	As per SRO								

<b>Evaluation by PEC<sup>3</sup>:</b>																									
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:																									
Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi																								
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi																								
Brand Name	Ketor Tablets 10mg																								
Registration Board meeting	321																								
<b>Decision: Approved.</b>																									
<b>7.</b>	<table border="1"> <tr> <td><b>Name, address of Applicant / Marketing Authorization Holder</b></td> <td><b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b></td> </tr> <tr> <td>Name, address of Manufacturing site.</td> <td>M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi</td> </tr> <tr> <td>Status of the applicant</td> <td> <input type="checkbox"/> Manufacturer  <input type="checkbox"/> Importer  <input checked="" type="checkbox"/> Is involved in none of the above (contract giver) </td> </tr> <tr> <td>Application Form Dy. No / Tracking ID &amp; date of submission</td> <td>Form 5F: Dy. No. 22136: 08-09-2023</td> </tr> <tr> <td>Details of fee submitted</td> <td>PKR 75,000/- : 08-08-2023</td> </tr> <tr> <td>The proposed proprietary name / brand name</td> <td><b>BAMIPID 100mg Tablet</b></td> </tr> <tr> <td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td> <td>Each Film Coated Tablet Contains: Rebamipide...100mg</td> </tr> <tr> <td>Pharmacotherapeutic Group of (API)</td> <td>Anti-gastritis</td> </tr> <tr> <td>Reference to Finished product specifications</td> <td>JP</td> </tr> <tr> <td>The status in reference regulatory authorities</td> <td>PMDA Approved</td> </tr> <tr> <td>For generic drugs (me-too status)</td> <td>Mucosta 100mg tablet by Otsuka</td> </tr> <tr> <td>Proposed Pack size</td> <td>As per SRO</td> </tr> </table>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22136: 08-09-2023	Details of fee submitted	PKR 75,000/- : 08-08-2023	The proposed proprietary name / brand name	<b>BAMIPID 100mg Tablet</b>	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rebamipide...100mg	Pharmacotherapeutic Group of (API)	Anti-gastritis	Reference to Finished product specifications	JP	The status in reference regulatory authorities	PMDA Approved	For generic drugs (me-too status)	Mucosta 100mg tablet by Otsuka	Proposed Pack size	As per SRO
<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>																								
Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi																								
Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)																								
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22136: 08-09-2023																								
Details of fee submitted	PKR 75,000/- : 08-08-2023																								
The proposed proprietary name / brand name	<b>BAMIPID 100mg Tablet</b>																								
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rebamipide...100mg																								
Pharmacotherapeutic Group of (API)	Anti-gastritis																								
Reference to Finished product specifications	JP																								
The status in reference regulatory authorities	PMDA Approved																								
For generic drugs (me-too status)	Mucosta 100mg tablet by Otsuka																								
Proposed Pack size	As per SRO																								
<b>Evaluation by PEC<sup>3</sup>:</b>																									
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:																									
Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi																								
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi																								
Brand Name	Rebamipide 100mg tablet																								
Registration Board meeting	322																								
<b>Decision: Approved.</b>																									
<b>8.</b>	<table border="1"> <tr> <td><b>Name, address of Applicant / Marketing Authorization Holder</b></td> <td><b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b></td> </tr> <tr> <td>Name, address of Manufacturing site.</td> <td>M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi</td> </tr> <tr> <td>Status of the applicant</td> <td> <input type="checkbox"/> Manufacturer  <input type="checkbox"/> Importer  <input checked="" type="checkbox"/> Is involved in none of the above (contract giver) </td> </tr> <tr> <td>Application Form Dy. No / Tracking ID &amp; date of submission</td> <td>Form 5F: Dy. No. 22141: 08-09-2023</td> </tr> </table>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22141: 08-09-2023																
<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>																								
Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi																								
Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)																								
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22141: 08-09-2023																								

Details of fee submitted	PKR 75,000/- : 08-08-2023
The proposed proprietary name / brand name	<b>ARIZIN 1.5mg Capsule</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cariprazine HCl eq. to Cariprazine...1.5mg
Pharmacotherapeutic Group of (API)	Antipsychotics
Reference to Finished product specifications	Innovator Specification
The status in reference regulatory authorities	USFDA Approved
For generic drugs (me-too status)	Not available
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	Caripz 1.5mg capsules
Registration Board meeting	324

**Decision: Approved.**

<b>9.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22142: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 08-08-2023
	The proposed proprietary name / brand name	<b>ARIZIN 3mg Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cariprazine HCl eq. to Cariprazine...3mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	Caripz 3mg capsules
Registration Board meeting	324

**Decision: Approved.**



<b>10.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>								
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22143: 08-09-2023								
	Details of fee submitted	PKR 75,000/- : 08-08-2023								
	The proposed proprietary name / brand name	<b>ARIZIN 4.5mg Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cariprazine HCl eq. to Cariprazine...4.5mg								
	Pharmacotherapeutic Group of (API)	Antipsychotics								
	Reference to Finished product specifications	Innovator Specification								
	The status in reference regulatory authorities	USFDA Approved								
	For generic drugs (me-too status)	Not available								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi</td> </tr> <tr> <td>Brand Name</td> <td>Caripz 4.5mg capsules</td> </tr> <tr> <td>Registration Board meeting</td> <td>324</td> </tr> </table>			Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi	Brand Name	Caripz 4.5mg capsules	Registration Board meeting	324
Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi									
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi									
Brand Name	Caripz 4.5mg capsules									
Registration Board meeting	324									
<b>Decision: Approved.</b>										
<b>11.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore</b>								
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22144: 08-09-2023								
	Details of fee submitted	PKR 75,000/- : 08-08-2023								
	The proposed proprietary name / brand name	<b>ARIZIN 6mg Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cariprazine HCl eq. to Cariprazine...6mg								
	Pharmacotherapeutic Group of (API)	Antipsychotics								
	Reference to Finished product specifications	Innovator Specification								
	The status in reference regulatory authorities	USFDA Approved								
	For generic drugs (me-too status)	Not available								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
Brand Name	Caripz 6mg capsules
Registration Board meeting	324

**Decision: Approved.**

<b>12.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Munawar Pharma Pvt Ltd. 31-Km Ferozpur Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22460: 12-09-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>ASSUNATE 30mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Artesunate...30mg
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain
	Reference to Finished product specifications	Ph. Int Specifications
	The status in reference regulatory authorities	WHO recommended formulation
	For generic drugs (me-too status)	Arcenate Injection by Sami Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	BIOART 30mg IV Injection
Registration Board meeting	331

**Decision: Approved.**

<b>13.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Munawar Pharma Pvt Ltd. 31-Km Ferozpur Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22459: 12-09-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023

The proposed proprietary name / brand name	<b>ASSUNATE 60mg Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Artesunate...60mg
Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain
Reference to Finished product specifications	Ph. Int Specifications
The status in reference regulatory authorities	WHO recommended formulation
For generic drugs (me-too status)	Arcenate Injection by Sami Pharma
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	BIOART 60mg IV Injection
Registration Board meeting	331

**Decision: Approved.**

<b>14.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Munawar Pharma Pvt Ltd. 31-Km Ferozpur Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22461: 12-09-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>ASSUNATE 120mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Artesunate...120mg
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain
	Reference to Finished product specifications	Ph. Int Specifications
	The status in reference regulatory authorities	WHO recommended formulation
	For generic drugs (me-too status)	Arcenate Injection by Sami Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	BIOART 120mg IV Injection
Registration Board meeting	331

**Decision: Approved.**

<b>15.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan</b>								
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19552: 07-08-2023								
	Details of fee submitted	PKR 75,000/- : 12-05-2023								
	The proposed proprietary name / brand name	<b>CEFIXIFAAS 200mg/5ml Dry Powder Suspension</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of Reconstituted Suspension Contains: Cefixime as Trihydrate...200mg								
	Pharmacotherapeutic Group of (API)	Cephalosporin								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	USFDA								
	For generic drugs (me-too status)	Cefiget suspension by Getz								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Reliance Pharma, Plot # 8, Street No. S-8, RCCI, Industrial Estate, Rawat Islamabad.</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>TAVIZEM 200mg/5ml suspension</td> </tr> <tr> <td>Registration Board meeting</td> <td>323</td> </tr> </table>			Applicant firm	M/s Reliance Pharma, Plot # 8, Street No. S-8, RCCI, Industrial Estate, Rawat Islamabad.	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	Brand Name	TAVIZEM 200mg/5ml suspension	Registration Board meeting	323
Applicant firm	M/s Reliance Pharma, Plot # 8, Street No. S-8, RCCI, Industrial Estate, Rawat Islamabad.									
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.									
Brand Name	TAVIZEM 200mg/5ml suspension									
Registration Board meeting	323									
<b>Decision: Approved.</b>										
<b>16.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 &amp; 63-67, Sector 27, Korangi Industrial Area, Karachi</b>								
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27098: 16-11-2023								
	Details of fee submitted	PKR 75,000/- : 12-09-2023								
	The proposed proprietary name / brand name	<b>TAMSIN-D 0.5/0.4 mg Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains; Dutasteride (as softgel capsule) ....0.5mg Tamsulosin HCl (as 0.2% modified release pellets) ..... 0.4mg								
	Pharmacotherapeutic Group of (API)	Drugs used in benign prostatic hypertrophy								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	USFDA								

	For generic drugs (me-too status)	Max flow D Capsule by CCL Pharmaceuticals.
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58- A2, Korangi Creek Industrial Park (KCIP) Karachi.
	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	TAMCURE-D Capsule
	Registration Board meeting	333
<b>Decision: Approved.</b>		
17.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore</b>
	Name, address of Manufacturing site.	M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27247: 20-11-2023
	Details of fee submitted	PKR 75,000/- : 29-04-2022
	The proposed proprietary name / brand name	<b>MECOZAM 500ug/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Mecobalamin.....500mcg
	Pharmacotherapeutic Group of (API)	Cyanocobalamin and analogues
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	PMDA Japan Approved
	For generic drugs (me-too status)	Beacom injection by GT Pharma.
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 GT Pharma (Pvt) Ltd. 713 Sundar Industrial Estate Lahore.
	Brand Name	Macxee Injection 500mcg/ml
	Registration Board meeting	333
<b>Decision: Approved.</b>		
18.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore</b>
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25900: 26-10-2023
Details of fee submitted	PKR 75,000/- : 21-12-2022
The proposed proprietary name / brand name	<b>MPS Dry Powder Injection 500mg</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Methylprednisolone as Sodium Succinate...500mg
Pharmacotherapeutic Group of (API)	Glucocorticoids for systemic use
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	SOLU-MEDROL Injection by Pfizer Pakistan Limited
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Brand Name	PRESTIA 500mg Injection (IV/IM)
Registration Board meeting	331

**Decision: Approved.**

<b>19.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore</b>
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25901: 26-10-2023
	Details of fee submitted	PKR 75,000/- : 21-12-2022
	The proposed proprietary name / brand name	<b>MPS Dry Powder Injection 1g</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Methylprednisolone as Sodium Succinate...1g
	Pharmacotherapeutic Group of (API)	Glucocorticoids for systemic use
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	SOLU-MEDROL Injection by Pfizer Pakistan Limited
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small Industrial Estate, Taxila, Pakistan.
Manufacturer firm	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 35-A, Small

		Industrial Estate, Taxila, Pakistan.
	Brand Name	Prestia 1g Injection (IV/IM)
	Registration Board meeting	331

**Decision: Approved.**

<b>20.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26378: 01-11-2023
	Details of fee submitted	PKR 75,000/- : 04-09-2023
	The proposed proprietary name / brand name	<b>ARDIS 4mg Sachet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast as Sodium...4mg
	Pharmacotherapeutic Group of (API)	Leukotriene modifiers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Lucast Sachet by AGP
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
Manufacturer firm	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
Brand Name	JOSEF 4mg Sachet
Registration Board meeting	331

**Decision: Approved.**

<b>21.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19295: 03-08-2023
	Details of fee submitted	PKR 75,000/- : 05-06-2023
	The proposed proprietary name / brand name	<b>LOMINE-D Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Cholecalciferol (Vitamin D3)...5mg
	Pharmacotherapeutic Group of (API)	Vitamin D

	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	ANSM France
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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
Registration Board meeting	323

#### Decision: Approved.

<b>22.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19382: 04-08-2023
	Details of fee submitted	PKR 75,000/- : 18-07-2023
	The proposed proprietary name / brand name	<b>COLICRAFT 2MIU Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to 68mg Colistimethate Base Activity...2 MIU
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Colistimethate sodium for injection of M/s Mukhtar Enterprises
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	Colicraft Injection I.V 2MIU
Registration Board meeting	324

#### Decision: Approved.

<b>23.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad



	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26376: 01-11-2023								
	Details of fee submitted	PKR 75,000/- : 03-10-2023								
	The proposed proprietary name / brand name	<b>ESOL 40mg Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole Sodium Eq. to Esomeprazole (Lyophilized)...40mg								
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Esomine 40mg Injection Lawari International								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td><td>M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat</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>Esonext 40mg Injection</td></tr> <tr> <td>Registration Board meeting</td><td>330</td></tr> </table>			Applicant firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat	Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.	Brand Name	Esonext 40mg Injection	Registration Board meeting	330
Applicant firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat									
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.									
Brand Name	Esonext 40mg Injection									
Registration Board meeting	330									
<b>Decision: Approved.</b>										
<b>24.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>								
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27022: 15-11-2023								
	Details of fee submitted	PKR 75,000/- : 03-10-2023								
	The proposed proprietary name / brand name	<b>MZOL 40mg Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole Sodium Eq. to Omeprazole...40mg								
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										

Applicant firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	Omepranext Injection 40mg IV
Registration Board meeting	324

**Decision: Approved.**

<b>25.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Munawar Pharma Pvt Ltd. 31-Km Ferozpur Road, Lahore, Pakistan</b>
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22478: 13-09-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>OMEPRAX 40mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole Sodium Eq. to Omeprazole...40mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	Omepranext Injection 40mg IV
Registration Board meeting	324

**Decision: Approved.**

<b>26.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25778: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 13-09-2023
	The proposed proprietary name / brand name	<b>BACTUM 2.25gm IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium Eq. to Piperacillin...2gm

		Tazobactam Sodium Eq. to Tazobactam...0.25gm
	Pharmacotherapeutic Group of (API)	Penicillin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product 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 No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	PIPRABEN Injection 2.25g Injection
Registration Board meeting	316

**Decision: Approved.**

<b>27.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25779: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 13-09-2023
	The proposed proprietary name / brand name	<b>BACTUM 4.5gm IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin Sodium Eq. to Piperacillin...4gm Tazobactam Sodium Eq. to Tazobactam...0.5gm
	Pharmacotherapeutic Group of (API)	Penicillin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Tazop Injection of Global Pharmaceuticals
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product 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 No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	PIPRABEN Injection 4.5g Injection
Registration Board meeting	316

**Decision: Approved.**

<b>28.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>
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Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20957: 24-08-2023
Details of fee submitted	PKR 75,000/- : 27-07-2023
The proposed proprietary name / brand name	<b>FLOVIS 10mg Tablet</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin...10mg
Pharmacotherapeutic Group of (API)	Antidiabetic
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Emsyn tablets of M/s The Searle Company
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Soglu 10mg Tablet
Registration Board meeting	313

#### Decision: Approved.

<b>29.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20956: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 27-07-2023
	The proposed proprietary name / brand name	<b>FLOVIS 25mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin...25mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Emsyn tablets of M/s The Searle Company
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Soglu 25mg Tablet
Registration Board meeting	313

**Decision: Approved.**

<b>30.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20952: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 27-07-2023
	The proposed proprietary name / brand name	<b>FLOVIS-M 5/850 mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin...5mg Metformin Hcl...850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Xenglu-Met Tablet of Hilton Pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Soglu-Met 5mg/850mg Tablet
Registration Board meeting	320

**Decision: Approved.**

<b>31.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20953: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 27-07-2023
	The proposed proprietary name / brand name	<b>FLOVIS-M 12.5/850 mg Tablet</b>

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin...12.5mg Metformin Hcl...850mg
Pharmacotherapeutic Group of (API)	Antidiabetic
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Xenglu-Met Tablet of Hilton Pharma
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Soglu-Met 12.5mg/850mg Tablet
Registration Board meeting	320

#### Decision: Approved.

<b>32.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20955: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 27-07-2023
	The proposed proprietary name / brand name	<b>FLOVIS-M 12.5/1000 mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin...12.5mg Metformin Hcl...1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Xenglu-Met Tablet of Hilton Pharma
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Soglu-Met 12.5mg/1000mg Tablet
Registration Board meeting	320

#### Decision: Approved.

<b>33.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad</b>								
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20954: 24-08-2023								
	Details of fee submitted	PKR 75,000/- : 27-07-2023								
	The proposed proprietary name / brand name	<b>FLOVIS-M 5/1000 mg Tablet</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin....5mg Metformin Hcl...1000mg								
	Pharmacotherapeutic Group of (API)	Antidiabetic								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	USFDA								
	For generic drugs (me-too status)	Xenglu-Met Tablet of Hilton Pharma								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.</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>Soglu-Met 5mg/1000mg Tablet</td> </tr> <tr> <td>Registration Board meeting</td> <td>320</td> </tr> </table>			Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.	Brand Name	Soglu-Met 5mg/1000mg Tablet	Registration Board meeting	320
Applicant firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.									
Manufacturer firm	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.									
Brand Name	Soglu-Met 5mg/1000mg Tablet									
Registration Board meeting	320									
<b>Decision: Approved.</b>										
<b>34.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Sapien Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore</b>								
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25445: 20-10-2023								
	Details of fee submitted	PKR 75,000/- : 19-09-2023								
	The proposed proprietary name / brand name	<b>SERONEM 500mg Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...500mg								
	Pharmacotherapeutic Group of (API)	Antibiotic								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	USFDA								
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals								
	Proposed Pack size	As per SRO								

<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	
Brand Name	ASPINEM 500 mg Injection IV	
Registration Board meeting	323	
<b>Decision: Approved.</b>		
<b>35.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore</b>
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25446: 20-10-2023
	Details of fee submitted	PKR 75,000/- : 19-09-2023
	The proposed proprietary name / brand name	<b>SERONEM 1g Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	
Brand Name	ASPINEM 1gm Injection	
Registration Board meeting	323	
<b>Decision: Approved.</b>		
<b>36.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Stallion Pharmaceuticals Pvt Ltd 581, Sundar Industrial Estate Lahore</b>
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26945: 13-11-2023



Details of fee submitted	PKR 75,000/- : 07-08-2023
The proposed proprietary name / brand name	<b>FERRITOSE 50mg/ml Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Iron as Ferric Carboxymaltose...50mg
Pharmacotherapeutic Group of (API)	Iron preparation
Reference to Finished product specifications	Innovator's specs
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Ferinject Injection of RG
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore
Brand Name	Greeninject 50mg/ml Injection
Registration Board meeting	320

#### Decision: Approved.

<b>37.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad</b>
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21899: 05-09-2023
	Details of fee submitted	PKR 75,000/- : 16-08-2023
	The proposed proprietary name / brand name	<b>FERBOXY 50mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Iron as Ferric Carboxymaltose...50mg
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	Innovator's specs
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Ferinject Injection of RG
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore
Brand Name	Greeninject 50mg/ml Injection
Registration Board meeting	320

<b>Decision: Approved.</b>										
<b>38.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26534: 03-11-2023								
	Details of fee submitted	PKR 75,000/- : 12-09-2023								
	The proposed proprietary name / brand name	<b>BETAKIN 20gm Cream</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Cream Contains: Betamethasone as Valerate...0.1%								
	Pharmacotherapeutic Group of (API)	Corticosteroids								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Betnovate cream by GSK								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>VALBE 20 gm Cream</td> </tr> <tr> <td>Registration Board meeting</td> <td>313</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	VALBE 20 gm Cream	Registration Board meeting	313
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	VALBE 20 gm Cream									
Registration Board meeting	313									
<b>Decision: Approved.</b>										
<b>39.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26532: 03-11-2023								
	Details of fee submitted	PKR 75,000/- : 12-09-2023								
	The proposed proprietary name / brand name	<b>BETAKIN 20gm Ointment</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Ointment Contains: Betamethasone as Valerate...0.1%								
	Pharmacotherapeutic Group of (API)	Corticosteroids								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Betnovate ointment by GSK								
	Proposed Pack size	As per SRO								

<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Brand Name	VALBE 20gm Ointment	
Registration Board meeting	313	
<b>Decision: Approved.</b>		
<b>40.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26533: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 12-09-2023
	The proposed proprietary name / brand name	<b>BETAKIN 60ml Lotion</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Lotion Contains: Betamethasone as Valerate...0.1%
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Betnovate lotion by GSK
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Brand Name	VALBE 60ml Lotion	
Registration Board meeting	313	
<b>Decision: Approved.</b>		
<b>41.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s ICU Pharmaceuticals. Khewat 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhpura</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24555: 09-10-2023

Details of fee submitted	PKR 75,000/- : 02-09-2023
The proposed proprietary name / brand name	<b>ACCU-D 5mg/ml Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Cholecalciferol...5mg
Pharmacotherapeutic Group of (API)	Vitamin D3
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	ANSM France approved
For generic drugs (me-too status)	Novel-D Injection by Danas Pharma
Proposed Pack size	As per SRO

#### **Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	3D Injection 5mg/mL (Oral / IM)
Registration Board meeting	323

#### **Decision: Approved.**

<b>42.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26530: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 24-07-2023
	The proposed proprietary name / brand name	<b>DALIX 5mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Cholecalciferol...5mg
	Pharmacotherapeutic Group of (API)	Vitamin D3
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	ANSM France approved
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma
	Proposed Pack size	As per SRO

#### **Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	3D Injection 5mg/mL (Oral / IM)
Registration Board meeting	323

<b>Decision: Approved.</b>										
<b>43.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20958: 24-08-2023								
	Details of fee submitted	PKR 75,000/- : 01-08-2023								
	The proposed proprietary name / brand name	<b>BIO-D3 Soft Gel Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Cholecalciferol...50,000 IU								
	Pharmacotherapeutic Group of (API)	Vitamin D3								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA approved								
	For generic drugs (me-too status)	Solar-D Soft gelatin Capsule 50,000 IU by Crystolite pharma								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>3-D Capsule</td> </tr> <tr> <td>Registration Board meeting</td> <td>312</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	3-D Capsule	Registration Board meeting	312
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	3-D Capsule									
Registration Board meeting	312									
<b>Decision: Approved.</b>										
<b>44.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25786: 25-10-2023								
	Details of fee submitted	PKR 75,000/- : 25-09-2023								
	The proposed proprietary name / brand name	<b>WRD-D 50,000 IU Softgel Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Cholecalciferol...50,000 IU								
	Pharmacotherapeutic Group of (API)	Vitamin D3								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA approved								

	For generic drugs (me-too status)	Solar-D Soft gelatin Capsule 50,000 IU by Crystolite pharma
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Brand Name	3-D Capsule
	Registration Board meeting	312
<b>Decision: Approved.</b>		
<b>45.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wnsfeld Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25782: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 29-08-2023
	The proposed proprietary name / brand name	<b>CHOL-D Soft Gel Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Cholecalciferol...50,000 IU
	Pharmacotheapeutic Group of (API)	Vitamin D3
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Solar-D Soft gelatin Capsule 50,000 IU by Crystolite pharma
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Brand Name	3-D Capsule
	Registration Board meeting	312
<b>Decision: Approved.</b>		
<b>46.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer

	<input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20959: 24-08-2023
Details of fee submitted	PKR 75,000/- : 01-08-2023
The proposed proprietary name / brand name	<b>BIODOR 500mg Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. To Doripenem...500mg
Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
Reference to Finished product specifications	JP
The status in reference regulatory authorities	Finibax Intravenous Infusion 0.5g (PMDA Japan Approved)
For generic drugs (me-too status)	Dorinam Injection by ICI
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	DORIGEN 500mg Injection
Registration Board meeting	316

**Decision: Approved.**

<b>47.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26538: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>SOMPRAZ 40mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole as Sodium...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Nexum Injection by Getz
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	ESOGEN Injection 40mg IV
Registration Board meeting	312

**Decision: Approved.**

<b>48.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26679: 06-11-2023
	Details of fee submitted	PKR 75,000/- : 10-10-2023
	The proposed proprietary name / brand name	<b>IMIGEN 250mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate...250mg Cilastatin as Sodium...250mg
	Pharmacotherapeutic Group of (API)	Anti Bacterial
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Cilapen Injection by Bosh
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	Cilagen 250mg Injection IV
Registration Board meeting	330

**Decision: Approved.**

<b>49.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26680: 06-11-2023
	Details of fee submitted	PKR 75,000/- : 10-10-2023
	The proposed proprietary name / brand name	<b>IMIGEN 500mg Injection</b>



	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as Monohydrate...500mg Cilastatin as Sodium...500mg
	Pharmacotherapeutic Group of (API)	Anti Bacterial
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Cilapen Injection by Bosh
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Brand Name	Cilagen 500mg Injection IV
	Registration Board meeting	330
<b>Decision: Approved.</b>		
<b>50.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22131: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 24-07-2023
	The proposed proprietary name / brand name	<b>I-FER 100mg/5ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Ampoule Contains: Iron sucrose eq. to elemental Iron.....100mg
	Pharmacotherapeutic Group of (API)	Iron
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	TGA
	For generic drugs (me-too status)	G-Fer Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Brand Name	BIOSUC Injection 100 mg/5ml
	Registration Board meeting	313
<b>Decision: Approved.</b>		

<b>51.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK.</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26529: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 25-09-2023
	The proposed proprietary name / brand name	<b>ATHRETO 10mg Soft Gelatin Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...10mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 10mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>52.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK.</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26528: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 25-09-2023
	The proposed proprietary name / brand name	<b>ATHRETO 20mg Soft Gelatin Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 20mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>53.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26682: 06-11-2023
	Details of fee submitted	PKR 75,000/- : 25-09-2023
	The proposed proprietary name / brand name	<b>RETINOR 10mg Soft Gel Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...10mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 10mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>54.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26681: 06-11-2023

Details of fee submitted	PKR 75,000/- : 25-09-2023
The proposed proprietary name / brand name	<b>RETINOR 20mg Soft Gel Capsule</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg
Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
Reference to Finished product specifications	BP
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Oratane Capsule by Crystolite
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 20mg Capsule
Registration Board meeting	312

#### Decision: Approved.

<b>55.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26535: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>ISOJEL 10mg Soft Gel Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...10mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 10mg Capsule
Registration Board meeting	312

#### Decision: Approved.

<b>56.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26536: 03-11-2023								
	Details of fee submitted	PKR 75,000/- : 17-08-2023								
	The proposed proprietary name / brand name	<b>ISOJEL 20mg Soft Gel Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg								
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne								
	Reference to Finished product specifications	BP								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Oratane Capsule by Crystolite								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>BIOTAN 20mg Capsule</td> </tr> <tr> <td>Registration Board meeting</td> <td>312</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	BIOTAN 20mg Capsule	Registration Board meeting	312
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	BIOTAN 20mg Capsule									
Registration Board meeting	312									
<b>Decision: Approved.</b>										
<b>57.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wenovo Pharmaceuticals Plot # 31&amp; 32 Punjab Small Industrial Estate Taxila</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25780: 25-10-2023								
	Details of fee submitted	PKR 75,000/- : 03-10-2023								
	The proposed proprietary name / brand name	<b>EKOTIN 10mg Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...10mg								
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne								
	Reference to Finished product specifications	BP								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Oratane Capsule by Crystolite								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 10mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>58.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wenovo Pharmaceuticals Plot # 31&amp; 32 Punjab Small Industrial Estate Taxila</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25781: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 03-10-2023
	The proposed proprietary name / brand name	<b>EKOTIN 20mg Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 20mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>59.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25783: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 29-08-2023

The proposed proprietary name / brand name	<b>ISOWIN 10mg Soft Gel Capsule</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...10mg
Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
Reference to Finished product specifications	BP
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Oratane Capsule by Crystolite
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 10mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>60.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wnsfeld Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25784: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 29-08-2023
	The proposed proprietary name / brand name	<b>ISOWIN 20mg Soft Gel Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Oratane Capsule by Crystolite
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIOTAN 20mg Capsule
Registration Board meeting	312

**Decision: Approved.**

<b>61.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25785: 25-10-2023								
	Details of fee submitted	PKR 75,000/- : 25-09-2023								
	The proposed proprietary name / brand name	<b>SOKEFA 20mg Capsule</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gel Capsule Contains: Isotretinoin...20mg								
	Pharmacotherapeutic Group of (API)	Retinoids for treatment of acne								
	Reference to Finished product specifications	BP								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Oratane Capsule by Crystolite								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>BIOTAN 20mg Capsule</td> </tr> <tr> <td>Registration Board meeting</td> <td>312</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	BIOTAN 20mg Capsule	Registration Board meeting	312
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	BIOTAN 20mg Capsule									
Registration Board meeting	312									
<b>Decision: Approved.</b>										
<b>62.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20962: 24-08-2023								
	Details of fee submitted	PKR 75,000/- : 01-08-2023								
	The proposed proprietary name / brand name	<b>BIOZIC 600mg/300ml Infusion</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Linezolid...600mg/300ml								
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	USFDA								
	For generic drugs (me-too status)	Nezkil Infusion by Continental pharma								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										



The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	LINZOGEN 600mg/300ml Solution for Infusion
Registration Board meeting	320

**Decision: Approved.**

<b>63.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22133: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 24-07-2023
	The proposed proprietary name / brand name	<b>LINZIT 600mg/300ml Infusion</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Linezolid...600mg/300ml
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Nezkil Infusion by Continental pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	LINZOGEN 600mg/300ml Solution for Infusion
Registration Board meeting	320

**Decision: Approved.**

<b>64.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26539: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 12-09-2023

The proposed proprietary name / brand name	<b>KOMLINZ 600mg/300ml Infusion</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Linezolid...600mg/300ml
Pharmacotherapeutic Group of (API)	Antibacterials for systemic use
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Nezkil Infusion by Continental pharma
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	LINZOGEN 600mg/300ml Solution for Infusion
Registration Board meeting	320

**Decision: Approved.**

<b>65.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26539: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 12-09-2023
	The proposed proprietary name / brand name	<b>NEAMIN 500mcg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Mecobalamin...500mcg
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Methycobal Injection by Hilton
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	Mecogen Injection 500mcg
Registration Board meeting	316

**Decision: Approved.**

<b>66.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22132: 08-09-2023								
	Details of fee submitted	PKR 75,000/- : 24-07-2023								
	The proposed proprietary name / brand name	<b>MOFLOX 400mg/250ml Infusion</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Moxifloxacin Hcl...400mg/250ml								
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Avelox Injection by Bayer								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>Mecogen Injection 500mcg</td> </tr> <tr> <td>Registration Board meeting</td> <td>320</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	Mecogen Injection 500mcg	Registration Board meeting	320
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	Mecogen Injection 500mcg									
Registration Board meeting	320									
<b>Decision: Approved.</b>										
<b>67.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20961: 24-08-2023								
	Details of fee submitted	PKR 75,000/- : 01-08-2023								
	The proposed proprietary name / brand name	<b>BIOFLOX 400mg/250ml Infusion</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Moxifloxacin Hcl...400mg/250ml								
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Avelox Injection by Bayer								
	Proposed Pack size	As per SRO								

<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Brand Name	Mecogen Injection 500mcg	
Registration Board meeting	320	
<b>Decision: Approved.</b>		
<b>68.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20961: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 01-08-2023
	The proposed proprietary name / brand name	<b>NALBUGEN 10mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Nalbuphine HCl...10mg
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	
Brand Name	BIONAL Injection 10mg/mL	
Registration Board meeting	297	
<b>Decision: Approved.</b>		
<b>69.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20964: 24-08-2023

Details of fee submitted	PKR 75,000/- : 01-08-2023
The proposed proprietary name / brand name	<b>NALBUGEN 20mg/ml Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Nalbuphine HCl...20mg
Pharmacotherapeutic Group of (API)	Morphinan derivatives
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Nalbin Injection by Global Pharma
Proposed Pack size	As per SRO

#### **Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	BIONAL Injection 20mg/mL
Registration Board meeting	297

#### **Decision: Approved.**

<b>70.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi</b>
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20960: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 01-08-2023
	The proposed proprietary name / brand name	<b>TAMSTONE 0.4mg Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Tamsulosin hydrochloride (as sustained release pellets).....0.4mg
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Tamsolin Capsule by Getz
	Proposed Pack size	As per SRO

#### **Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi
Brand Name	TAMOGEN 0.4mg Capsule
Registration Board meeting	320

<b>Decision: Approved.</b>										
<b>71.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar</b>								
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26537: 03-11-2023								
	Details of fee submitted	PKR 75,000/- : 17-08-2023								
	The proposed proprietary name / brand name	<b>OZEM 40mg Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole as Sodium...50mg								
	Pharmacotherapeutic Group of (API)	PPI								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	MHRA								
	For generic drugs (me-too status)	Risek Injection by Getz								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi</td> </tr> <tr> <td>Brand Name</td> <td>Reflex 40mg Injection</td> </tr> <tr> <td>Registration Board meeting</td> <td>312</td> </tr> </table>			Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi	Brand Name	Reflex 40mg Injection	Registration Board meeting	312
Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi									
Brand Name	Reflex 40mg Injection									
Registration Board meeting	312									
<b>Decision: Approved.</b>										
<b>72.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Basel Pharmaceuticals. 227, Phase-II, Multan Industrial Estate, Multan</b>								
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22328: 11-09-2023								
	Details of fee submitted	PKR 75,000/- : 17-08-2023								
	The proposed proprietary name / brand name	<b>BASOPENUM 500mg IV Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...500mg								
	Pharmacotherapeutic Group of (API)	Antibiotic								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA								

	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Brand Name	DEWNEM Injection 500mg
	Registration Board meeting	312
<b>Decision: Approved.</b>		
73.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Basel Pharmaceuticals. 227, Phase-II, Multan Industrial Estate, Multan</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22329: 11-09-2023
	Details of fee submitted	PKR 75,000/- : 17-08-2023
	The proposed proprietary name / brand name	<b>BASOPENUM 1g IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
	<b>Evaluation by PEC<sup>3</sup>:</b>	
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Brand Name	DEWNEM Injection 1g
	Registration Board meeting	312
<b>Decision: Approved.</b>		
74.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Unimark Pharmaceuticals Pvt Ltd. Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer

		<input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24681: 10-10-2023	
Details of fee submitted	PKR 75,000/- : 25-09-2023	
The proposed proprietary name / brand name	<b>MEROMARK 500mg IV Injection</b>	
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...500mg	
Pharmacotherapeutic Group of (API)	Antibiotic	
Reference to Finished product specifications	USP	
The status in reference regulatory authorities	MHRA	
For generic drugs (me-too status)	Merrem Injection by Global	
Proposed Pack size	As per SRO	

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 500mg
Registration Board meeting	312

#### Decision: Approved.

<b>75.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Unimark Pharmaceuticals Pvt Ltd. Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24682: 10-10-2023
	Details of fee submitted	PKR 75,000/- : 25-09-2023
	The proposed proprietary name / brand name	<b>MEROMARK 1g IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:



Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 1g
Registration Board meeting	312

**Decision: Approved.**

<b>76.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Panacea Pharmaceuticals. Plot. No. 4, Street No. S-6, National Industrial zone Rawat, Islamabad</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26505: 02-11-2023
	Details of fee submitted	PKR 75,000/- : 06-10-2023
	The proposed proprietary name / brand name	<b>PANOMER 500mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 500mg
Registration Board meeting	312

**Decision: Approved.**

<b>77.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Panacea Pharmaceuticals. Plot. No. 4, Street No. S-6, National Industrial zone Rawat, Islamabad</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26504: 02-11-2023
Details of fee submitted	PKR 75,000/- : 06-10-2023
The proposed proprietary name / brand name	<b>PANOMER 1g IV Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...1g
Pharmacotherapeutic Group of (API)	Antibiotic
Reference to Finished product specifications	USP
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Merrem Injection by Global
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 1g
Registration Board meeting	312

#### Decision: Approved.

<b>78.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26503: 02-11-2023
	Details of fee submitted	PKR 75,000/- : 05-10-2023
	The proposed proprietary name / brand name	<b>PINEM 500mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-

		4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 500mg	
Registration Board meeting	312	

**Decision: Approved.**

<b>79.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>
	Name, address of Manufacturing site.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26502: 02-11-2023
	Details of fee submitted	PKR 75,000/- : 05-10-2023
	The proposed proprietary name / brand name	<b>PINEM 1g IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad
Brand Name	DEWNEM Injection 1g
Registration Board meeting	312

**Decision: Approved.**

<b>80.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22764: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-BACTUM 1gm Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium...500mg Sulbactam as Sodium...500mg
	Pharmacotherapeutic Group of (API)	Antibiotic

Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	PMDA
For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	CEBACTUM 1gm Injection
Registration Board meeting	326

#### Decision: Approved.

<b>81.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22765: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-BACTUM 2gm Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium...1g Sulbactam as Sodium...1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., <b>Bulgaria:</b> Sulcef 1g/1g powder for solution for injection <b>Lithuania:</b> Sulcef 1g/1g powder for solution for injection <b>Slovakia:</b> Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	CEBACTUM 2gm Injection
Registration Board meeting	326

#### Decision: Approved.

<b>82.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>								
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27867: 30-11-2023								
	Details of fee submitted	PKR 75,000/- : 13-11-2023								
	The proposed proprietary name / brand name	<b>VOPRA 10mg Tablet</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan fumarate eq. to Vonoprazan .....10mg								
	Pharmacotherapeutic Group of (API)	Antiulcer								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	PMDA								
	For generic drugs (me-too status)	Vonozan Tablet by M/s Getz								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.</td> </tr> <tr> <td>Brand Name</td> <td>KALSEPH 10mg tablet</td> </tr> <tr> <td>Registration Board meeting</td> <td>322</td> </tr> </table>			Applicant firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.	Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.	Brand Name	KALSEPH 10mg tablet	Registration Board meeting	322
Applicant firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.									
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.									
Brand Name	KALSEPH 10mg tablet									
Registration Board meeting	322									
<b>Decision: Approved.</b>										
<b>83.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pine Pharmaceuticals. Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat</b>								
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27868: 30-11-2023								
	Details of fee submitted	PKR 75,000/- : 13-11-2023								
	The proposed proprietary name / brand name	<b>VOPRA 20mg Tablet</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan fumarate eq. to Vonoprazan .....20mg								
	Pharmacotherapeutic Group of (API)	Antiulcer								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	PMDA								
	For generic drugs (me-too status)	Vonozan Tablet by M/s Getz								

	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Brand Name	KALSEPH 20mg tablet
	Registration Board meeting	322
<b>Decision: Approved.</b>		
<b>84.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22757: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-D3 Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Cholecalciferol.....5 mg
	Pharmacotherapeutic Group of (API)	Vitamin D
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	ANSM France
	For generic drugs (me-too status)	Indrop D Injection by Neutro
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Manufacturer firm	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Brand Name	CARA-D3 5mg/1ml
	Registration Board meeting	326
<b>Decision: Approved.</b>		
<b>85.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22758: 15-09-2023
Details of fee submitted	PKR 75,000/- : 13-07-2023
The proposed proprietary name / brand name	<b>Q-FER Injection 100mg/5ml</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Ampoule Contains: Iron Sucrose Eq. to Elemental Iron...100mg
Pharmacotherapeutic Group of (API)	Iron
Reference to Finished product specifications	BP
The status in reference regulatory authorities	TGA
For generic drugs (me-too status)	Venofer 100 mg/5ml by M/s RG
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
Manufacturer firm	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
Brand Name	Iron Sucrose 100mg/5ml injection
Registration Board meeting	321

#### Decision: Approved.

<b>86.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22761: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>ESS-OMGE 40mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole as Sodium...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Nexum Injection by Getz
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Ezole 40mg Dry powder Vial

Registration Board meeting		327
<b>Decision: Approved.</b>		
87.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22760: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>OMGE 40mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole as Sodium...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Risek Injection by Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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		Ozole 40mg dry powder vial IV
Registration Board meeting		322
<b>Decision: Approved.</b>		
88.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22756: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-TORO 30mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Ketorolac Tromethamine...30mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory agent, non-steroid
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MRA



	For generic drugs (me-too status)	Toradol Injection by M/s Barrett Hodgson
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Asian Continental (Pvt) Ltd., D/32 SITE Super Highway Karachi.
	Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name	Vintera 30mg/ml Injection
	Registration Board meeting	320
<b>Decision: Approved.</b>		
<b>89.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22767: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-SET 4mg/2ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Ondansetron as Hcl Dihydrate...4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Onset Injection by M/s Pharmedic
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Applicant firm	M/s Asian Continental (Pvt) Ltd., D/32 SITE Super Highway Karachi.
	Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name	Stawia 4mg/2ml injection
	Registration Board meeting	326
<b>Decision: Approved.</b>		
<b>90.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer

	<input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22768: 15-09-2023
Details of fee submitted	PKR 75,000/- : 13-07-2023
The proposed proprietary name / brand name	<b>Q-SET 8mg/4ml Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule Contains: Ondansetron as Hcl Dihydrate...8mg
Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
Reference to Finished product specifications	USP
The status in reference regulatory authorities	MRA
For generic drugs (me-too status)	Onset Injection by M/s Pharmedic
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Asian Continental (Pvt) Ltd., D/32 SITE Super Highway Karachi.
Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
Brand Name	Stawia 8mg/4ml injection
Registration Board meeting	326

#### Decision: Approved.

<b>91.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Estate Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22766: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>Q-SET 4mg/5ml Syrup</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl Dihydrate...4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Onset Syrup by M/s Pharmedic
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Applicant firm	M/s Asian Continental (Pvt) Ltd., D/32 SITE Super Highway Karachi.
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Manufacturer firm	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
Brand Name	Stawia 4mg/5ml Syrup
Registration Board meeting	326

**Decision: Approved.**

<b>92.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25530: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDIZEK 40mg Dry Powder</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole as Sodium...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Risek Injection by Getz
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Ozole 40mg dry powder vial IV
Registration Board meeting	322

**Decision: Approved.**

<b>93.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25528: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDEXUM 40mg Dry Powder Vial</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole as Sodium...40mg

	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MRA
	For generic drugs (me-too status)	Nexum Injection by Getz
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Ezole 40mg Dry powder Vial
Registration Board meeting	327

**Decision: Approved.**

<b>94.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25534: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>SUN-D3 5mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Cholecalciferol.....5mg
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	ANSM France
	For generic drugs (me-too status)	Indrop D Injection by Neutro
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	V-Drop 5mg/ml Injection
Registration Board meeting	323

**Decision: Approved.**

<b>95.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
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Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25527: 23-10-2023
Details of fee submitted	PKR 75,000/- : 27-09-2023
The proposed proprietary name / brand name	<b>MEDEKOLINE 1gm/4ml Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Contains: Citicoline as Sodium...1gm
Pharmacotherapeutic Group of (API)	Psychostimulant and nootropic
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	AIFA Italy
For generic drugs (me-too status)	Citolin injection by M/s Global Pharma
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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
Registration Board meeting	323

#### Decision: Approved.

<b>96.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25549: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>COLIMED 34mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colisitmethate Sodium (1 M.I.U) Eq. to Colistin Base Activity...34mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Colistim Injection by Biocare
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 1 MIU powder for injection
Registration Board meeting	323

**Decision: Approved.**

<b>97.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25549: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>COLIMED 68mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colisitmethate Sodium (2 MIU) Eq. to Colistin Base Activity...68mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Colistim Injection by Biocare
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 2 MIU powder for injection
Registration Board meeting	323

**Decision: Approved.**

<b>98.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25551: 23-10-2023
Details of fee submitted	PKR 75,000/- : 27-09-2023
The proposed proprietary name / brand name	<b>COLIMED 150mg Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colisitmethate Sodium (4.5 MIU) Eq. to Colistin Base Activity...150mg
Pharmacotherapeutic Group of (API)	Antibiotic
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Colistim Injection by Biocare
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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 4.5 MIU powder for injection
Registration Board meeting	323

#### Decision: Approved.

<b>99.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25533: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>DECLOFAN 75mg/3ml Solution for Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Diclofenac Sodium...75mg/3ml
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Dicloran Injection by Sami
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Fanak 75mg/mL Solution for Injection
	Registration Board meeting	322

**Decision: Approved.**

100.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25526: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MED-SPA 40mg/2ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Drotaverine HCl Eq. to Drotaverine...40mg
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Approved in 3 European countries (Hungary, Romania, Bulgaria)
	For generic drugs (me-too status)	No-spa Injection by M/s Snofi pharma
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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
Registration Board meeting	323

**Decision: Approved.**

101.	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25532: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>IROSUC 100mg/5ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains:



		Iron III Hydroxide Sucrose Complex Eq. to Elemental Iron...100mg
	Pharmacotherapeutic Group of (API)	Anti-anaemic
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	TGA Australia
	For generic drugs (me-too status)	Venofer Injection by M/s OBS
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Iron Plus 100mg/5ml Injection
Registration Board meeting	323

**Decision: Approved.**

<b>102.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25531: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>KATORLAK 30mg/ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Ketorolac Tromethamine...30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Toradol injection by Martin Dow
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. 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	Ketorol 30mg/ml injection
Registration Board meeting	323

**Decision: Approved.**

<b>103.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>								
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25529: 23-10-2023								
	Details of fee submitted	PKR 75,000/- : 27-09-2023								
	The proposed proprietary name / brand name	<b>MEDECOBAL 500mcg/ml Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Mecobalamin...500mcg								
	Pharmacotherapeutic Group of (API)	Vitamin B12								
	Reference to Finished product specifications	Innovator's								
	The status in reference regulatory authorities	PMDA								
	For generic drugs (me-too status)	Biocobal Injection by Surge Laboratories								
	Proposed Pack size	As per SRO								
<b>Evaluation by PEC<sup>3</sup>:</b>										
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:										
<table border="1"> <tr> <td>Applicant firm</td> <td>M/s May &amp; Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td> </tr> <tr> <td>Manufacturer firm</td> <td>M/s May &amp; Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore</td> </tr> <tr> <td>Brand Name</td> <td>Co-min 500mcg/ml Injection</td> </tr> <tr> <td>Registration Board meeting</td> <td>321</td> </tr> </table>			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	Co-min 500mcg/ml Injection	Registration Board meeting	321
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	Co-min 500mcg/ml Injection									
Registration Board meeting	321									
<b>Decision: Approved.</b>										
<b>104.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>								
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore								
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)								
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25547: 23-10-2023								
	Details of fee submitted	PKR 75,000/- : 27-09-2023								
	The proposed proprietary name / brand name	<b>MEDERON 4mg/2ml Injection</b>								
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ondansetron as Hydrochloride dihydrate ..... 4mg								
	Pharmacotherapeutic Group of (API)	Anti-emetics								
	Reference to Finished product specifications	USP								
	The status in reference regulatory authorities	MHRA								

	For generic drugs (me-too status)	ONSET Injection by M/s Pharmedic
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Inset 4mg/2ml Injection
	Registration Board meeting	321
<b>Decision: Approved.</b>		
<b>105.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25548: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDERON 8mg/4ml Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ondansetron as Hydrochloride dihydrate .....8mg
	Pharmacotherapeutic Group of (API)	Anti-emetics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	ONSET Injection by M/s Pharmedic
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Inset 8mg/4ml Injection
	Registration Board meeting	321
<b>Decision: Approved.</b>		
<b>106.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25535: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDYCIN 500mg Dry Powder injection</b>

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Vancomycin HCl Eq. to Vancomycin...500mg
Pharmacotherapeutic Group of (API)	Antibacterial
Reference to Finished product specifications	USP
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Cinva Injection by CCL
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Myocin 500mg Dry Powder vial I.V
Registration Board meeting	324

#### Decision: Approved.

<b>107.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25536: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDYCIN 1g Dry Powder injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Vancomycin HCl Eq. to Vancomycin...1g
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Cinva Injection by CCL
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Myocin 1g Dry Powder vial I.V
Registration Board meeting	324

#### Decision: Approved.

<b>108.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25545: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>WATER FOR INJECTION 5ml</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Water for Injection...5ml
	Pharmacotherapeutic Group of (API)	Solvent/ Diluent
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Water for injection by Vision pharma
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	WFI 5 ml Injection
	Registration Board meeting	322
<b>Decision: Approved.</b>		
<b>109.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s May & Baker (Pvt) Ltd. 45-km Dina Nath, Multan Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25546: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>WATER FOR INJECTION 10ml</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Water for Injection...10ml
	Pharmacotherapeutic Group of (API)	Solvent/ Diluent
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Water for injection by Vision pharma
	Proposed Pack size	As per SRO
	<b>Evaluation by PEC<sup>3</sup>:</b>	
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	WFI 10 ml Injection
	Registration Board meeting	322
<b>Decision: Approved.</b>		
<b>110.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore

Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20794: 23-08-2023
Details of fee submitted	PKR 75,000/- : 17-07-2023
The proposed proprietary name / brand name	<b>DEFLU 0.5mg/ml Syrup</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Desloratadine...0.5mg
Pharmacotherapeutic Group of (API)	Antihistamines -H1 antagonists
Reference to Finished product specifications	Innovator's
The status in reference regulatory authorities	AEMPS Spain
For generic drugs (me-too status)	Desora Syrup of Continental Pharma
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	VARIDINE SYRUP
Registration Board meeting	297

#### Decision: Approved.

<b>111.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22597: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 26-07-2023
	The proposed proprietary name / brand name	<b>SYLOC 50mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lacosamide.....50 mg
	Pharmacotherapeutic Group of (API)	Other Anti-epileptics
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Lalap Tablet by Genix Pharma
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Warner 50 mg tablet
Registration Board meeting	326

#### Decision: Approved.

<b>112.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>				
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore				
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)				
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22598: 14-09-2023				
	Details of fee submitted	PKR 75,000/- : 26-07-2023				
	The proposed proprietary name / brand name	<b>SYLOC 100mg Tablet</b>				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lacosamide.....100 mg				
	Pharmacotherapeutic Group of (API)	Other Anti-epileptics				
	Reference to Finished product specifications	Innovator's				
	The status in reference regulatory authorities	USFDA				
	For generic drugs (me-too status)	Lalap Tablet by Genix Pharma				
	Proposed Pack size	As per SRO				
<b>Evaluation by PEC<sup>3</sup>:</b>						
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:						
<table border="1"> <tr> <td>Brand Name</td> <td>Warner 100 mg tablet</td> </tr> <tr> <td>Registration Board meeting</td> <td>326</td> </tr> </table>			Brand Name	Warner 100 mg tablet	Registration Board meeting	326
Brand Name	Warner 100 mg tablet					
Registration Board meeting	326					
<b>Decision: Approved.</b>						
<b>113.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone, Sheikhpura Road, Lahore</b>				
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore				
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)				
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22599: 14-09-2023				
	Details of fee submitted	PKR 75,000/- : 19-07-2023				
	The proposed proprietary name / brand name	<b>HIGHZOLE 20mg Capsule</b>				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Enteric Coated Pellets...20mg				
	Pharmacotherapeutic Group of (API)	PPI				
	Reference to Finished product specifications	USP				
	The status in reference regulatory authorities	USFDA				
	For generic drugs (me-too status)	Risek Capsule by Getz				
	Proposed Pack size	As per SRO				
<b>Evaluation by PEC<sup>3</sup>:</b>						
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:						

Brand Name	Gosoft 20mg Capsule
Registration Board meeting	329

**Decision: Approved.**

<b>114.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone,Sheikhupura Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22599: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 19-07-2023
	The proposed proprietary name / brand name	<b>HIGHZOLE 40mg Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Enteric Coated Pellets...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Risek Capsule by Getz
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Gosoft 40mg Capsule
Registration Board meeting	329

**Decision: Approved.**

<b>115.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22596: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 04-09-2023
	The proposed proprietary name / brand name	<b>OMJET 40mg Capsule</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Enteric Coated Pellets...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Risek Capsule by Getz



	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Gosoft 40mg Capsule
	Registration Board meeting	329
<b>Decision: Approved.</b>		
<b>116.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s High-Cure Research Laboratories. 19-Km Tayyaba Industrial Zone, Sheikhupura Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21409: 30-08-2023
	Details of fee submitted	PKR 75,000/- : 19-07-2023
	The proposed proprietary name / brand name	<b>S-INSTA 40/1680 mg Sachet Powder for Oral Suspension</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole...40mg Sodium Bicarbonate...1680mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Risek insta sachet by Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Faast 40mg/1680mg Sachet for oral suspension
	Registration Board meeting	307
<b>Decision: Approved.</b>		
<b>117.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20793: 23-08-2023
	Details of fee submitted	PKR 75,000/- : 26-07-2023
	The proposed proprietary name / brand name	<b>S-INSTA 20/1680 mg Sachet Powder for Oral Suspension</b>

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole...20mg Sodium Bicarbonate...1680mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Risek insta sachet by Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Faast 20mg/1680mg Sachet for oral suspension
	Registration Board meeting	307
<b>Decision: Approved.</b>		
<b>118.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20792: 23-08-2023
	Details of fee submitted	PKR 75,000/- : 26-07-2023
	The proposed proprietary name / brand name	<b>S-INSTA 40/1680 mg Sachet Powder for Oral Suspension</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole...40mg Sodium Bicarbonate...1680mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Risek insta sachet by Getz
		Proposed Pack size
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Faast 40mg/1680mg Sachet for oral suspension
	Registration Board meeting	307
<b>Decision: Approved.</b>		
<b>119.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer

	<input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20793: 23-08-2023
Details of fee submitted	PKR 75,000/- : 26-07-2023
The proposed proprietary name / brand name	<b>ORNDAN 4mg/5ml Syrup</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as HCl Dihydrate...4mg
Pharmacotherapeutic Group of (API)	Antiemetic
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Zofran Syrup by GSK
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	ONDATRO Syrup 4mg/5ml
Registration Board meeting	317

**Decision: Approved.**

<b>120.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 &amp; A-256 to A-259, H.I.T.E. Lasbela Balochistan</b>
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27029: 15-11-2023
	Details of fee submitted	PKR 75,000/- : 06-10-2023
	The proposed proprietary name / brand name	<b>SUNCELL 5mg/ml injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Cholecalciferol.....5mg
	Pharmacotherapeutic Group of (API)	Vitamin D
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	ANSM France
	For generic drugs (me-too status)	Indrop D Injection by Neutro
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Care-D 5mg/ml Injection
Registration Board meeting	316

**Decision: Approved.**

<b>121.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
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	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25537: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>DORIPAN 250mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Anhydrous Doripenem...250mg
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Ronim Injection by M/s Genix
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Dori-F Injection
	Registration Board meeting	323
<b>Decision: Approved.</b>		
<b>122.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25538: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>DORIPAN 500mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Anhydrous Doripenem...500mg
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Ronim Injection by M/s Genix
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		

	Brand Name	Dori-F Injection
	Registration Board meeting	323

**Decision: Approved.**

<b>123.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25541: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDIPENEM 500mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...500mg
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Mero-F 500mg Injection
Registration Board meeting	323

**Decision: Approved.**

<b>124.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25542: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>MEDIPENEM 1g IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem Trihydrate Eq. to Meropenem...1g
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global

	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Mero-F 1000mg Injection
	Registration Board meeting	323
<b>Decision: Approved.</b>		
<b>125.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22762: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>PIPTAZ 2.25gm Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin as Sodium...2gm Tazobactam as Sodium...0.25gm
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Tanzo Injection by M/s Bosch
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Fletazo Injection 2.25g
	Registration Board meeting	323
<b>Decision: Approved.</b>		
<b>126.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22763: 15-09-2023
	Details of fee submitted	PKR 75,000/- : 13-07-2023
	The proposed proprietary name / brand name	<b>PIPTAZ 2.25gm Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin as Sodium...4gm Tazobactam as Sodium...0.5gm

Pharmacotherapeutic Group of (API)	Antibiotics
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Tanzo Injection by M/s Bosch
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Fletazo Injection 4.5g
Registration Board meeting	323

**Decision: Approved.**

<b>127.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25543: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>TANZOMED 2.25gm Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin as Sodium...2gm Tazobactam as Sodium...0.25gm
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Tanzo Injection by M/s Bosch
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Fletazo Injection 2.25g
Registration Board meeting	323

**Decision: Approved.**

<b>128.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25544: 23-10-2023
Details of fee submitted	PKR 75,000/- : 27-09-2023
The proposed proprietary name / brand name	<b>TANZOMED 4.5gm Injection</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Piperacillin as Sodium...4gm Tazobactam as Sodium...0.5gm
Pharmacotherapeutic Group of (API)	Antibiotics
Reference to Finished product specifications	USP
The status in reference regulatory authorities	USFDA
For generic drugs (me-too status)	Tanzo Injection by M/s Bosch
Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Fletazo Injection 4.5g
Registration Board meeting	323

#### Decision: Approved.

<b>129.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25539: 23-10-2023
	Details of fee submitted	PKR 75,000/- : 27-09-2023
	The proposed proprietary name / brand name	<b>EGMENTAN 500mg/100mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Amoxicillin as Sodium...500mg Clavulanic Acid as Potassium Clavulanate...100mg
	Pharmacotherapeutic Group of (API)	Antibiotics
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Calamox Injection by Bosch Pharma
	Proposed Pack size	As per SRO

#### Evaluation by PEC<sup>3</sup>:

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Flementin Injection
Registration Board meeting	324

#### Decision: Approved.



<b>130.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Medella Pharmaceuticals Pvt Ltd. Plot No 569/570, Sundar Industrial Estate, Raiwind Road Lahore</b>				
	Name, address of Manufacturing site.	M/s Fleming Pharmaceuticals Pvt Ltd. 23 Km, Sheikhpura Road, Lahore				
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)				
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25540: 23-10-2023				
	Details of fee submitted	PKR 75,000/- : 27-09-2023				
	The proposed proprietary name / brand name	<b>EGMENTAN 1000mg/200mg Injection</b>				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Amoxicillin as Sodium...1000mg Clavulanic Acid as Potassium Clavulanate...200mg				
	Pharmacotherapeutic Group of (API)	Antibiotics				
	Reference to Finished product specifications	BP				
	The status in reference regulatory authorities	MHRA				
	For generic drugs (me-too status)	Calamox Injection by Bosch Pharma				
	Proposed Pack size	As per SRO				
<b>Evaluation by PEC<sup>3</sup>:</b>						
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:						
<table border="1"> <tr> <td>Brand Name</td> <td>Flementin Injection</td> </tr> <tr> <td>Registration Board meeting</td> <td>324</td> </tr> </table>			Brand Name	Flementin Injection	Registration Board meeting	324
Brand Name	Flementin Injection					
Registration Board meeting	324					
<b>Decision: Approved.</b>						

<b>131.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore</b>
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20950: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023
	The proposed proprietary name / brand name	<b>VONMA 10mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate...10mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Vonozan Tablet by M/s Getz
	Proposed Pack size	As per SRO

<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Brand Name	Vonozen 10mg Tablet	
Registration Board meeting	308	
<b>Decision: Approved.</b>		
<b>132.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore</b>
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20951: 24-08-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023
	The proposed proprietary name / brand name	<b>VONMA 20mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate...20mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Vonozan Tablet by M/s Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
Brand Name	Vonozen 20mg Tablet	
Registration Board meeting	308	
<b>Decision: Approved.</b>		
<b>133.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhpura</b>
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26500: 02-11-2023
	Details of fee submitted	PKR 75,000/- : 06-09-2023
	The proposed proprietary name / brand name	<b>PENRO 500mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...500mg
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA

	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Ropen (Meropenem) 500mg injection
	Registration Board meeting	323
<b>Decision: Approved.</b>		
<b>134.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhpura</b>
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26501: 02-11-2023
	Details of fee submitted	PKR 75,000/- : 06-09-2023
	The proposed proprietary name / brand name	<b>PENRO 1000mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...1000mg
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
	<b>Evaluation by PEC<sup>3</sup>:</b>	
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Ropen 1g Injection
	Registration Board meeting	323
<b>Decision: Approved.</b>		
<b>135.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK</b>
	Name, address of Manufacturing site.	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19296: 03-08-2023
	Details of fee submitted	PKR 75,000/- : 05-06-2023
	The proposed proprietary name / brand name	<b>LOPENEM 500mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...500mg

	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	MENEPOR 500 mg Injection IV
	Registration Board meeting	296
<b>Decision: Approved.</b>		
<b>136.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK</b>
	Name, address of Manufacturing site.	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19289: 03-08-2023
	Details of fee submitted	PKR 75,000/- : 05-06-2023
	The proposed proprietary name / brand name	<b>LOPENEM 1g IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...1g
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	MENEPOR 1g Injection IV
	Registration Board meeting	296
<b>Decision: Approved.</b>		
<b>137.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad</b>
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24773: 11-10-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023

	The proposed proprietary name / brand name	<b>MEROMAG 500mg Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...500mg
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	RONEM 500 mg Injection IV
	Registration Board meeting	307
<b>Decision: Approved.</b>		
<b>138.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad</b>
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24772: 11-10-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023
	The proposed proprietary name / brand name	<b>MEROMAG 1g Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate...1g
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA
	For generic drugs (me-too status)	Merrem Injection by Global
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	RONEM 1gm Injection IV
	Registration Board meeting	307
<b>Decision: Approved.</b>		
<b>139.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore</b>
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)

Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22056: 07-09-2023
Details of fee submitted	PKR 75,000/- : 08-08-2023
The proposed proprietary name / brand name	<b>MICROGIN 500mg/100ml Infusion</b>
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Metronidazole...500mg
Pharmacotherapeutic Group of (API)	Nitro-imidazole Antimicrobials
Reference to Finished product specifications	BP
The status in reference regulatory authorities	MHRA
For generic drugs (me-too status)	Flagyl Infusion of Sanofi Aventis
Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	MetroWel Infusion
Registration Board meeting	333

**Decision: Approved.**

<b>140.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Simz Pharmaceuticals Pvt Ltd. Plot No. 574-575, Punjab Industrial Estate, Lahore</b>
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhpura
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21182: 28-08-2023
	Details of fee submitted	PKR 75,000/- : 07-07-2023
	The proposed proprietary name / brand name	<b>SIMESO 40mg IV Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Esomeprazole Sodium Eq. to Esomeprazole...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Nexum Injection of Getz
	Proposed Pack size	As per SRO

**Evaluation by PEC<sup>3</sup>:**

The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Esovar 40mg Injection
Registration Board meeting	312

**Decision: Approved.**

<b>141.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Simz Pharmaceuticals Pvt Ltd. Plot No. 574-575, Punjab Industrial Estate, Lahore</b>
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	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhpura
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21183: 28-08-2023
	Details of fee submitted	PKR 75,000/- : 07-07-2023
	The proposed proprietary name / brand name	<b>OMEPSA 40mg IV Lyophilized Injection</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole Sodium Eq. to Omeprazole...40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA
	For generic drugs (me-too status)	Risek Injection of Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Varizole 40mg Injection
	Registration Board meeting	312
<b>Decision: Approved.</b>		
<b>142.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore</b>
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27743: 28-11-2023
	Details of fee submitted	PKR 75,000/- : 27-10-2023
	The proposed proprietary name / brand name	<b>VONOZEN 10mg Tablet</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate...10mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	PMDA
	For generic drugs (me-too status)	Vonozen Tablet by M/s Getz
	Proposed Pack size	As per SRO
<b>Evaluation by PEC<sup>3</sup>:</b>		
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:		
	Brand Name	Vonozen 10mg Tablet
	Registration Board meeting	308

<b>Decision: Approved.</b>						
<b>143.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</b>				
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar				
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)				
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25787: 25-10-2023				
	Details of fee submitted	PKR 75,000/- : 31-07-2023				
	The proposed proprietary name / brand name	<b>PRUKEN 1mg Tablet</b>				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate...1mg				
	Pharmacotherapeutic Group of (API)	Selective, high affinity serotonin (5-HT4) receptor agonist				
	Reference to Finished product specifications	Innovator's				
	The status in reference regulatory authorities	EMA Approved				
	For generic drugs (me-too status)	Prutide Tablet by CCL				
	Proposed Pack size	As per SRO				
<b>Evaluation by PEC<sup>3</sup>:</b>						
The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:						
<table border="1"> <tr> <td>Brand Name</td> <td>Tablet Pruco 1 mg</td> </tr> <tr> <td>Registration Board meeting</td> <td>330</td> </tr> </table>			Brand Name	Tablet Pruco 1 mg	Registration Board meeting	330
Brand Name	Tablet Pruco 1 mg					
Registration Board meeting	330					
<b>Decision: Approved.</b>						
<b>144.</b>	<b>Name, address of Applicant / Marketing Authorization Holder</b>	<b>M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK</b>				
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar				
	Status of the applicant	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Is involved in none of the above (contract giver)				
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25788: 25-10-2023				
	Details of fee submitted	PKR 75,000/- : 31-07-2023				
	The proposed proprietary name / brand name	<b>PRUKEN 2mg Tablet</b>				
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate...2mg				
	Pharmacotherapeutic Group of (API)	Selective, high affinity serotonin (5-HT4) receptor agonist				
	Reference to Finished product specifications	Innovator's				
	The status in reference regulatory authorities	EMA Approved				
	For generic drugs (me-too status)	Prutide Tablet by CCL				
	Proposed Pack size	As per SRO				
<b>Evaluation by PEC<sup>3</sup>:</b>						



The applied product to be manufactured by the contract manufacturer has already been approved by Registration Board. The details of the already approved product are as follows:

Brand Name	Tablet Pruco 2 mg
Registration Board meeting	330

**Decision: Approved.**

#### Agenda Item: Short availability Molecules

DRAP Authority in its 184<sup>th</sup> dated 26<sup>th</sup> June 2024 decided as under;

The Authority in light of information received from CALSD decided that registration applications of lipid emulsion shall be considered out of queue by the Registration Board in order to ensure the availability of the products in the market.”

#### Agenda of Evaluator Adil Saeed

<b>145.</b>	<b>Name, address of Applicant / Importer</b>	<b>M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan.</b>
	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 a Distributor.
	Name and address of marketing authorization holder (abroad)	Xi'an Libang Pharmaceutical Co., Ltd. West door outside , Guo Town, Chengcang District, Baoji City Shannxi China.
	Name, address of manufacturer(s)	Xi'an Libang Pharmaceutical Co., Ltd. West door outside , Guo Town, Chengcang District, Baoji City Shannxi China.
	Name of exporting country	China.
	Status of the applicant	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Importer <input type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: J7P-65P-S8PH: 08.03.2024
	Details of fee submitted	PKR 150,000/- slip No. 0548151883 PKR 150,000/- slip No. 674610235856
	The proposed proprietary name / brand name	<b>LIPOSOLE (MCT/LCT 20% Fat Emulsion Injection)</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml glass bottle contains; soybean oil .....100mg/mL Medium-Chain Triglycerides.....100mg/mL
	Pharmacotherapeutic Group of (API)	Fat Emulsion (Solution for parenteral nutrition) ATC Code: B05BA02.
	Reference to Finished product specifications	As per Innovators Specification
	The status in reference regulatory authorities	Lipofundin MCT/LCT 20 %, emulsion for infusion MHRA Approved.
	For generic drugs (me-too status)	Lipofundin MCT/LCT 20 %, emulsion for infusion Reg No. 011084
	Proposed Pack size	1's
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	<b>CoPP:</b> Firm has uploaded CoPP (No. 20230036) dated 26.10.2023, valid till 25.10.2025 issued by Shaanxi Medical Products Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer. (Verifiable online) For product Medium and Long Chain Fat Emulsion Injection (C8-24Ve) 250ml 20%.

	Details of letter of authorization / sole agency agreement	Firm has uploaded Distribution Certificate between Xian LiBang Pharmaceutical Co Ltd. No. 22, Keji Yi Road, Xian Hi-Tech Industrial Development Zone, Xian City, Shaanxi China and M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Valid till 30.10.2028. For product Medium and Long Chain Fat Emulsion Injection (C8-24Ve) 250ml 20%.
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**Evaluation by PEC (IX):**

1. Why stability of drug product is not done as per conditions of Zone Iva?
2. COPP and letter of authorization uploaded are not legalized.

S. No.	Observation	Reply
1	Why stability of drug product is not done as per conditions of Zone Iva?	Stability data submitted as per conditions of Zone Iva.
2	COPP and letter of authorization uploaded are not legalized.	Firm has submitted following response; “For the Letter of Authorization, we have attached a copy that has been attested by the China Council for the Promotion of International Trade (CCPIT). The original document will be submitted in hard copy as soon as possible.  Regarding the Certificate of Pharmaceutical Product (COPP), we have submitted the electronic version (e-COPP) with the certificate number: 20230036, which is valid until October 25, 2025. This certificate can be verified directly from the National Medical Products Administration (NMPA) database using the following link: <a href="http://english.nmpa.gov.cn/database.html">http://english.nmpa.gov.cn/database.html</a> Since this certificate can be verified online, we believe there is no need for additional legalization.”

Details of COPP verified online:

Can be verified from official website of NMPA.( [NMPA Database](#))

Certificate No. shaanxi20230036

Image of certificate on web database is given below;

Certificate NO	No.Shaanxi20230036
证明类别	已在中国批准上市药品
Certificate Classification	Pharmaceutical Product Approved in China
产品名称	中/长链脂肪乳注射液 (C8-24Ve)
Name of Product	Medium and Long Chain Fat Emulsion Injection(C8-24Ve) ; Injection
剂型	注射剂
Dosages Form of the Product	Injection
规格	250ml 20%
Strength	250ml 20%
商品名	力邦特
Trade Name	LBT
产品批准文号	国药准字H20123433
Number of product license (DMF number)	Approved No.: H20123433
批准(备案)时间	2022-08-02
Date of Issue	Aug.02,2022
该药品规格是否获得许可可在中国市场上使用	是
Is this product strength licensed to be placed on the market for use in China	YES
药品生产企业或者药品上市许可持有人名称	西安力邦制药有限公司
Name of Manufacturer or Product-license Holder	Xi'an Libang Pharmaceutical Co., Ltd.

**Decision: The Board decided to approve as per policy for inspection abroad.  
The firm will present the attested original Distribution Certificate/ Letter of Authorization.**

146.	Name, address of Applicant / Importer	M/s Otsuka Pakistan Limited. F/4-9, H.I.T.E., Hub, Balochistan.
	Details of Drug Sale License of importer	License No: Address: Address of Godown: Status:
	Name and address of marketing authorization holder (abroad)	Guangdong Otsuka Pharmaceutical Co., Ltd. High & New Technology Industries Development Area, Ronggui Street, Shunde District, Foshan City, Guangdong Province, P.R.China.
	Name, address of manufacturer(s)	Guangdong Otsuka Pharmaceutical Co., Ltd. High & New Technology Industries Development Area, Ronggui Street, Shunde District, Foshan City, Guangdong Province, P.R.China.
	Name of exporting country	China.
	Status of the applicant	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Importer <input type="checkbox"/> Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: BE3-5UL-B4Z7: 15.05.2024
	Details of fee submitted	PKR 150,000/- slip No. 44985613 PKR 150,000/- slip No. 507520662
	The proposed proprietary name / brand name	<b>FATOLIP 250ml Injection.</b>
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	<b>Each 250ml HDPE Bottle contains;</b> soybean oil .....25g Medium-Chain Triglycerides.....25g

Pharmacotherapeutic Group of (API)	Fat Emulsion (Solution for parenteral nutrition) ATC Code: B05BA02.
Reference to Finished product specifications	As per Innovators Specification
The status in reference regulatory authorities	Lipofundin MCT/LCT 20 %, emulsion for infusion MHRA Approved.
For generic drugs (me-too status)	Lipofundin MCT/LCT 20 %, emulsion for infusion Reg No. 011084
Proposed Pack size	1's
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	<b>CoPP:</b> Firm has uploaded CoPP (No. Guangdong20230255) dated 13.09.2023, valid till 25.09.2025 issued by Guangdong Medical Products Administration. The certificate confirms the free sale status of the product along with GMP status of the manufacturer. (Verifiable online) For product Medium and Long Chain Fat Emulsion Injection (C8-24Ve) 250ml
Details of letter of authorization / sole agency agreement	Firm has uploaded Letter of Authorization between Guangdong Otsuka Pharmaceutical Co. Ltd. and Otsuka Pakistan Limited. Valid till 30.10.2028. For product Medium and Long Chain Fat Emulsion Injection (C8-24Ve), dated 06.05.2024.

#### **Evaluation by PEC (IX):**

1. Dossier is submitted for both strengths 100ml and 250ml. The firm has stated that their 250ml strength may be considered and fee should also be considered for it.
2. Application is submitted from DML No. 000281 account. Fee is submitted from same DML no. 000281, whereas applied product is imported. Firm has attached copy of DSL also.
3. Copy of DSL uploaded is not readable.
4. Container closure system is different than the innovator product.
5. Copy of executed BMR of trial batches are not attached.
6. Why stability of drug product is not done as per conditions of Zone IVa?
7. Supporting data like chromatograms are not provided in 3.2.P.5 Validation of analytical procedures neither in stability studies data 3.2.P.8
8. COPP and letter of authorization uploaded are not legalized.

**Decision: The board was informed that deficiencies have been communicated to the firm. The board deferred the case for submission of reply to communicated deficiencies.**

## **Registration-II**

### **Case No. 01: M/s. Venus Pharma 23 Km Multan Road Lahore.**

Assistant Registrar (Writ-I), Lahore High Court, Lahore vide letter dated 15-06-2024 has enclosed order sheet of Lahore High Court, Lahore in W.P No. 37766/2024 dated 13.06.2024 filed by M/s. Venus Pharma 23 Km Multan Road Lahore Vs Federation of Pakistan & others. The Honorable court has ordered as under:

*"It is contended by learned counsel that petitioner's application for renewal of registration is pending before respondent No. 03, but the same is not being taken up for decision and in the meanwhile, respondent-Deptt has started taking conceive measures against petitioner. Further submits that he would be satisfied if a direction is issued to respondent No.03 to decide pending application strictly in accordance with law and keeping in view order issued on 01-02-2023, by the Drugs Appellate Board in its 163<sup>rd</sup> Sitting Held on 20<sup>th</sup> December, 2022.*

*2. When confronted, learned Law Officer has expressed no objection on disposal of this petition as requested by learned counsel for petitioner.*

3. In view of above, I am inclined to dispose of this petition while directing respondent No.03 to decide pending application strictly in accordance with law and keeping in view above referred order dated 01-02-2023, after hearing petitioner and all concerned, through speaking order withing a period of fifteen days from the date of receipt of certified copy of this order.”

Registration Board in its various meetings has considered the case *Registration Status of Formulations (Diclofenac Potassium 75mg & 100mg and Famotidine 10mg/5ml)* not approved by Reference Regulatory Authorities & Previous Decisions Taken by the Registration Board in its 250<sup>th</sup> & 258<sup>th</sup> and finally in its 317<sup>th</sup> meeting held on 16-17 May, 2022 decided as under:

**Decision of 317<sup>th</sup> meeting:**

In light of the foregoing discussions, risk-benefit analysis and public health impact of Diclofenac Potassium 75mg and 100mg, the Board made following decisions:

- i. Suspended all drug registrations of Diclofenac Potassium 75mg and 100mg under Section 7 (11) (d) read with Section 42 of the Drugs Act, 1976 in the larger public interest, with immediate effect as these are neither approved by any Reference Regulatory Authority nor any safety and efficacy data regarding them is available with any registration holder. Period of suspension will be for one (01) year or till demonstration of its safety and efficacy by conducting indigenous clinical trials in accordance with the Bio Study Rules, 2017 or its approval by the Reference Regulatory Authorities, whichever is earlier. After provision of aforementioned data, cases of such pharmaceutical firms shall be considered on merit by Registration Board.
- ii. Suspended manufacturing and import of these drug products immediately and directed to withdraw available stocks from the market in the larger public interest. QA&LT Division, DRAP will monitor and implement the decision in coordination with the respective provincial governments.
- iii. Recommended Licensing Division, DRAP for approval of Qualified person for Pharmacovigilance (QPPV) / Local Safety Officer (LSO) whichever is applicable in licensed pharmaceutical units and advised PE&R and BE&R Divisions for implementing similar action for importers of finished drug products as required under Pharmacovigilance Rules, 2022.
- iv. Final decision regarding pharmaceutical firms who have obtained interim relief from the Hon’ble Lahore High Court, Lahore shall be announced after decision and direction by the Hon’ble Court. Legal Affairs Division is requested to place the instant decision before the Hon’ble Court and seek expeditious disposal of the matter in the larger public interest.
- v. Recommended DRAP Authority for out of queue consideration of registration applications of Diclofenac Potassium 50mg, 25mg and 12.5mg Tablet and 50mg Sachet in order to facilitate the registration holders affected by the instant decision.

As per above decision of the Board, suspension letters were issued to all manufacturers including

M/s. Venus Pharma 23 Km Multan Road Lahore regarding Valron-P 75 Tablets Diclofenac Potassium, Reg. No. 078831 dated 01-06-2022.

Later on various firms have submitted appeals in The Appellate Board against above sated decision of the Registration Board. Accordingly, Appellate Board in its 162<sup>nd</sup> meeting held on 30<sup>th</sup> August, 2022 and 163<sup>rd</sup> meeting held on 01<sup>st</sup> February, 2023 decided as under:

- i. Allow the appeals and resumption of the manufacturing and sale of the drugs Diclofenac Potassium 75mg & 100mg.
- ii. The pack size of 100 mg tablet will be reduced to pack of three tablets in order to avoid misuse potential.
- iii. Sale of both drugs will be prescription only by a qualified practitioner.
- iv. Pharmacovigilance data will be generated and submitted regularly to the Pharmacy Services Division in accordance with Pharmacovigilance Rules, 2022.
- v. The manufacturer will provide safety and efficacy studies approved by any credible sources to Pharmacy Services Division for review and submission to Registration Board. If no such studies are available, the PPMA will contact Pharmacy Services Division for conduction of safety and efficacy trial as per Bio Study Rules, 2017.
- vi. This decision will be applicable to only those firms/companies who are in appeals before the Appellate Board.
- vii. After the safety and efficacy data establishment, the Registration Board will consider the pending and new applications of this drug.

Case is submitted before the board for its consideration, in the light of orders of Lahore High Court, Lahore in W.P No. 37766/2024 dated 13.06.2024, please.

**Decision:**        **Registration Board, in light of orders of Lahore High Court, Lahore, decided to call M/s. Venus Pharma 23 Km Multan Road Lahore for personal hearing on 04<sup>th</sup> July, 2024.**

### **Post Registration-I**

**Case No. 1:        Speaking Orders in the Light of Orders of Lahore High Court, Lahore in W.P No. 34697/2024 Dated 03.06.2024.**

Assistant Registrar (Writ-I), Lahore High Court, Lahore vide letter dated 06.06.2024 has enclosed order sheet of Lahore High Court, Lahore in W.P No. 34697/2024 dated 03.06.2024 filed by M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd Vs Federation of Pakistan & others. The Honorable court ordered as under:

*“In view of the above, I am inclined to direct respondent No. 3 to decide the pending applications strictly in accordance with law, after hearing petitioner and all concerned and through a speaking order. This shall be done within a period of 30 days from the date of receipt of certified copy of this order, under intimation to the Deputy Registrar (Judicial) of this Court and till then, no adverse action shall be taken against the petitioner. The instant petition stands **disposed of accordingly**. ”.*

Facts of the case are as under:

- i. M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd Vs Federation of Pakistan has requested for rational claim of their product namely Qalsium-D, Registration No. 083220. The firm has requested for change of specifications from USP Specifications to Manufacturer’s Specifications.
- ii. The case was placed before the 68<sup>th</sup> meeting of Post Registration Variation Committee (PRVC) held on 05<sup>th</sup> October, 2021 with remarks that as far as comparison with B.P is concerned all parameters are equivalent or stringent to B.P except assay limit of Vitamin-D. The Assay limit in B.P is 90-120% of the stated amount while assay limit adopted by the firm is 90-165% of the declared contents. Justification limit provided by the firm is that “upper limit is broader due to formulation contains 50% excess quantity of Vitamin-D”. The committee after deliberation decided to refer the case to registration board on the ground that “*since the assay limit for Vitamin-D is more stringent in B.P (90-120%) than that of Manufacturer’s Specifications (90-165%)*.”
- iii. In the light of recommendation of PRVC, the case was placed before Registration Board in its 313<sup>th</sup> meeting held on 16<sup>th</sup> to 18<sup>th</sup> November, 2021. Wherein the board decided as under:  
*“the board deliberated the matter and decided to grant B.P Specifications, since the assay limit for Vitamin-D is more stringent in B.P (90-120%) than that of Manufacturer’s Specifications (90-165%)”.*  
Accordingly, decision of the registration board was conveyed to the firm vide letter No. F.313-DRB/2021 dated 22<sup>nd</sup> June, 2022.
- iv. The firm vide application dated 20.02.2024 applied stating that;  
*“This is with reference to letter No. 313-DRB/2021 dated June 22, 2022 issued for approval of the Pharmacopeial specification of QalSium-D Chewable Tablets Reg. No. 083220. Kindly note that it is not possible to fully implement Pharmacopeial specification due to the absence of an appropriate assay method for Cholecalciferol in British Pharmacopeia in the relevant Calcium and Cholecalciferol Chewable Tablets monograph, also communicated through letter No. RAF/DRAP/Reg-015/0124 dated January 02, 2024.”.*
- v. The firm after almost 20 months has requested for the change of specifications from B.P Specifications to Manufacturer’s Specifications against the decision of the Registration Board taken in its 313<sup>th</sup> meeting held on 16<sup>th</sup> to 18<sup>th</sup> November, 2021.

In the light of orders of Lahore High Court, Lahore in W.P No. 34697/2024 dated 03.06.2024, Registration Board gave the opportunity of hearing to the petitioner in its 337<sup>th</sup> meeting held on 28<sup>th</sup> June, 2024.

Mr. Mazhar Shams (Regulatory Affairs Lead) & Mr. Ejaz Ahmad (Senior Regulatory Affairs Manager) from M/s Haleon Pakistan Limited, Karachi appeared before the 337<sup>th</sup> meeting of Registration Board held on 28<sup>th</sup> June, 2024. In the proceeding of the Registration Board meeting the representative of the applicant has briefed about the case and subsequently submitted their written statement vide its letter No. RAF/DRAP/Reg-071/0624 dated 28-06-2024 (reproduced as under):



RAF/DRAP/Reg-071/0624  
Dated: June 28, 2024Secretary  
Drug Registration Board,  
Drugs Regulatory Authority of Pakistan,  
M/o NHS, Regulation & Coordination,  
Government of Pakistan,  
Islamabad.**SUBJECT: - QalSium D Manufacturer's Specification:**

Dear Sir,

We appreciate you providing us the chance to present our case to this distinguished board and provide our perspective on why QalSium D Chewable Tablets Regn. No. 083220 ought to be issued a manufacturer's specification rather than a pharmacopeia. We are restating our stance below in accordance with our previous registration requests and the legal justifications in accordance with local law:

1. QalSium D chewable tablets were initially registered on February 14, 2009, with the **manufacturer's specification** to M/s Novartis Pharma as Qalsan D chewable tablets, later renamed to QalSium D chewable tablets on October 3, 2019 (copy of both letters attached).
2. After the global merger of Novartis and GlaxoSmithKline's Consumer Healthcare operations later in 2017, this product was locally moved to GlaxoSmithKline Consumer Healthcare Pakistan Limited (now Haleon Pakistan Limited). Notably, we were awarded USP specifications even though, at the time of product transfer, we applied as manufacturer specifications with all supporting technical documentation (copy of transfer letter annexed).
3. Given that QalSium D is a chewable tablet and that USP does not include chewable tablets, QalSium D is not covered by the USP specification. We reapplied without any pharmacopeial specifications, requesting the grant of the manufacturer's specification instead.
4. In 2022, we were awarded the BP specification, although the quantity of cholecalciferol (vitamin D) is less than the testing requirement mentioned under the BP, which is as below, and the BP specification is also annexed here:

**British Pharmacopoeia Assay for Cholecalciferol:**

Weigh and powder 20 tablets. Carry out the method of liquid chromatography, appendix III D, protect from light throughout the procedure and using the following solutions.

- (1) Shake a quantity of the powdered tablets containing 0.1mg of cholecalciferol with about 170ml of methanol (90%) for 5 minutes and then mix with ultrasound for 5 minutes, dilute to 200ml with methanol (90%), mix, centrifuge, and filter through a glass-fibre filter (Whatman GF/C is suitable).

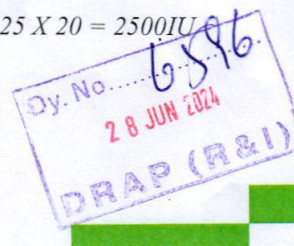
**Calculation:**

Each QalSium D chewable tablets contains Cholecalciferol 125IU.

As per BP method- required 20 tablets contains  $125 \times 20 = 2500\text{IU}$

Dy. No. 345 Add. Dir (R-I)

Dated. 02-07-24



W/S



Each IU of Cholecalciferol contains 0.025mcg

20 tablets contain 2500 IU X 0.025mcg = 62.5mcg or 0.0625mg which is less than the required quantity of 0.1mg in the test.

5. We again, therefore, at the start of 2024, reapplied the registration board for the revision of the product, specification from BP to its initial registered specification since 2009, i.e., the manufacturer's specification.
6. QalSium D Chewable Tablets is as per the recommendations of United States Pharmacopoeia (USP). It is available in Calcium with Vitamin D Tablets Monograph in Dietary supplements/Calcium chapter of USP. Following is the snippet from the USP.

**Calcium with Vitamin D Tablets****DEFINITION**

Calcium with Vitamin D Tablets contain NLT 90.0% and NMT 125.0% of the labeled amount of calcium (Ca), derived from substances generally recognized as safe, and NLT 90.0% and NMT 165.0% of the labeled amount of vitamin D, as cholecalciferol (C<sub>27</sub>H<sub>44</sub>O) or ergocalciferol (C<sub>28</sub>H<sub>44</sub>O). They contain no other vitamins or minerals for which nutritional value is claimed. They may contain other labeled added substances or additional ingredients in amounts that are unobjectionable.

USP permits the use of the calcium with vitamin D and does not describe the amounts. USP emphasizes the use of unobjectionable amounts. See Annexure I for full article.

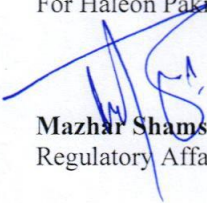
7. There is various formulation with similar strength available in US as one mentioned below (copy of letter available with us is annexed):

Brand name	Active pharmaceutical ingredients	Company name
Calcium 250 + D Tablets	Each tablet contains: Calcium. 250 mg Vitamin D3. 125 IU	21st Century Laboratories, 2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A.

8. Additionally, please take note that the WHO allows 500 mg of calcium to support the QalSium D formulation under its recommended daily allowance (RDA) (a copy is attached).

Considering the foregoing points, we respectfully request that the prestigious registration board allow our request and provide us with the manufacturer's specifications rather than any pharmacopeial specifications, as these are not relevant to this product.

With regards,  
For Haleon Pakistan Ltd.

  
**Mazhar Shams**  
Regulatory Affairs Lead



i. The Firm at Sr. No. 04 of written statement claims that their product does not comply with BP monograph, as the quantity of Vitamin D in their formulation is less than that of required for assay testing in BP monograph.

The Board deliberated that monographs issued by all the Pharmacopoeias are not strength specific but are applicable on all strengths of a drug product. In the instant case monograph of Calcium and Vitamin D Chewable tablet is available in British Pharmacopoeia.

ii. Claim of the firm at Sr. No. 07 of written statement that the same combination is available in US. The firm also claims at S. No. 6 of the written statement that in USP this combination falls under the chapter of dietary supplement. Additionally, QalSium-D is registered as Chewable tablet, while monograph of chewable tablet is not available in USP as mentioned at Sr. No. 03 of written statement.

The Board deliberated that claim of the firm is not justifiable as the product in question is registered as pharmaceutical drug product and is not a dietary supplement. Furthermore, monograph of the chewable is not available in USP, as pharmaceutical drug product.

iii. The firm even could not provide any evidence of registration / availability of said combination in any Reference Regulatory Authority as pharmaceutical drug product, except a letter written by the firm M/s 21<sup>st</sup> Century Laboratories, USA addressed to office of Special Nutritionals (HFS-450), FDA-CFSAN, for provision of notice of statement of this combination as dietary supplement.

Keeping in view personal hearing of M/s. Haleon Formerly M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd and subsequent submission of written statement by the firm, Registration Board did not accede to the request of the firm for change of specifications from BP Specifications to Manufacturer's Specifications.

## **Item No. II. Biological Evaluation and Research Division**

### **Case. No.1. CHANGE OF MARKETING AUTHORIZATION HOLDER (MAH), ADDITION OF QUALITY CONTROL SITES, PRIMARY & SECONDARY PACKAGING SITES AND RELEASE SITE.**

M/s. Roche Pakistan Limited, 1<sup>st</sup> Floor, 37-B Block-6 P.E.C.H.S, Karachi, Pakistan, has applied for addition of sites involved in manufacturing activities for their already registered biological drug as per following details:

<b>Sr. No</b>	<b>Reg. No. and date</b>	<b>Brand Name</b>	<b>Existing name of Marketing Authorization Holder (MAH) and MANUFACTURER</b>	<b>ADDITION OF SITES INVOLVED IN MANUFACTURING ACTIVITY</b>
<b>1.</b>	Reg. No. 111110  Dated: Jan 20 <sup>th</sup> , 2022	Polivy 140 mg Injection Each Single Vial contains: Polatuzumab vedotin-piiq..... 140 mg	<b>MAH:</b> M/s Genentech, Inc, (A member of Roche Group), 1 DNA way, PDRO Building 35, MS 355J, S San Fran, CA 94080 United States of America. <b>MANUFACTURER:</b> M/s BSP Pharmaceuticals SpA, Via Appia Km 65,561, Latina Scalo (LT) 04013 Italy.	<b>MAH:</b> M/s. Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.  <b>Manufacturing and Primary Packaging Site</b> M/s BSP Pharmaceuticals S.p.A. Via Appia Km 65.561, 04013 Latina Scalo (LT), Italy. <b>Quality Control Site</b> <b>1.</b> BSP Pharmaceuticals S.p.A. Via Appia Km 65.561, 04013 Latina Scalo (LT), Italy <b>2.</b> F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland <b>3.</b> Lonza AG, Lonzastrasse, 3930 Visp, Switzerland. <b>Secondary Packaging Site</b> <b>1.</b> F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland. <b>2.</b> Roche Diagnostics GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany

				<b>Release Site</b> <b>1. F.Hoffmann - La Roche Basel,</b> Grenzacherstrasse 124, 4058 Basel, Switzerland.
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There is no sop for addition of addition of quality control sites, primary & secondary packaging sites and release site in registration letter.

The case has been evaluated as per current approved PRV guidelines for change of **Marketing Authorization Holder (MAH) in exporting country** for pharmaceutical and biological products and tabulated as under:

Documents Required as per SOP	Documents Submitted by the Firm	Remarks
Application with required fee as per relevant SRO	Application has been submitted with fee of Rs. 300,000/-	
Copy of registration letter and last renewal status.	Copy of Registration Letter dated 20th Jan, 2022 has been submitted.	
Approval of new MAH from regulatory body of exporting country or Legalized Certificate of Pharmaceutical Product (CoPP) mentioning new Market Authorization Holder (MAH).	The firm has submitted EMA eCPP bearing Certificate No. 07/21/165370 The CoPP specifies free sale status of applied product in exporting country. The CoPP also confirms GMP compliant status of the manufacturer.	
Legalised authority letter/sole agent letter (original) from new Market Authorization Holder (MAH) abroad.	Roche Companies Relationship letter and product specific agreement has been submitted.	

**Following are the conditions for change in Market Authorization Holder (MAH) in exporting country.**

- i. The manufacturing site remains unchanged.
- ii. The registration holder shall remain the same.
- iii. Undertaking from MA holder in exporting country that No litigation is pending at any forum / court of law concerning with the proposed change

**Decision:** Registration Board after detailed deliberation decided to approved change in MA Holder, manufacturing and primary packaging site, quality control site, secondary packaging site and release site as mentioned in column 4 below:

1	2	3	4
Reg. No.	Brand Name	Existing name of Marketing Authorization Holder (MAH) and MANUFACTURER	New Approved Sites Involved in Manufacturing Activity
Reg. No. 111110	Polivy 140 mg Injection Each Single Vial contains: Polatuzumab vedotin-piiq..... 140 mg	<b>MAH:</b> M/s Genentech, Inc, (A member of Roche Group), 1 DNA way, PDRO Building 35, MS 355J, S San Fran, CA 94080 United States of America. <b>MANUFACTURER:</b> M/s BSP Pharmaceuticals SpA, Via Appia Km 65,561, Latina Scalo (LT) 04013 Italy.	<b>MAH:</b> M/s. Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. <b>Manufacturing and Primary Packaging Site</b> M/s BSP Pharmaceuticals S.p.A. Via Appia Km 65.561, 04013 Latina Scalo (LT), Italy. <b>Quality Control Site</b> M/s F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland <b>Secondary Packaging Site</b> M/s F. Hoffmann-La Roche AG Wurmisweg 4303 Kaiseraugst Switzerland. <b>Release Site</b> M/s F.Hoffmann - La Roche Basel, Grenzacherstrasse 124, 4058 Basel, Switzerland.



**Drug Regulatory Authority of Pakistan**  
(Pharmaceutical Evaluation & Registration Division)

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**Registration Board 337 Meeting Minutes:**

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	<b>idealpharma</b> 18-km ferozpure road lahore (000146) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (117-LSR-T4SU, 2024-03-26) Fee Paid: 75000.0 Paid Date: 2023-09-25 (Adil Saeed)	Proposed Name: <b>Esodeal 40mg dry powder vial</b> Each vial Contains: Esomeprazole Sodium eq. to Esomeprazole = 40mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Nexum 40mg vial Pack Size(s): as per DPC-As per SRO Previous Approval: Esozium 40mg dry powder vial 327th meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
2	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Welmark Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-B, Industrial estate, Hattar, KPK, 000614 Tracking ID: (2BD-EDD-PWS3, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Tenfo 25mg Tablet</b> Each film coated tablet contains: Tenofovir Alafenamide Fumarate eq to Tenofovir Alafenamide.....25mg As per Innovators Specification RRA Status: UK MHRA Approved Me Too Status: Tenofovir Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109 Pack Size(s): As per SRO-As per SRO Previous Approval: Teno 25mg Tablet, DRB 324th

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Teno 25mg Tablet, DRB 324th	
	<b>Decision:</b> Approved	
3	<b>Jinnah Pharmaceuticals Pvt Ltd</b> 13 Km Lahore Road Multan (000578) Contract Manufacturing <b>ISLAM PHARMACEUTICALS , 7 KM</b> PASRUR ROAD SIALKOT PAKISTAN, 000885 Tracking ID: (319-L2J-Y3ZT, 2024-03-25) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>ROLAC-J 30mg/ml Injection (Ketorolac Tromethamine)</b> Each 1ml Solution contains Ketorolac tromethamine 30mg United States Pharmacopeia RRA Status: MEHRA APPROVED Me Too Status: Toradol 30mg/ml Injection (Ketorolac Tromethamine 30mg/ml (MS Barret Hodgson Pakistan Pack Size(s): 1mlx5`s-As per SRO Previous Approval: DRB M-326
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
4	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Wnsfeild Pharmaceuticals, Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK, 000610</b> Tracking ID: (2YP-MZ7-Q2G3, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Esomepp 20mg + 375mg Tablet</b> Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR ..... 20mg Naproxen as enteric coated core ..... 375mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Glomov 20/375mg tablet by M/s Global Pharmaceutical (Pakistan) Reg No 109338 Pack Size(s): As per SRO-As per SRO Previous Approval: Esonyp 20/375mg DR Tablet, DRB 324

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Approved by name of Esonyp 20/375mg DR Tablet in 324th RB	
	<b>Decision:</b> Approved	
5	<b>Fast Pharmaceuticals (Pvt) Ltd.</b> Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. <b>(000954)</b> Contract Manufacturing <b>Bio-Next Pharmaceuticals,</b> Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad, 000910 Tracking ID: (3ZX-D53-SGB1, 2024-03-25) Fee Paid: 75000.0 Paid Date: 2024-01-29 (Adil Saeed)	Proposed Name: <b>Merofas</b> Each vial contains: Meropenem (as trihydrate) blended with sodium carbonate.....500mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Meronem ICI Pakistan Pack Size(s): 1 vial-Controlled Previous Approval: 331 Nawan Pharma
	<b>Evaluation Remarks:</b> MENEPOR 500 mg	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
6	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. <b>(000644)</b> Contract Manufacturing <b>Biogen Pharmaceuticals</b> , 8Km, Chakbeli Road Rawat, Rawalpindi, 000911 Tracking ID: (4UP-9VY-SGHU, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Chol-D Capsule</b> Each soft gel Capsule Contains: Cholecalciferol.....50,000 I U United States Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Solar-D Soft gelatin CaPsule by Crystolite Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: 3-D CAPSULE BY BIOGEN PHARMA, DRB 312
	<b>Evaluation Remarks:</b> Approved by name of 3-D CAPSULE in 312th meeting of RB	
	<b>Decision:</b> Approved	
7	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat <b>(000882)</b> Contract Manufacturing <b>Biogen Pharmaceuticals</b> , 8-Km, Chakbeli Road, Rawat, Rawalpindi. , 000911 Tracking ID: (5M2-SLG-XT82, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Isowen 20mg Capsule</b> Each Soft Gel Capsule Contains:- Isotretinoin.....20mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO Previous Approval: Biotan 20mg Capsule, DRB 312
	<b>Evaluation Remarks:</b> Biotan 20mg Capsule, DRB 312	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
8	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (5T8-BHX-6BG2, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Cefket 2.5gm Injection</b> Each vial Contains: Ceftazidime (as pentahydrate).....2000mg Avibactam (as sodium salt).....500mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Zavicefta Injection by Pfizer (Reg No. 106848) Pack Size(s): As per SRO-As per SRO Previous Approval: Cefzect 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b> Cefzect 2.5gm Injection, DRB 330	
	<b>Decision:</b> Approved	
9	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>M/s Biogen Pharmaceuticals</b> , 8Km, Chakbeli Road Rawat, Rawalpindi, 000911 Tracking ID: (796-YND-XNHM, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Isofold 10mg Capsule</b> Each soft gel capsule Contains: Isotretinoin. ....10mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO Previous Approval: BIOTAN 10mg Capsule, DRB 312
	<b>Evaluation Remarks:</b> Approved by name of BIOTAN 10mg Capsule, in 312th meeting of RB,	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
10	<b>De-Mont Research Laboratories (Pvt.) Ltd.</b> 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan ( <b>000844</b> ) Contract Manufacturing <b>Variant Pharmaceuticals (Pvt) Ltd.,</b> PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN, 000914 Tracking ID: (7HR-29P-D5G2, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2023-12-21 (Adil Saeed)	Proposed Name: <b>Lemox 400mg/250ml Infusion</b> Each ml contains: Moxiflocacin as (HCl)...1.6mg (250 ml Infusion contains Moxifloxacin as (HCl)...400mg) As per Innovators Specification RRA Status: USFDA Approved (Moxifloxacin Hydrochloride 1.6 mg/ml solution for infusion, FRESENIUS KABI USA) Me Too Status: Avelox 400mg/250ml Infusion Pack Size(s): 1s-As per SRO Previous Approval: Moxivar 400mg/250ml Infusion, (M 331)
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
11	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. ( <b>000644</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals,</b> Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (9BY-Q9H-7Q71, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Tegit 60mg Tablet</b> Each film coated tablet contains: Ticagrelor ... 60mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Anplag 60mg Tablet Pharmevo (Pvt) Ltd Reg. No.93105 Pack Size(s): As per SRO-As per SRO Previous Approval: Tigawin 60mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Tigawin 60mg Tablet in 331st meeting of RB.	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
12	<b>Sarco Chemicals Industries</b> 17-Km. Lahore Road Multan (000203) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd</b> , Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore, 000789 Tracking ID: (9D7-MM1-4121, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2023-11-07 (Adil Saeed)	Proposed Name: <b>Medzole 20mg/500mg Tablet</b> Each Modified release Tablet Contains: Naproxen.....500mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg(Immediate released coat) As per Innovators Specification RRA Status: Vimovo 500/20mg modified-release tablet M/s Grunenthal Ltd Marketing authorization number: PL 50414/ Me Too Status: Glomov 500mg/20mg Tablet M/s Gobaal Registration# 109338 Pack Size(s): 1x10's, 2x10's, 3x10-As per SRO Previous Approval: Napsom 20/500 mg Tablet Approved in Meeting no. 331
	<b>Evaluation Remarks:</b> Approved by name Napsom 20/500 mg Tablet in 331st meeting of RB.	
	<b>Decision:</b> Approved	
13	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kalalwala stop, 20- KM, Lahore Jaranwala Road Lahore., 000951 Tracking ID: (A13-SVU-7EGQ, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Imastin 500mg Injection</b> Each vial Contains: Imipenem as Monohydrate (USP).....250mg Cilastatin as Sodium (USP).....250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Tienam Injection of OBS Pakistan Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Nemcil Injection ,DRB 323
	<b>Evaluation Remarks:</b> Nemcil 500mg Injection ,DRB 323	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
14	<b>SAMI Pharmaceuticals Pvt. Ltd.</b> F-95 Hub River Road S.I.T.E Karachi (000072) Contract Manufacturing <b>CSH Phamaceuticals (Pvt.) Ltd,</b> 32-Km, Ferozepur Road, Lahore-Pakistan, 000737 Tracking ID: (9NA-7ZH-ZD6T, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-10 (Adil Saeed)	Proposed Name: <b>OXICLAVO 62.5mg/ml Drops</b> Each ml contains: (after reconstitution) Amoxicillin Trihydrate Equivalent to Amoxicillin.....50 mg Potassium Clavulanate equivalent to Clavulanic Acid.....12.5 mg United States Pharmacopeia RRA Status: Augmentin 312.5mg/5ml Suspension Me Too Status: Amclav 62.5mg Drops Pack Size(s): As per SRO-As per SRO Previous Approval: Fortecin Dry Powder Infant Drops, Approved in DRB M-331
	<b>Evaluation Remarks:</b> The case was discussed for transfer of registration of product from M/s LCI to M/s The Searle Company (DML No. 000016) and manufacturing was transferred to M/s CSH Pharma Lahore. The data was submitted on Form 5F (CTD) and case was approved by the board in 331st meeting.	
	<b>Decision:</b> Approved	
15	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (AU6-MAU-ZLDQ, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-03-22 (Adil Saeed)	Proposed Name: <b>MAREO-500MG INJECTION IV/ IM</b> Each Vial Contains: Meropenem Trihydrate eq. to. Meropenem.....500mg United States Pharmacopeia RRA Status: Merrem Injection (USFDA Approved) Me Too Status: Merrem Injection of Global Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-312 By the Name of MEROGEN Injection 500MG
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
16	<b>SAMI Pharmaceuticals Pvt. Ltd.</b> F-95 Hub River Road S.I.T.E Karachi (000072) Contract Manufacturing <b>CSH Pharmaceuticals (Pvt.) Ltd,</b> 32-Km, Ferozepur Road, Lahore-Pakistan, 000737 Tracking ID: (AD3-P38-WPJ9, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-10 (Adil Saeed)	Proposed Name: <b>OXICLAVO FORTE 457mg/5ml Suspension</b> Each 5 ml contains: (after reconstitution) Amoxicillin Trihydrate Equivalent to Amoxicillin.....400 mg Potassium Clavulanate equivalent to Clavulanic acid .....57 mg United States Pharmacopeia RRA Status: Augmentin 457mg Suspension Me Too Status: Amclav 457mg Suspension Pack Size(s): As per SRO-As per SRO Previous Approval: Fortecin Dry Suspension, Approved in DRB M-331
	<b>Evaluation Remarks:</b> The case was discussed for transfer of registration of product from M/s LCI to M/s The Searle Company (DML No. 000016) and manufacturing was transferred to M/s CSH Pharma Lahore. The data was submitted on Form 5F (CTD) and case was approved by the board in 331st meeting.	
	<b>Decision:</b> Approved	
17	<b>Scilife Pharma Private Limited</b> FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (000837) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt.) Ltd.,</b> PLOT # 129 SUNDER INDUSTRIAL ESTATE, LAHORE, 000789 Tracking ID: (AG5-PRD-1ZJE, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2023-11-23 (Adil Saeed)	Proposed Name: <b>Scirica CR 82.5mg Tablet</b> Each Film Coated Extended Release tablet contains: Pregabalin.....82.5mg (As per innovators specifications) As per Innovators Specification RRA Status: Product is USFDA approved. Lyrica CR 82.5mg tablet,Pfizer INC, NY, NY 10017(Made in Singapore) Me Too Status: N/A Pack Size(s): 1 x 10 (10)-As per SRO,2 x 10 (20)-As per SRO,2 x 7 (14)-As per SRO,3 x 10 (30)-As per SRO Previous Approval: Gabal 82.5mg ER tablet, MINUTES OF 324th MEETING OF REGISTRATION BOARD HELD ON 24th to 26th January,

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
18	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (BY5-82T-AELN, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Nevibo 20mg Tablet</b> Each uncoated tablet contains: Nebivolol (as HCl)..... 20mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Nabiz 20mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Nabiz 20mg Tablet, in 331st meeting of RB.	
	<b>Decision:</b> Approved	
19	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat, 000882 Tracking ID: (D3Q-5JG-XVMD, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Adil Saeed)	Proposed Name: <b>Trella 50mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 66.5mg equivalent to Trelagliptin ..... 50 mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Trella 50mg Tablet, DRB 331	
	<b>Decision:</b> Approved	
20	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Wnsfeild Pharmaceuticals,</b> Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar., 000610 Tracking ID: (DX1-Y8H-2AL2, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>TECOR 90MG TABLET</b> Each Film Coated Tablet Contains: TICAGRELOR.....90mg (Product complies BP Specs) British Pharmacopeia RRA Status: USFDA & MHRA approved Me Too Status: Anplag 90mg Tablet M/s Pharmevo (Pvt) Ltd Reg. No.89382 Pack Size(s): As Per SRO-As per SRO Previous Approval: Tigawin Tablet 90mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
21	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wezen Pharmaceuticals,</b> Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. , 000882 Tracking ID: (G3L-886-DGMA, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Dexxlo 60mg Capsule</b> Each capsule contains: Dexlansoprazole (as dual delayed release pellets).....60mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: DEXZEN 60mg Capsule, DRB 330

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
22	<b>jupiter Pharma</b> Plot No 25 Street S-6 RCCI Rawat Rawalpindi ( <b>000838</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (H55-2H2-N2SD, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Adil Saeed)	Proposed Name: <b>Trella 50mg Tablet</b> COMPOSITION: Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....50mg (Product complies Innovators Specs) As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Trella 50mg Tablet in 331st meeting of RB.	
	<b>Decision:</b> Approved	
23	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (HYT-MQ6-J6YL, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>DROCORT-500MG INJECTION IV/ IM</b> each vial contains: Hydrocortisone sodium succinate eq. to. Hydrocortisone.....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone Injection By Global Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-307 By the Name of BIOCORT 500MG INJECTION

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
24	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar ( <b>000574</b> ) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (JXH-7U9-6VUV, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>OBBITTA 5MG TABLET</b> Each Film Coated Tablet Contains: Obeticholic Acid.....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112710 Pack Size(s): As Per SRO-As per SRO Previous Approval: B-Kolic Tablet 5 mg, DRB 331
	<b>Evaluation Remarks:</b> B-Kolic Tablet 5 mg in 331st meeting of RB.	
	<b>Decision:</b> Approved	
25	<b>Scilife Pharma Private Limited</b> FD-57/58-A2, Korangi Creek Industrial Park (KCIP) ( <b>000837</b> ) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt.) Ltd.</b> , PLOT # 129 SUNDER INDUSTRIAL ESTATE, LAHORE, 000789 Tracking ID: (JVW-T6S-8LW7, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2023-11-23 (Adil Saeed)	Proposed Name: <b>Scirica CR 165mg Tablet</b> Each Film Coated Extended Release tablet contains: Pregabalin.....165 mg (As per innovators specifications) As per Innovators Specification RRA Status: Product is USFDA approved. Lyrica CR 165mg tablet,Pfizer INC, NY, NY 10017(Made in Singapore) Me Too Status: N/A Pack Size(s): 1 x 10 (10)-As per SRO,2 x 10 (20)-As per SRO,2 x 7 (14)-As per SRO,3 x 10 (30)-As per SRO Previous Approval: Gabal 165mg ER tablet, MINUTES OF 324th MEETING OF REGISTRATION BOARD HELD ON 24th to 26th January,

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
26	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Wnsfeild Pharmaceuticals,</b> Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (LL2-JEN-4MXS, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Levcart 1gm Injection</b> Each 5ml ampoule Contains: Levocarnitine ..... 1gm United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Pack Size(s): As per SRO-As per SRO Previous Approval: L-Carta 1gm Injection, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of L-Carta 1gm Injection, in DRB 331st meeting	
	<b>Decision:</b> Approved	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
27	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. <b>(000644)</b> Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (LU6-LPP-YJ23, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Tegit 90mg Tablet</b> Each film coated tablet contains: Ticagrelor ... 90mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Anplag 90mg Tablet M/s Pharnevo (Pvt) Ltd Reg. No.89382 Pack Size(s): As per SRO-As per SRO Previous Approval: Tigawin 90mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Tigawin 90mg Tablet in DRB 331 meeting.	
	<b>Decision:</b> Approved	
28	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, <b>(000992)</b> Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (M5V-PW8-B1XL, 2024-03-25) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>AXIFLOX-400MG/250ML SOLUTION FOR INFUSION</b> Each Vial of 250ml Contains: Moxifloxacin (as hydrochloride).....400mg As per Innovators Specification RRA Status: Avelox-400mg/250ml Solution For Infusion (MHRA Approved) Me Too Status: Avelox Injection By Bayer Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-320 By the Name of MOXIGEN 400MG/250ML SOLUTION FOR INFUSION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
29	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial estate, Hattar, KPK, 000610 Tracking ID: (MB8-3NS-91MD, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Levcart 1gm injection</b> Each 5ml ampoule Contains: Levocarnitine ..... 1gm United States Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Pack Size(s): As per SRO-As per SRO Previous Approval: L-Carta 1gm Injection, DRB 331
	<b>Evaluation Remarks:</b> L-Carta 1gm Injection, DRB 331	
	<b>Decision:</b> Approved	
30	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals</b> , Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (ME7-6RU-9PR4, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-23 (Adil Saeed)	Proposed Name: <b>CARTIN-1G INJECTION IV/IM</b> each Ampoule of 5ml contains 1gm (IV/ IM) Levocarnitine  RRA Status: Carnitor injection approved by US FDA Me Too Status: Metacartin Injection 1g/5ml (Genome Pharma, Reg. No. 103770) Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 CARNIT 1G INJECTION
	<b>Evaluation Remarks:</b> CARNIT 1G INJECTION in 331st meeting of RB	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
31	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (MHR-D5J-NYA4, 2024-03-20) Fee Paid: 75000.0 Paid Date: 2024-03-19 (Adil Saeed)	Proposed Name: <b>ONSOL-8MG/4ML INJECTION IV/ IM</b> Each 4ml contains: Ondansetron as HCl Dihydrate.....8 mg United States Pharmacopeia RRA Status: Zofran®, Novartis, Zofran® Injection is Approved in USFDA Me Too Status: Zofran Injection By Novartis (Reg. No. 020669) Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-330 By the Name of RestOn Injection 8mg/ 4ml IV/ IM
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
32	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Biogen Pharmaceuticals,</b> 8Km, Chakbeli Road Rawat, Rawalpindi, 000911 Tracking ID: (NAT-991-21LE, 2024-03-06) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Adil Saeed)	Proposed Name: <b>Isofold 20mg Capsule</b> Each soft gel capsule Contains: Isotretinoin.....20mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO Previous Approval: BIOTAN 20mg Capsule, DRB 312
	<b>Evaluation Remarks:</b> Approved by name of BIOTAN 20mg Capsule, in 312th RB	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
33	<b>Trigon Pharmaceuticals (Private) Ltd</b> 8-k.m thokar raiwind road Lahore (000342) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore., 000951 Tracking ID: (NSY-6LE-8H8Q, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Adil Saeed)	Proposed Name: <b>IMASTIN 500mg INJECTION</b> Each vial Contains: Imipenem as Monohydrate (USP).....250mg Cilastatin as Sodium (USP).....250mg (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Tienam Injection of OBS Pakistan Karachi Pack Size(s): As Per SRO-As per SRO Previous Approval: Nemcil 500mg Injection, DRB 323
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
34	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (P31-5S8-ARJ6, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>DROCORT-250MG INJECTION IV/ IM</b> each vial contains: Hydrocortisone sodium succinate eq. to. Hydrocortisone .....250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone Injection By Global Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-307 By the Name of BIOCORT 250MG INJECTION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
35	<b>Fast Pharmaceuticals (Pvt) Ltd.</b> Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. <b>(000954)</b> Contract Manufacturing <b>Bio-Next Pharmaceuticals</b> , Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad, 000910 Tracking ID: (P47-794-GPXQ, 2024-03-25) Fee Paid: 75000.0 Paid Date: 2024-01-29 (Adil Saeed)	Proposed Name: <b>Merofas</b> Each vial contains: Meropenem (as trihydrate) blended with sodium carbonate.....1000mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Meronem ICI Pakistan Pack Size(s): 1 vial-Controlled Previous Approval: 331 Nawan Pharma
	<b>Evaluation Remarks:</b> MENEPOR 1g	
	<b>Decision:</b> Approved	
36	<b>Welwrdr Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar <b>(000574)</b> Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (P5A-BDQ-7APM, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>BEMPID 180 TABLET</b> Each Film Coated Tablet Contains: Bempedoic Acid.....180mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: NA Pack Size(s): As Per SRO-As per SRO Previous Approval: PDM 180 mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
37	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Wnsfeild Pharmaceuticals</b> , Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar., 000610 Tracking ID: (PU7-SVR-GTMH, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>L?CARTA 1GM INJECTION</b> Each Ampoule (5mL) Contains: Levocarnitine (USP) .....1000mg (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Shamco traders Pack Size(s): As Per SRO-As per SRO Previous Approval: L-Carta 1gm injection, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
38	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kalalwala stop, 20- KM, Lahore Jaranwala Road Lahore., 000951 Tracking ID: (Q33-5NA-QWUZ, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Imastin 1gm Injection</b> Each vial Contains: Imipenem as Monohydrate (USP)..... 500mg Cilastatin as Sodium (USP)..... 500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Tienam Injection of OBS Pakistan Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Nemcil Injection ,DRB 323
	<b>Evaluation Remarks:</b> Nemcil Injection ,DRB 323	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
39	<b>jupiter Pharma</b> Plot No 25 Street S-6 RCCI Rawat Rawalpindi ( <b>000838</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Block-A, Phase-V, Industrial Estate, hattar, KPK, 000610 Tracking ID: (Q5P-5H7-N7NV, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Adil Saeed)	Proposed Name: <b>Teggor 60mg Tablet</b> Each Film Coated Tablet Contains: TICAGRELOR.....60mg (Product complies BP Specs) British Pharmacopeia RRA Status: EMA Approved Me Too Status: Anplag 60mg Tablet by PharmEvo Pack Size(s): As per SRO-As per SRO Previous Approval: Tigawin 60mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Tigawin 60mg Tablet in 331st meeting of RB	
	<b>Decision:</b> Approved	
40	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (Q5W-YW9-YZVL, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>COLESTI-2 MIU INJECTION IV</b> each Vial Contains: Colistimethate sodium 2MIU equivalent to 68mg colistin base activity  RRA Status: Colomycin 2 MIU (IU) Injection (MHRA Approved) Me Too Status: Colistimethate Injection 2 MIU By Mukhtar Enterprises Reg. No. 094757 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-297 By the Name of LISTIM INJECTION 2 MIU IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
41	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar ( <b>000574</b> ) Contract Manufacturing <b>M/s Wallace Pharma Evolutions,</b> Kala Wala Stop 20?KM, LAHORE JARANWALA ROAD, LAHORE, 000951 Tracking ID: (Q7G-ZVZ-49Y4, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>TAZOCIN 4.5GM INJECTION</b> Each Vial Contains: Piperacillin as Sodium .....4g Tazobactam as Sodium.....500mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: MHRA approved Me Too Status: Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As Per SRO-As per SRO Previous Approval: TAZOCIN 4.5gm Injection, DRB 331
	<b>Evaluation Remarks:</b> TAZOCIN 4.5gm Injection, in 331st meeting of RB	
	<b>Decision:</b> Approved	
42	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (QNT-6ZM-YX8D, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>SOLDROP-D SOFTGEL CAPSULES</b> Each soft gel Capsule Contains: Cholecalciferol.....50,000 IU United States Pharmacopeia RRA Status: In Vita D3 5 0,000 IU soft Capsules (MHRA Approved) Me Too Status: Solar-D Soft gelatin Capsule 50000 IU by Crystolite Phama (Reg#094359) Pack Size(s): As Per SRO-As per SRO Previous Approval: 3-D Capsule
	<b>Evaluation Remarks:</b>	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
43	<b>idealpharma</b> 18-km ferozpure road lahore (000146) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (RBZ-V9W-7BQT, 2024-03-26) Fee Paid: 75000.0 Paid Date: 2023-09-25 (Adil Saeed)	Proposed Name: <b>Idevin 500mg Dry Powder for injection</b> Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 500mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Risek 40mg vial Pack Size(s): as per DPC-As per SRO Previous Approval: vancomin 500mg Dry Powder for injection 324th meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
44	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kalawala Stop, 20- Km, Lahore Jaranwala Road, Lahore, 000951 Tracking ID: (S5R-ZA2-9XME, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Adil Saeed)	Proposed Name: <b>TAZOCIN 2.25gm Injection</b> Each Vial Contains: Piperacillin as Sodium (USP) ..... 2000mg Tazobactam as Sodium (USP) .....250mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As per SRO-As per SRO Previous Approval: Tazocin Injection, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Tazocin 2.25g Injection in 331st meeting of RB	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
45	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (RP7-4WW-5EB7, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>FLOPIN 100mg/15mg TABLET</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglutamic Acid .....15mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Trevia R2 (15/100mg) by Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: Flopin 15/100 mg Tablet, 333
	<b>Evaluation Remarks:</b> Flopin 15/100 mg Tablet, approved in 333rd meeting of RB.	
	<b>Decision:</b> Approved	
46	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Wallace Pharma Evolutions,</b> Kala Wala Stop 20?KM, LAHORE JARANWALA ROAD, LAHORE, 000951 Tracking ID: (SAY-HBH-NEGE, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Adil Saeed)	Proposed Name: <b>TAZOCIN 2.25GM INJECTION</b> Each Vial Contains: Piperacillin as Sodium .....2000mg Tazobactam as Sodium .....250mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: MHRA approved Me Too Status: Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As Per SRO-As per SRO Previous Approval: TAZOCIN 2.25gm Injection, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
47	<b>jupiter Pharma</b> Plot No 25 Street S-6 RCCI Rawat Rawalpindi ( <b>000838</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar,KPK, 000610 Tracking ID: (SLY-UQZ-D4W7, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Adil Saeed)	Proposed Name: <b>Teggor 90mg Tablet</b> Each Film Coated Tablet Contains: TICAGRELOR.....90mg (Product complies BP Specs) British Pharmacopeia RRA Status: EMA Approved Me Too Status: Anplag 90mg Tablet by PharmEvo Pack Size(s): As per SRO-As per SRO Previous Approval: Tigawin 90mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Tigawin 90mg Tablet in 331st meeting of RB.	
	<b>Decision:</b> Approved	
48	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad ( <b>000955</b> ) Contract Manufacturing <b>Bio-Labs (Pvt) Ltd.</b> , 145, Industrial Trangle, Kahuta Road, 000296 Tracking ID: (SPS-HJR-J7B8, 2024-03-05) Fee Paid: 75000.0 Paid Date: 2023-11-22 (Adil Saeed)	Proposed Name: <b>Tiglin</b> Each vial Contains: Tigecycline .....50mg United States Pharmacopeia RRA Status: USFDA Tigecycline 50mg Injection Me Too Status: Tygacil Inj Wyeth Pakistan Pack Size(s): 1 vial-Controlled Previous Approval: Bactcil Injection 330 DRB

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Approved by name of Bactcil Injection in 330th RB	
	<b>Decision:</b> Approved	
49	<b>jupiter Pharma</b> Plot No 25 Street S-6 RCCI Rawat Rawalpindi ( <b>000838</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (SQD-NX8-GABQ, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Adil Saeed)	Proposed Name: <b>Trella 100mg Tablet</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....100mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin 100mg Tablet by Wezen Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Trella 100mg Tablet in 331st meeting of RB	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
50	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kalawala Stop, 20- Km, Lahore Jaranwala Road, Lahore, 000951 Tracking ID: (SV9-584-8VZB, 2024-03-08) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Adil Saeed)	Proposed Name: <b>TAZOCIN 4.5gm Injection</b> Each Vial Contains: Piperacillin asSodium (USP) ..... 4000mg Tazobactam as Sodium (USP) .....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As per SRO-As per SRO Previous Approval: Tazocin Injection, DRB 331
	<b>Evaluation Remarks:</b> Tazocin Injection, DRB 331	
	<b>Decision:</b> Approved	
51	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (TWW-Z3Z-4XPW, 2024-03-20) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>STOMZOL-40MG INJECTION IV</b> each Vial contains: Omeprazole as Sodium.....40mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Risek Injection of Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-312 By the Name of REFLEX INJECTION 40MG IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
52	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (UYL-R4G-Y9RV, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Adil Saeed)	Proposed Name: <b>SOLDRO-5MG INFUSION</b> each 100ml vial contains: Zoledronic acid as monohydrate.....5mg As per Innovators Specification RRA Status: Zoledronic Acid 5mg/ 100ml Solution for Infusion (MHRA Approved) Me Too Status: Zometa Infusion By M/s Novartis Pharma, Karachi. Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-333 By the Name of GEN-ZOLE 5MG/100ML INFUSION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
53	<b>Swiss Pharmaceuticals Pvt. Ltd.</b> A/159, S.I.T.E.-II, Super Highway (000438) Contract Manufacturing <b>SERAPH PHARMACEUTICAL,</b> Plot#210, Industrial Triangle, Kahuta road, Islamabad, Pakistan, 000860 Tracking ID: (WJ7-RBE-3Y7P, 2024-03-11) Fee Paid: 75000.0 Paid Date: 2024-02-23 (Adil Saeed)	Proposed Name: <b>Loprid 2mg Tablet</b> Each film coated tablet contains: Prucalopride Succinate.....2mg (Innovator Specifications) As per Innovators Specification RRA Status: Motegrity 2mg Tablet Me Too Status: Notogrity 2mg Tablet Pack Size(s): 2x7's-As per SRO Previous Approval: Notogrity 2mg Tablet DRB 331
	<b>Evaluation Remarks:</b> Approved by name of Notogrity 2mg Tablet in 331st meeting of RB.	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
54	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Biogen Pharmaceuticals</b> , 8-Km, Chakbeli Road, Rawat, Rawalpindi. , 000911 Tracking ID: (XEZ-V7R-46LZ, 2024-03-12) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Adil Saeed)	Proposed Name: <b>Chol-D Capsule</b> Each Soft Gel Capsule Contains:- Cholecalciferol.....50,000 IU United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solar-D Soft gelatin Capsule by Crystolite Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: 3-D Capsule, DRB 312
	<b>Evaluation Remarks:</b> 3-D Capsule, DRB 312	
	<b>Decision:</b> Approved	
55	<b>idealpharma</b> 18-km ferozpure road lahore (000146) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (YG4-9PD-56RN, 2024-03-26) Fee Paid: 75000.0 Paid Date: 2023-09-25 (Adil Saeed)	Proposed Name: <b>Ideron 8mg/4ml Injection</b> Each 4ml Contains: Ondansetron as Hydrochloride dihydrate = 8MG United States Pharmacopeia RRA Status: FDA Approved Me Too Status: onset 8mg/4ml injection Pack Size(s): as per DPC-As per SRO Previous Approval: Baktron 8MG/4ml Injection 321 meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
56	<b>jupiter Pharma</b> Plot No 25 Street S-6 RCCI Rawat Rawalpindi ( <b>000838</b> ) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar,KPK, 000644 Tracking ID: (ZTN-313-Y3EU, 2024-03-27) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Adil Saeed)	Proposed Name: <b>Esonap 20mg + 500mg Tablet</b> Each Modified release Tablet contains: Naproxen .....500mg (as Enteric Coated Core) Esomeprazole as Magnesium Trihydrate .....20mg ( as Immediate Release Coat) ( As per Innovators Specif As per Innovators Specification RRA Status: EMA Approved Me Too Status: Eznepo MR Tablet 500/20mg Reg# 117966 by Wnsfeild Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Vimovo 500mg/20mg DR Tablet, DRB 312th Meeting
	<b>Evaluation Remarks:</b> Approved as Vimovo 500mg/20mg DR Tablet in 312th Meeting of RB.	
	<b>Decision:</b> Approved	
57	<b>Onyx Pharmaceuticals</b> 30-A small Industrial Estate mansehra ( <b>000440</b> ) Contract Manufacturing <b>Bio-Mark Pharmaceuticals</b> , 527 Sundar Industrial Estate, Lahore, 000863 Tracking ID: (12D-RRJ-NM5Q, 2023-12-29) Fee Paid: 75000.0 Paid Date: 2023-03-07 (Ammar Ashraf Awan)	Proposed Name: <b>Indazole 20mg Capsule</b> Each capsule contains: Esomeprazole (as enteric coated pellets).....20mg United States Pharmacopeia RRA Status: Nexium Capsules by Novartis Me Too Status: Nexium Capsules by Novartis Pack Size(s): 14 & 28's-As per SRO Previous Approval: Staesso 20mg capsule (Meeting no. 329)
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
58	<b>Swiss Pharmaceuticals Pvt. Ltd.</b> A/159, S.I.T.E.-II, Super Highway (000438) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-km Chakbeli Road, Rawat, Rawalpindi - Pakistan, 000911 Tracking ID: (1EU-6AJ-JG1, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2021-10-14 (Ammar Ashraf Awan)	Proposed Name: <b>D-Abs</b> Each soft gel capsule contains: Cholecalciferol.....50,000 I.U. United States Pharmacopeia RRA Status: InVita D3 50,000 IU soft capsules by McGregor Cory limited Me Too Status: Dan-D 50,000IU Capsule Pack Size(s): 5's-As per SRO Previous Approval: 3-D Capsule, DRB-M 312th
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
59	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. , 000644 Tracking ID: (1UP-433-QPAL, 2024-02-22) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Cefket 2.5gm Injection</b> Each vial Contains: Ceftazidime (as pentahydrate).....2000mg Avibactam (as sodium salt).....500mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Zavicefta Injection by Pfizer (Reg No. 106848) Pack Size(s): As Per SRO-As per SRO Previous Approval: CEFZECT 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
60	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad ( <b>000572</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot #122, Block A, Industrial Estate, Hattar, Haripur, KPK, 000610 Tracking ID: (1GS-819-VL2H, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Ammar Ashraf Awan)	Proposed Name: <b>Vonofix 10mg + 100mg Tablet</b> Each Tablet Contains: Aspirin as Enteric Coated Tablet (USP).....100mg Vonoprazan as fumarate as Immediate Release Layer.....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: Registration Status = Registered by JAPAN - PMDA Product Name = Cabpirin 10mg + 100mg Tablets Ja Me Too Status: WNSFEILD Pharmaceuticals Pack Size(s): As per SRO -As per SRO Previous Approval: 324 meeting
	<b>Evaluation Remarks:</b> Reference of previous approval is for Venospa tablet approved in 324th RB meeting	
	<b>Decision:</b> Approved .	
61	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat ( <b>000882</b> ) Contract Manufacturing <b>Biogen Pharmaceuticals</b> , 8-Km, Chakbeli Road, Rawat, Rawalpindi. , 000911 Tracking ID: (2W7-L1P-U77W, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Ammar Ashraf Awan)	Proposed Name: <b>Isowen 10mg Capsule</b> Each Soft Gel Capsule Contains:- Isotretinoin.....10mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO Previous Approval: Biotan 10mg Capsule, DRB 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
62	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (2Q5-BU9-TS6Z, 2024-05-24) Fee Paid: 75000.0 Paid Date: 2024-05-15 (Ammar Ashraf Awan)	Proposed Name: <b>Voriza Tablets 10mg</b> Each film coated tablet contains Vonoprazan as Fumarate .....10mg Product Specs: Innovator's As per Innovators Specification RRA Status: TAKECAB 10mg of Takeda Pharmaceutical Company Limited, Japan approved by PMDA Japan Me Too Status: Vonozan 10mg Tablets of M/s Getz Pharma Pvt Ltd. – Karachi. Pack Size(s): 14's , 28's , 30's-As per SRO Previous Approval: “Vonesta 10mg Tablets” of M/s Ferozsons Laboratories Limited, approved in 320th Meeting of Registrat
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
63	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat ( <b>000882</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial estate, Hattar, KPK, 000610 Tracking ID: (3VT-ZX8-DBBH, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Ammar Ashraf Awan)	Proposed Name: <b>Azzota 40mg Tablet</b> Each Uncoated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil .....80mg (Product Complies Innovator's Specs) As per Innovators Specification RRA Status: UK MHRA Approved Me Too Status: Zelwist Tablet by Wnsfeild Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Azilta 80mg Tablet, DRB 326
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
64	<b>himark laboratories (pvt.) Ltd</b> 37-A sundar industrial estate lahore (000909) Contract Manufacturing <b>INVICTUS PHARMACEUTICAL</b> , Plot No. 21 & 26 Street No. NS-2 (W-5) National Industrial Zone Rawat, Islamabad , 000892 Tracking ID: (3ZH-7ZP-J3HZ, 2024-05-27) Fee Paid: 75000.0 Paid Date: 2024-01-11 (Ammar Ashraf Awan)	Proposed Name: <b>Fekast 1g (IV) Injection</b> Ceftriaxone sodium as ceftriaxone ..... 1gm United States Pharmacopeia RRA Status: ceftriaxone injection 1g of M/s Lupin Pharma (USFDA) approved Me Too Status: Topcef 1g (IV) Injection Pack Size(s): 1's-As per SRO Previous Approval: In-Xone 1g (IV) Injection, meeting No 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
65	<b>Sarco Chemicals Industries</b> 17-Km. Lahore Road Multan (000203) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd</b> , Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore, 000789 Tracking ID: (4MG-SQT-GMGM, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-11-10 (Ammar Ashraf Awan)	Proposed Name: <b>Pregab 82.5mg CR Tablet</b> Each Film Coated Extended Release Tablet Contains: Pregabalin .....82.5mg As per Innovators Specificatio RRA Status: PREGABALIN EXTENDED RELEASE tablet 82.5mg M/s Alvogen, Inc.Morristown, NJ 07960 USA (USFDA approved) Me Too Status: Lyrica CR 82.5mg Extended release Tablet M/s Pfizer INC, NY Pack Size(s): 3x10's, 1x10's, 2x10-As per SRO Previous Approval: Gabal 82.5mg CR tablet, Meeting #324

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
66	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (4MH-R8E-XXM7, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Ammar Ashraf Awan)	Proposed Name: <b>Flopin 15mg + 100mg Tablet</b> Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid ..... 15mg Sitagliptin as Phosphate Monohydrate ..... 100mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Trevia R2 (15/100mg) by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Flopin Tablet, DRB 333 Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
67	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Winbrains Research Laboratories</b> , Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK, 000725 Tracking ID: (4QA-D1L-XMVD, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-10 (Ammar Ashraf Awan)	Proposed Name: <b>Lakzol 1% Cream</b> Each Gm Contains: Luliconazole...10 mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Lunaz 1% Cream, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
68	<b>Fast Pharmaceuticals (Pvt) Ltd.</b> Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (000954) Contract Manufacturing <b>Bio-Labs (Pvt) Ltd.</b> , 145, Industrial Trangle, Kahuta Road, 000296 Tracking ID: (58Q-T2A-AAUT, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2024-01-29 (Ammar Ashraf Awan)	Proposed Name: <b>Fe-C</b> Each ml contains: Iron as Ferric Carboxymaltose 50mg As per Innovators Specification RRA Status: USFDA Me Too Status: FCM Injection Genix Pharma Pack Size(s): 10ml-Controlled Previous Approval: MaletEvo Injection 131
	<b>Evaluation Remarks:</b> Reference of previous approval is of Maltevo injection approved in 331st RB meeting.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
69	<b>Polyfine Chempharma</b> 51 Industrial Estate Hayatabad Peshawar, Pakistan <b>(000216)</b> Contract Manufacturing <b>Biogen Life Sciences,</b> 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (5YA-1W5-W674, 2024-02-06) Fee Paid: 75000.0 Paid Date: 2023-08-17 (Ammar Ashraf Awan)	Proposed Name: <b>Propenem 500mg Injection</b> Each vial containMeropenem Trihydrate eq. to Meropenem .....500mg blended with Sodium bicarbonate United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Merem 500mg Injection Pack Size(s): 1's-As per SRO Previous Approval: Merogen 500mg Injection , 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
70	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura <b>(000976)</b> Contract Manufacturing <b>May &amp; Baker Pvt Ltd,</b> 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (63S-LLL-7UQ8, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Vancocin Dry Powder Injection 1gm</b> Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 1 G United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Vancomycin injection 1gm Pack Size(s): as per DPC-As per SRO Previous Approval: Bakrofor 100mg/5ml Injection Meeting # 323

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Myocin 1gm injection, approved in 324th meeting of Registration Board	
	<b>Decision:</b> Approved	
71	<b>Swiss Pharmaceuticals Pvt. Ltd.</b> A/159, S.I.T.E.-II, Super Highway (000438) Contract Manufacturing <b>WnsFeild Pharmaceutical</b> , Plot #122, Block A, Phase V, Industrial Estate, Hattar, Haripur, KPK, 000610 Tracking ID: (6JH-PTR-SAGN, 2024-04-15) Fee Paid: 75000.0 Paid Date: 2024-02-23 (Ammar Ashraf Awan)	Proposed Name: <b>Asvon 10mg/100mg Tablet</b> Each film coated tablet contains: Vonoprazan as Fumarate (outer immediate release layer).....10mg Aspirin (as enteric coated inner core) .....100mg As per Innovators Specification RRA Status: Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan) Me Too Status: N/A Pack Size(s): 3×10's-As per SRO Previous Approval: Venospa 10/100mg Tablet, DRB 324
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
72	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Welmark Pharmaceuticals</b> , Plot NO. 122, Block-B, Phase-V, Industrial Estate, Hattar, KPK. , 000614 Tracking ID: (6PS-2H9-4LJU, 2024-04-30) Fee Paid: 75000.0 Paid Date: 2024-04-01 (Ammar Ashraf Awan)	Proposed Name: <b>Dappo 5mg Tablets</b> Each Film Coated Tablet contains: Dapagliflozin as Propanediol Monohydrate .....5mg (Product Complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Dapa 5mg Tablet by Hilton Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: DAPAZIN 5MG TABLET BY WELMARK PHARMA
	<b>Evaluation Remarks:</b> Reference of previous approval is of Dapazin 5mg tablet approved in 326th meeting of Registration Board	
	<b>Decision:</b> Approved .	
73	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (72X-A49-BTY2, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Dolazen DS</b> Each Orally Disintegrating Tablet contains: Olanzapine ..... 20mg United States Pharmacopeia RRA Status: Zyprexa Velotab 20mg Me Too Status: NA Pack Size(s): 7's,10's,14's,20's,2-As per SRO Previous Approval: Olagen ODT Tablet 20mg, 331 DRB Meeting
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
74	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>BiogenLife Sciences</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (76P-UYE-W6YA, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>ISOWINK 20MG CAPSULE</b> EACH SOFT GEL CAPSULE CONTAINS:- ISOTRETINOIN.....20MG British Pharmacopeia RRA Status: UK MHRA APPROVED Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO Previous Approval: BIOTAN 20MG CAPSULE, DRB 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
75	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (7LW-DEP-9PAH, 2024-05-16) Fee Paid: 75000.0 Paid Date: 2024-05-15 (Ammar Ashraf Awan)	Proposed Name: <b>Aprima Tablets 28 Days Starter Pack</b> Each Pack Contains: 04 Tablets of Aprima 10mg Each film coated tablet contains Apremilast .....10mg Product Specs: Innovator's 04 Tablets of Aprima 20mg Each film coated tablet contains Apremilast .....20mg Product Specs: Innovator's 47 Tablets of Aprima 30mg Each film coated tablet contains Apremilast .....30mg Product Specs: Innovator's As per Innovators Specification RRA Status: OTEZLA Tablets 28 Days Starter Pack of Amgen Inc. Thousand Oaks, CA 91320-1799 U.S.A approved by USFDA Me Too Status: Apezla Tablets 28 Days Starter Pack of M/s Ferozsons Laboratories Limited. Pack Size(s): 55's-As per SRO Previous Approval: "Apriva Tablets Combo Pack" of M/s Ferozsons Laboratories Limited, approved in 326th Meeting of Regi
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
76	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. ( <b>000790</b> ) Contract Manufacturing <b>M/s Wezen Pharmaceuticals</b> , Plot No. 23 & 24 S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (7M1-X6S-VJ1M, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-18 (Ammar Ashraf Awan)	Proposed Name: <b>TRELGO 50mg TABLET</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....50mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA approved Me Too Status: Trelaglip 100 mg tablet Manufacturer: M/s The Searle Company Pack Size(s): As Per SRO-As per SRO Previous Approval: TABLET TRELLA 50 MG, 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
77	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Wnsfeild Pharmaceuticals,</b> Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar., 000610 Tracking ID: (7XG-L5R-82UH, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>TECOR 60MG TABLET</b> Each Film Coated Tablet Contains: TICAGRELOR.....60mg (Product complies BP Specs) British Pharmacopeia RRA Status: USFDA & MHRA approved Me Too Status: Anplag 60mg Tablet Pharmevo (Pvt) Ltd Reg. No.93105 Pack Size(s): As Per SRO-As per SRO Previous Approval: Tigawin Tablet 60mg, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
78	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat, 000882 Tracking ID: (8EY-1ET-N87M, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>Trella 100mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 133mg equivalent to Trelagliptin ..... 100mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
79	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (000644) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (8SU-N6L-56WW, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Ammar Ashraf Awan)	Proposed Name: <b>Trelgo 50mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 66.5mg equivalent to Trelagliptin ..... 50 mg As per Innovators Specification RRA Status: PMDA approved Zafatek® Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
80	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (9LU-PGJ-DHYX, 2024-04-18) Fee Paid: 75000.0 Paid Date: 2024-04-01 (Ammar Ashraf Awan)	Proposed Name: <b>FLOPIN 100MG/5mg Tablet</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglutamic Acid .....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Trevia R2 (5/100mg) 14 Tablets By GetZ Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Flopin Tablet, by Weather Folds Pharma, DRB 333
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
81	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (AD8-2P8-L42Q, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-02-03 (Ammar Ashraf Awan)	Proposed Name: <b>Cefket 2.5gm Injection</b> Each Vial Contains: Cefprozil as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: ZAVICEFTA 2.5GM INJECTION BY PFIZER Pack Size(s): As per SRO-As per SRO Previous Approval: CEFZECT 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
82	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.,</b> 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (ATL-7ZS-X5NB, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Deszo Film Coated Tablet 3mg</b> Each Film Coated tablet contains: Eszopiclone ----- 3mg United States Pharmacopeia RRA Status: LUNESTA (1mg, 2mg, 3mg) film coated tablets, USFDA Approved Me Too Status: Clonexa 3mg Tablet by M/s Atco Laboratories Pack Size(s): 7's, 10's, 14's, 20-As per SRO Previous Approval: Zopic 3mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
83	<b>sanofi-aventis Pakistan Limited</b> Plot 23, Sector 22, Korangi Industrial Area, (000007) Contract Manufacturing <b>Ferozsons Laboratories Limited,</b> P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan, 000038 Tracking ID: (AW7-MXX-25VM, 2024-05-22) Fee Paid: 75000.0 Paid Date: 2024-05-07 (Ammar Ashraf Awan)	Proposed Name: <b>Emjard M Tablets</b> Each film-coated tablet contains:Empagliflozin.....5mgMetformin hydrochloride.....500mg  RRA Status: Synjardy tablets (USFDA Approved) Me Too Status: Empagen-M Tablet 5/500mg by Ferozsons Laboratories Limited (Reg # 105335) Pack Size(s): 10's-As per SRO,14's-As per SRO,28's-As per SRO,30's-As per SRO Previous Approval: Empagen-M 5mg/500mg Tablets, 296th Meeting minutes

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
84	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.,</b> 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (AZQ-8Q8-9NBQ, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Depadol Sachet 75mg/25mg</b> Each sachet contains: Tramadol HCl..... 75mg Dexketoprofen (As dexketoprofen trometamol).....25mg As per Innovators Specification RRA Status: Skudexa 75mg/25mg Granules, Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare 1 Me Too Status: N/A Pack Size(s): 2's, 3's, 10's, 15's-As per SRO Previous Approval: Dektrol Sachet 75mg/25mg, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
85	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (BME-9UZ-MVND, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Dolazen DS</b> Each Orally disintegrating Tablet contains: Olanzapine.....10mg United States Pharmacopeia RRA Status: Zyprexa Velotab 10mg Me Too Status: Zyprexa Zydys Tablet 10mg Pack Size(s): 7's,10's,14's,20's,2-As per SRO Previous Approval: Olagen ODT Tablet 10mg, 331 DRB Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
86	<b>Highnoon Laboratories Ltd</b> 17.5 KM, Multan Road, ( <b>000155</b> ) Contract Manufacturing <b>Hudson Pharma Pvt. Ltd</b> , D-93 North Western Industrial Zone, Port Qasim Authority, Karachi., 000842 Tracking ID: (BQG-SS8-YR2V, 2024-02-22) Fee Paid: 75000.0 Paid Date: 2023-08-16 (Ammar Ashraf Awan)	Proposed Name: <b>BETATEC RESPULES</b> Each 2ml Respule contains: Beclometasone dipropionate...0.8mg As per Innovators Specification RRA Status: Product is registered in Italian Medicine Agency (AIFA), with the brand name “Clenil” by Chiesi Farm Me Too Status: Manufacturer name: Chiesi Farmaceutici, Italy. Importer: Chiesi Pharmaceutical (Pvt.) Ltd. Brand name: Clenil, Strength: 0.8mg/2ml, Registration number: 014091 Pack Size(s): 2ml * 1's-As per SRO,2ml * 10's-As per SRO,2ml * 5's-As per SRO Previous Approval: 320
	<b>Evaluation Remarks:</b> Registration Board was apprised that the instant case has previously been considered in 336th meeting of Registration Board.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Deferred The Board noted the information and decided to process the case as per Decision of 336th meeting.	
87	<b>Greater Pharmaceuticals Pvt Limited</b> Plot 35 Street SS-3 Rawat Industrial Estate Rawat <b>(000896)</b> Contract Manufacturing <b>Seraph Pharmaceutical</b> , Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan, 000860 Tracking ID: (BWQ-YL4-QV3G, 2024-04-22) Fee Paid: 75000.0 Paid Date: 2024-03-18 (Ammar Ashraf Awan)	Proposed Name: <b>Greatcef 400mg Capsule</b> Each capsule contains: Cefixime trihydrate .....400mg Any Other RRA Status: SUPRAX by Lupin Limited, USA FDA Me Too Status: Trispan by seraph Pharma Pack Size(s): 1x5s-As per SRO Previous Approval: Trispan 100mg/5ml
	<b>Evaluation Remarks:</b> Reference of previous approval is for Saf-Xime 400mg capsule approved in 297th meeting of Registration Board	
	<b>Decision:</b> Approved .	
88	<b>Polyfine Chempharma</b> 51 Industrial Estate Hayatabad Peshawar, Pakistan <b>(000216)</b> Contract Manufacturing <b>Biogen Life Sciences</b> , 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (D71-919-2JYN, 2024-02-06) Fee Paid: 75000.0 Paid Date: 2023-08-17 (Ammar Ashraf Awan)	Proposed Name: <b>Propenem 1gm Injection</b> Each vial containMeropenem Trihydrate eq. to Meropenem .....1gm blended with Sodium bicarbonate United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Merem 1gm Injection Pack Size(s): 1's-As per SRO Previous Approval: Merogen 500mg Injection , 312

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
89	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572) Contract Manufacturing <b>Focus &amp;Rulz Pharmaceuticals (PVT)LTD</b> , 44, Industrial Triangle,area Kahuta road, Islamabad, Pakistan, 000628 Tracking ID: (DBU-5H5-5LRY, 2024-04-29) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Ammar Ashraf Awan)	Proposed Name: <b>Linoz 100mg/5ml Dry suspension</b> Each 5ml contains: Linezolid.....100mg As per Innovators Specification RRA Status: Zyvox 100mg/5ml suspension (Pfizer) USA Me Too Status: Barizold 100mg/5ml suspension(Barrett Hodgson pakistan Pack Size(s): As per SRO -As per SRO Previous Approval: 324 meeting
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Zolincid suspesnion approved in 324th meeting of Registration Board.	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
90	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (DPM-X8U-JLST, 2024-04-18) Fee Paid: 75000.0 Paid Date: 2024-03-22 (Ammar Ashraf Awan)	Proposed Name: <b>MAREO-1GM INJECTION IV/ IM</b> Each Vial Contains: Meropenem Trihydrate eq. to. Meropenem.....1gm United States Pharmacopeia RRA Status: Merrem Injection (USFDA Approved) Me Too Status: Merrem Injection of Global Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-312 By the Name of MEROGEN Injection 1GM
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
91	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( 000655) Contract Manufacturing <b>Ferozsons Laboratories Limited,</b> P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (DGW-UBT-S7AX, 2024-04-18) Fee Paid: 75000.0 Paid Date: 2024-03-25 (Ammar Ashraf Awan)	Proposed Name: <b>Empolin-L Tablets 5mg/10mg</b> Each Film Coated Tablet Contains: Linagliptin.....5mg Empagliflozin.....10mg As per Innovators Specification RRA Status: GLYXAMBI 5mg/10mg of Boehringer Ingelheim Pharmaceutical, Inc approved by USFDA. Me Too Status: Diampa LT Tablets 5mg/10mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's , 28's -As per SRO Previous Approval: "Empagen-L Tablets 5mg/10mg" of M/s Ferozsons Laboratories Limited, approved in 297th Meeting of Re
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
92	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (DX2-HL9-MS2M, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Ammar Ashraf Awan)	Proposed Name: <b>Flopin 5mg + 100mg Tablet</b> Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid ..... 5mg Sitagliptin as Phosphate Monohydrate ..... 100mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Trevia R2 (5/100mg) by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Flopin Tablet, DRB 333 Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
93	<b>Greater Pharmaceuticals Pvt Limited</b> Plot 35 Street SS-3 Rawat Industrial Estate Rawat (000896) Contract Manufacturing <b>Seraph Pharmaceutical</b> , Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan, 000860 Tracking ID: (DXP-SUY-35GJ, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2024-03-18 (Ammar Ashraf Awan)	Proposed Name: <b>Greatxone 250mg Injection IM</b> Each Vial contains Ceftriaxone as sodium....250mg United States Pharmacopeia RRA Status: Rocephin 250mg Powder for Injection by Roche Products Limited, UK Medicines and Healthcare product Me Too Status: Droncef Injection 250mg IM by Seraph Pharmaceutical, Islamabad Pack Size(s): 1x1s-As per SRO Previous Approval: Droncef 250mg IM Injection

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Reference of previous approval is of Sixone 250mg IM injection approve din 307th RB meeting	
	<b>Decision:</b> Approved .	
94	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.</b> , 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (E24-5J1-WXNL, 2024-04-18) Fee Paid: 75000.0 Paid Date: 2024-04-05 (Ammar Ashraf Awan)	Proposed Name: <b>Daglox 150mg Film Coated Tablet</b> Elagolix Sodium 155.20 (eq to Elagolix.....150mg) As per Innovators Specification RRA Status: ORLISSA 150mg TABLET Manufactured by AbbVie Inc. approved by USFDA Me Too Status: N/A Pack Size(s): 7's, 14's, 28's-As per SRO Previous Approval: Elox 150mg Tablet, 331st Registration Board Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
95	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar ( <b>000574</b> ) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (E24-9VD-YE8X, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Ammar Ashraf Awan)	Proposed Name: <b>FLOPIN 100mg/5mg TABLET</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglutamic Acid .....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Trevia R2 (5/100mg) by Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: Flopin 5/100 mg Tablet, 333
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
96	<b>Winlet Pharmaceuticals (Pvt) Ltd.</b> 30-Km, Lahore Sargodha Raod, Sargodha ( <b>000874</b> ) Contract Manufacturing <b>M/s Biogen life sciences</b> , 8-km chakbeli road rawat Rawalpindi, 000911 Tracking ID: (E36-AUP-BJT4, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>d-let 50000 IU</b> Each soft gel capsule contains: Cholecalciferol ..... 50,000 I.U United States Pharmacopeia RRA Status: McGregor Cory Limited. Middleton Close, Banbury, Oxfordshire, OX16 4RS, United Kingdom Me Too Status: STEROL-D bY Genetics Pack Size(s): 1,s-Controlled Previous Approval: Succigen 250mg injection (M-307) reg. no. 109379
	<b>Evaluation Remarks:</b> Previous approval reference is of 3-D capsule approved in 312th meeting of Registration Board	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved ..	
97	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (EDG-HDL-Z57L, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Vosset 4mg/2ml Injection</b> Each 2ml Contains: Ondansetron as Hydrochloride dihydrate = 4mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: onset 4mg/2ml injection Pack Size(s): as per DPC-As per SRO Previous Approval: Baktron 4mg/2ml Injection approved in 321st meeting of RB
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
98	<b>Evolution Pharmaceuticals (Pvt.) Ltd.</b> Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. (000867) Contract Manufacturing <b>M/s Swera Pharmaceuticals</b> , M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, RCCI-Rawat, Islamabad, 000867 Tracking ID: (G57-ETU-P79X, 2024-02-06) Fee Paid: 75000.0 Paid Date: 2023-11-07 (Ammar Ashraf Awan)	Proposed Name: <b>ZOLTUM 40mg Injection</b> Each vials contains Omeprazole sodium eq. to Omeprazole .....40mg As per Innovators Specification RRA Status: Somezol Injection, Bosch pharma Plot No. 209, Shah Muhammad Rd, Sector 23 Korangi Industrial Area, Me Too Status: Omperazole 40mg powder for infusion, MHRA Approved Pack Size(s): 1,s-As per SRO Previous Approval: NO.F.5-6/2022-REG-II(M-322)



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Reference of previously approved product is of "Mepra 40mg " injection approved in 322nd meeting of Registration Board.	
	<b>Decision:</b> Approved .	
99	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (GWB-ZR6-5TNA, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>PROLIDE 2MG TABLET</b> Each film coated tablet contains: Prucalopride (as Succinate)..... 2 mg As per Innovators Specification RRA Status: UK MHRA APPROVED Me Too Status: Prutide Tablet 2mg Reg# 11640, by M/s Weather Folds Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Pruco Tablet, DRB 330
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
100	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Winbrains Research Laboratories</b> , Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan, 000725 Tracking ID: (H33-QZ6-919H, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>LAKZOL 1% CREAM</b> Each Gm Contains: Luliconazole...10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Lunaz 1% Cream, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
101	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.</b> , 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (HG5-Y22-JJ85, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Deszo Film Coated Tablet 1mg</b> Each Film Coated tablet contains: Eszopiclone ----- 1mg United States Pharmacopeia RRA Status: LUNESTA 1mg TABLET Me Too Status: Clonexa 1mg Tablet by M/s Atco Laboratories (Reg# 58428) Pack Size(s): 7's, 10's, 14's, 20-As per SRO Previous Approval: Zopic 1mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
102	<b>Genome Pharmaceuticals (Pvt.) Ltd,</b> Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. <b>(000454)</b> Contract Manufacturing <b>SERAPH PHARMACEUTICAL</b> , Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan, 000860 Tracking ID: (J27-6ZV-TSEY, 2024-04-15) Fee Paid: 75000.0 Paid Date: 2024-02-20 (Ammar Ashraf Awan)	Proposed Name: <b>GENOCAL 7.5mg/ml Injection</b> Each ampoule contains: Cholecalciferol (300,000IU) .....7.5mg British Pharmacopeia RRA Status: Xarenel® Injection is Approved in AIFA of Italy Me Too Status: D-Strong Injection 7.5mg (300,000IU) Pack Size(s): As per SRO-As per SRO Previous Approval: D-Strong Injection 7.5mg (300,000IU),330th Meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
103	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad <b>(000572)</b> Contract Manufacturing <b>WALLACE PHARMA EVOLUTIONS ,</b> <b>KALAWALA STOP, 20-KM, LAHORE</b> <b>JARANWALA ROAD, LAHORE , 000951</b> Tracking ID: (HTD-JX1-A847, 2024-04-30) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Ammar Ashraf Awan)	Proposed Name: <b>TAZOFIX 2.25gm Injection</b> Each Vial Contains: Piperacillin Sodium (USP) ..... 2000mg Tazobactam Sodium (USP) .....250mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: UK MHRA <a href="https://www.medicines.org.uk/emc/product/4748/smpc">https://www.medicines.org.uk/emc/product/4748/smpc</a> Product Name = PIPERACILLIN SODIUM + TAZ Me Too Status: Zosyn 2.25gm INJECTION (Regent Karachi by Cirin Pharma Hattar) Pack Size(s): As per SRO -As per SRO Previous Approval: 331 st meeting

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved	
104	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (HVN-TZ5-N6RZ, 2024-04-30) Fee Paid: 75000.0 Paid Date: 2024-04-03 (Ammar Ashraf Awan)	Proposed Name: <b>Empolin-M XR Tablets 10mg/1000mg</b> Each film coated tablet contains Empagliflozin.....10mg (as Immediate Release Coating) Metformin HCl.....1000mg (as Extended Release Core) As per Innovators Specification RRA Status: SYNJARDY XR 10mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Diampa-M XR Tablets 10mg/1000mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's , 28's -As per SRO Previous Approval: “Empagen-M XR Tablets 10/1000mg” of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
105	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan ( <b>000725</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat, 000882 Tracking ID: (L28-82D-MGWE, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Trelgo 100mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 133mg equivalent to Trelagliptin ..... 100mg As per Innovators Specification RRA Status: PMDA Japan approved Me Too Status: Treptin Tablet, Wezen Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
106	<b>Surge Laboratories (Pvt.) Ltd.</b> 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. ( <b>000484</b> ) Contract Manufacturing <b>Stallion Pharmaceuticals PVT, LTD</b> , 581- Sundar Industrial Estate, Lahore, 000783 Tracking ID: (L9R-35J-M1NW, 2024-04-15) Fee Paid: 75000.0 Paid Date: 2024-01-16 (Ammar Ashraf Awan)	Proposed Name: <b>Cipenem 500mg Injection</b> Each vial contains: Imipenem Monohydrate USP equivalent to Imipenem...500mg Cilastatin Sodium USP equivalent to Cilastatin.....500mg (USP Specs.) United States Pharmacopeia RRA Status: MHRA approved (Primaxin I.V. (Imipenem and Cilastatin for Injection) is being marketed by M/s “Merck Me Too Status: Cilapen 500mg Injection registered by Bosch Pharmaceuticals (Pvt) Ltd Pakistan Pack Size(s): 1 glass vial of Powd-As per SRO Previous Approval: Primaxin Injection, r 261st Meeting Registration Board
	<b>Evaluation Remarks:</b> Reference of previous approval is of ASPINEM 500 mg Injection approved in 323rd meeting of Registration Board	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
107	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (M4V-6E7-VJSQ, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Duradone</b> Each Film Coated Tablet Contains: Lurasidone HCL.....60mg As per Innovators Specification RRA Status: Latuda Tablet 60mg US FDA Me Too Status: Rasidone 60mg Tablet Pack Size(s): 10's & 30's-As per SRO Previous Approval: Lura Tablet 60mg, 331 DRB Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
108	<b>Weather Folds Pharmaceuticals</b> Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. ( <b>000644</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (N1L-QLP-VUTL, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Ammar Ashraf Awan)	Proposed Name: <b>Trelgo 100mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 133mg equivalent to Trelagliptin ..... 100mg As per Innovators Specification RRA Status: PMDA approved Zafatek® Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
109	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>BiogenLife Sciences</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (N5V-9T7-TG9Q, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>Chol-D 50,000 I.U Soft Gel Capsule</b> Each Soft Gel Capsule Contains:- Cholecalciferol.....50,000 I.U United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solar-D Soft gelatin Capsule 50,000 I.U by Crystolite Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: D-3 Capsule, DRB 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
110	<b>Fassgen Pharmaceuticals</b> PLOT # 67-1A- PHASE III. INDUSTRIAL EASTATE (000646) Contract Manufacturing <b> BIOGEN LIFE SCIENCES</b> , 8-Km, Chakbeli Road Rawat, Rawalpindi, Pakistan., 000911 Tracking ID: (N66-J9A-MTLZ, 2024-04-17) Fee Paid: 75000.0 Paid Date: 2023-11-21 (Ammar Ashraf Awan)	Proposed Name: <b>Acnepil 20 mg</b> Each soft gel capsule contains: Isotretinoin .....20mg  RRA Status: MHRA Approved Me Too Status: BIOTAN 20mg Capsule Pack Size(s): As per SRO-As per SRO Previous Approval: 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
111	<b>Highnoon Laboratories Ltd</b> 17.5 KM, Multan Road, (000155) Contract Manufacturing <b>Hudson Pharma Pvt. Ltd.</b> , D-93 North Western Industrial Zone, Port Qasim Authority, Karachi., 000842 Tracking ID: (N8E-R3G-ASQY, 2024-02-22) Fee Paid: 75000.0 Paid Date: 2023-08-16 (Ammar Ashraf Awan)	Proposed Name: <b>BETATEC S RESPULES</b> Each 2ml Respule contains: Beclometasone dipropionate...0.8mg Salbutamol sulphate 1.928mg equivalent to Salbutamol.....1.6mg As per Innovators Specification RRA Status: Product is registered in Italian Medicine Agency (AIFA), with the brand name “Clenil Compositum” by Me Too Status: Manufacturer name: Chiesi Farmaceutici, Italy. Importer: Chiesi Pharmaceutical (Pvt.) Ltd. Brand name: Clenil Compositum, Strength: 0.8mg+1.6mg/2ml, Registration number: 021199 Pack Size(s): 2ml * 1's-As per SRO,2ml * 10's-As per SRO,2ml * 5's-As per SRO Previous Approval: 322 (Pg# 503-509)
	<b>Evaluation Remarks:</b> Registration Board was apprised that the instant case has previously been considered in 336th meeting of Registration Board.	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Deferred The Board noted the information and decided to process the case as per Decision of 336th meeting.	
112	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (NLQ-3JD-A2XJ, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Dolazen DS</b> Each Orally Disintegrating Tablet Contains: Olanzapine.....15mg United States Pharmacopeia RRA Status: Zyprexa Velotab 15mg Me Too Status: NA Pack Size(s): 7's,10's,14's,20's,2-As per SRO Previous Approval: Olagen ODT Tablet 15mg, 331 DRB Meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
113	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.</b> , 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (NMX-QHW-Y9A5, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Deszo Film Coated Tablet 2mg</b> Each Film Coated tablet contains: Eszopiclone ----- 2mg United States Pharmacopeia RRA Status: LUNESTA (1mg, 2mg, 3mg) film coated tablets, USFDA Approved Me Too Status: Clonexa 2mg Tablet by M/s Atco Laboratories (Reg# 58429) Pack Size(s): 7's, 10's, 14's, 20'-As per SRO Previous Approval: Zopic 2mg Tablet, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
114	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (NNL-5V7-YBHE, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Haemofer 100mg/5ml Injection</b> Each 5ml Contains:IRON (III) HYDROXIDE SUCROSE COMPLEX Eq. to ELEMENTAL IRON.= 100mg British Pharmacopeia RRA Status: FDA Approved Venofer Injection Me Too Status: Ferosoft-S Injection Pack Size(s): as per DPC-As per SRO Previous Approval: Bakrofor 100mg/5ml Injection Meeting # 323
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Iron Plus 100mg/5ml approved in 323rd meeting of Registration Board.	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
115	<b>Seraph Pharmaceutical</b> Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (NZ4-R7A-628S, 2024-04-22) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Ammar Ashraf Awan)	Proposed Name: <b>MOXER 400mg/250ml INFUSION</b> Each vial of 250ml contains: Moxifloxacin (as hydrochloride).....400mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Moxiget 400mg/250ml Infusion Pack Size(s): 1's-As per SRO Previous Approval: Moxigen 400mg/250ml Infusion "320"
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
116	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (P3J-R39-NB3W, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Ammar Ashraf Awan)	Proposed Name: <b>FLOPIN 100mg/15mg TABLET</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglyutamic Acid .....15mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Trevia R2 (15/100mg) by Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: Flopin 15/100 mg Tablet, 333
	<b>Evaluation Remarks:</b> ..	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
117	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>M/s May &amp; Baker (Pvt) Ltd.,</b> , 45 Km, Dina Nath, Multan Road, Lahore., 000953 Tracking ID: (P85-MT3-61XX, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Stermet 4.5MIU Injection</b> Each vial Contains: Colistimethate Sodium (4.5M I.U) eq. to Colistin base activity = 150MG United States Pharmacopeia RRA Status: Approved by US FDA Me Too Status: Colistim 4.5MIU Injection Pack Size(s): As per SRO-As per SRO Previous Approval: Colmate 4.5 MIU powder for injection in 324th meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
118	<b>Welwink Pharmaceuticals</b> G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (000751) Contract Manufacturing <b>Wnsfeild Pharmaceuticals,</b> Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK, 000610 Tracking ID: (PME-H84-GDGE, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Ammar Ashraf Awan)	Proposed Name: <b>PROLIDE 1MG TABLET</b> Each film coated tablet contains: Prucalopride (as Succinate)..... 1mg As per Innovators Specification RRA Status: UK MHRA APPROVED Me Too Status: Prutide Tablet 1mg Reg# 116139, by M/s Weather Folds Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Pruco Tablet, DRB 330

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
119	<b>Sarco Chemicals Industries</b> 17-Km. Lahore Road Multan (000203) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd,</b> Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore, 000789 Tracking ID: (PYJ-HLZ-3UXN, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-11-10 (Ammar Ashraf Awan)	Proposed Name: <b>Pregab 165mg CR Tablet</b> Each Film Coated Extended Release Tablet Contains: Pregabalin.....165mg As per Innovators Specificatio RRA Status: PREGABALIN EXTENDED RELEASE tablet 165mg M/s Alvogen, Inc.Morristown, NJ 07960 USA (USFDA approved) Me Too Status: Lyrica CR 165mg Extended release Tablet M/s Pfizer INC, NY Pack Size(s): 3x10's, 1x10's, 2x10-As per SRO Previous Approval: Gabal 165mg CR tablet, Meeting #324
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
120	<b>Fassgen Pharmaceuticals</b> PLOT # 67-1A- PHASE III. INDUSTRIAL EASTATE (000646) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (Q8T-3VG-E8SV, 2024-04-17) Fee Paid: 75000.0 Paid Date: 2023-11-21 (Ammar Ashraf Awan)	Proposed Name: <b>Acnepil 10 mg</b> Each soft gel capsule contains: Isotretinoin .....10mg  RRA Status: Isotretinoin 10 mg soft capsules (Isotretinoin.....10mg) Me Too Status: BIOTAN 10mg Capsule Pack Size(s): As per SRO-As per SRO Previous Approval: BIOTAN 10mg Capsule, 312
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
121	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (QG8-YDS-92WA, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>No-Kamp 40mg/2ml Injection</b> Each 2ml ampoule Contains: Drotaverine Hydrochloride eq. to Drotaverine =40mg As per Innovators Specification RRA Status: ANSM Approved Me Too Status: No-Spa Injection Pack Size(s): as per DPC-As per SRO Previous Approval: Bakrofor 100mg/5ml Injection Meeting # 323
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Doviene 40mg/2mll approved in 323rd meeting of Registration Board.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
122	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>M/s May &amp; Baker (Pvt.) Ltd.,</b> 45 Km, Dina Nath, Multan Road, Lahore., 00953 Tracking ID: (QG9-DZN-6YUW, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>STERMET 1MIU INJECTION</b> Each vial contains: Colistimethate as sodium ..... 1MIU United States Pharmacopeia RRA Status: Approved by MHR of UK Me Too Status: Colistim 1MIU Injection Pack Size(s): As per SRO-As per SRO Previous Approval: Colmate 1 MIU powder for injection in 324th meeting
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
123	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Winbrains Research Laboratories,</b> PLOT #69/1, BLOCK B, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR., 000725 Tracking ID: (QHX-9ET-P1DJ, 2024-04-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Ammar Ashraf Awan)	Proposed Name: <b>MONEXI 5MG/ML EYE DROPS</b> Each mL Contains: Moxifloxacin (USP).....5mg (0.5%) (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: Azlox Ophthalmic Solution by Alza Pharmaceuticals 081625 Pack Size(s): As Per SRO-As per SRO Previous Approval: Monexi 5mg/5ml eye drops, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Previous Decision of 331st meeting for applied formulation form the contact manufacturer is as under:Registration Board approved the application of Monexi 5mg/5ml eye drops.performance report of the sterility test to be submitted	
	<b>Decision:</b> Approved	
124	<b>Genome Pharmaceuticals (Pvt.) Ltd,</b> Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (000454) Contract Manufacturing <b>SERAPH PHARMACEUTICAL,</b> Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan, 000860 Tracking ID: (QN7-YNS-J8D9, 2024-04-15) Fee Paid: 75000.0 Paid Date: 2024-02-20 (Ammar Ashraf Awan)	Proposed Name: <b>Genomalt Injection/Infusion 50 mg Iron/ml</b> Each 10ml ampoule contains: Ferric carboxymaltose corresponding to 500 mg iron.  RRA Status: Ferinject ® Dispersion for Injection/Infusion USFDA Me Too Status: Fercari Dispersion for Injection/Infusion 50 mg Iron/ml; 10 ml by Hilton Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Iron Inject Injection by seraph pharmaceutical in 331st DRB
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in p	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
125	<b>Biogen PHarma</b> 8-KM, Chak Beli Road, Rawat, (000639) Contract Manufacturing <b>Biogen Life Science</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi , 000911 Tracking ID: (R43-U6U-RLBQ, 2024-05-30) Fee Paid: 75000.0 Paid Date: 2024-05-30 (Ammar Ashraf Awan)	Proposed Name: <b>Bekum Injection 2g</b> Each vial contains: Meropenem Trihydrate eq.to meropenem .... 2 Gram (Blended with sodium carbonate) United States Pharmacopeia RRA Status: MEROPENEM Injection by Venus Pharma Germany approved And MHRA approved Me Too Status: Merem 2g Injection 2Gram Manufacturer Name Global Pharmaceutical Pack Size(s): 1's-As per SRO Previous Approval: Mi-PENEM Injection 2g.Minutes of 335th meeting of Registration Board
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
126	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572) Contract Manufacturing <b>Bio-Labs (PVT)Ltd</b> , Plot No.145 Industrial Triangle Kahuta Road Islamabd. , 000296 Tracking ID: (R46-S7J-NL4Y, 2024-05-16) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Ammar Ashraf Awan)	Proposed Name: <b>Colifix 68mg Injection</b> Each vial Contains: Colistimethate sodium (2MIU) eq. to 68mg Colistin Base Activity United States Pharmacopeia RRA Status: Colistimethate sodium 2MIU powder for solution for injection PANMEDICA (MHRA Approved) Me Too Status: Colistimethate sodium for injectionof Mukhtar Enterprises Lahore Reg#094757 Pack Size(s): 1's-As per SRO Previous Approval: 324 meeting
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
127	<b>Wezen Pharmaceuticals</b> Industrial Estate Rawat (000882) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial estate, Hattar, KPK, 000610 Tracking ID: (R4W-E9U-MZMU, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Ammar Ashraf Awan)	Proposed Name: <b>Azzota 40mg Tablet</b> Each Uncoated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil .....40mg (Product Complies Innovator's Specs) As per Innovators Specification RRA Status: UK MHRA Approved Me Too Status: Zelwist Tablet by Wnsfeild Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Azilta 40mg Tablet, DRB 326
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
128	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (RBZ-2TT-UW5Z, 2024-02-25) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Rotolac 30mg/ml Injection</b> Each ml Contains:Ketorolac Tromethamine= 30mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Toradol Injection Pack Size(s): as per DPC-As per SRO Previous Approval: Bakrofor 100mg/5ml Injection Meeting # 323
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Ketorol injection approved in 323rd meeting of Registration Board.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
129	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (S11-Q63-TU44, 2024-05-16) Fee Paid: 75000.0 Paid Date: 2024-05-15 (Ammar Ashraf Awan)	Proposed Name: <b>Devona Tablets 10mg</b> Each film coated tablet contains Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin .....10mg As per Innovators Specification RRA Status: FARXIGA 10mg Tablets of AstraZeneca Pharmaceuticals LP Wilmington, DE 19850 approved by USFDA. Me Too Status: Dapwiz 10mg Tablets of M/s Pharmevo Pvt Ltd. – Karachi. Pack Size(s): 10's, 14's-As per SRO Previous Approval: “Dekardi Tablets 10mg” of M/s Ferozsons Laboratories Limited, approved in 320th Meeting of Registrat
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
130	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (SL4-MVY-UD5R, 2024-02-29) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Duradone</b> Each Film Coated Tablet Contains: Lurasidone HCL ..... 120mg As per Innovators Specification RRA Status: Latuda Tablet 120mg US FDA Me Too Status: NA Pack Size(s): 10's & 30's-As per SRO Previous Approval: Lura Tablet 120mg, 331 DRB Meeting

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
131	<b>Welwrdr Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar ( <b>000574</b> ) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (SWV-AA3-MUPH, 2024-02-22) Fee Paid: 75000.0 Paid Date: 2023-12-28 (Ammar Ashraf Awan)	Proposed Name: <b>APPOXI 2.5MG TABLET</b> Each Film Coated Tablet Contains: Apixaban.....2.5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: ABAXIL 2.5 mg Tablets (Reg # 104678) M/s Saffron Pharmaceuticals (Pvt) Ltd. (DML # 000616) Pack Size(s): As Per SRO-As per SRO Previous Approval: AXNAP 2.5mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
132	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (T3Z-7Y1-9X6B, 2024-05-16) Fee Paid: 75000.0 Paid Date: 2024-05-15 (Ammar Ashraf Awan)	Proposed Name: <b>Aprima Tablets 30mg</b> Each film coated tablet contains Apremilast .....30mg Product Specs: Innovator's As per Innovators Specification RRA Status: OTEZLA 30mg Tablets of Amgen Inc. Thousand Oaks, CA 91320-1799 U.S.A approved by USFDA Me Too Status: Apremist 30mg Tablets of M/s Crystolite Pharmaceuticals Islamabad Pack Size(s): 4 x 14's-As per SRO Previous Approval: "Apriva Tablets 30mg" of M/s Ferozsons Laboratories Limited, approved in 326th Meeting of Registrati
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
133	<b>Greater Pharmaceuticals Pvt Limited</b> Plot 35 Street SS-3 Rawat Industrial Estate Rawat ( <b>000896</b> ) Contract Manufacturing <b>Seraph Pharmaceutical</b> , Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan, 000860 Tracking ID: (T7X-3YB-D3JU, 2024-04-19) Fee Paid: 75000.0 Paid Date: 2024-03-18 (Ammar Ashraf Awan)	Proposed Name: <b>Greatxone 500mg Injection IM</b> Each Vial contains Ceftriaxone as sodium....500mg United States Pharmacopeia RRA Status: Rocephin 500mg Powder for Injection by Roche Products Limited, UK Medicines and Healthcare product Me Too Status: Droncef Injection 500mg IM by Seraph Pharmaceutical, Islamabad Pack Size(s): 1x1s-As per SRO Previous Approval: Droncef 250mg IM Injection
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Sixone 500mg IM injection approved in 307th meeting of Registration Board	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
134	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (T9S-TGZ-XMG1, 2024-02-23) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Oramep 20mg capsule</b> Each capsule Contains:Omeprazole as EC pellets = 20mg As per Innovators Specification RRA Status: FDA Approved Me Too Status: Risek capsule Pack Size(s): as per DPC-As per SRO Previous Approval: omebak 20mg capsule 322nd meeting
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Ozole capsule approved in 322nd meeting of Registration Board.	
	<b>Decision:</b> Approved	
135	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (U3U-MUS-XQ59, 2024-05-29) Fee Paid: 75000.0 Paid Date: 2024-05-23 (Ammar Ashraf Awan)	Proposed Name: <b>KETRIOL-1MCG INJECTION IV/ IM</b> Each ml ampoule contains:- Calcitriol.....1mcg United States Pharmacopeia RRA Status: CALCIJEX® (calcitriol injection) 1 mcg/mL (FDA Approved) Me Too Status: Rotacal 1 mcg Injection Reg. No. 107285 By Rotex Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-335 By the Name of Calcigen 1mcg/ml Injection

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
136	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (VAM-LED-VGTZ, 2024-04-19) Fee Paid: 75000.0 Paid Date: 2024-03-25 (Ammar Ashraf Awan)	Proposed Name: <b>Empolin-L Tablets 5mg/25mg</b> Each Film Coated Tablet Contains: Linagliptin.....5mg Empagliflozin.....25mg As per Innovators Specification RRA Status: GLYXAMBI 5mg/25mg of Boehringer Ingelheim Pharmaceutical, Inc approved by USFDA. Me Too Status: Diampa LT Tablets 5mg/25mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's , 28's -As per SRO Previous Approval: “Empagen-L Tablets 5mg/25mg” of M/s Ferozsons Laboratories Limited, approved in 313th Meeting of Re
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
137	<b>Seraph Pharmaceutical</b> Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (WEM-426-Q17E, 2024-04-22) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Ammar Ashraf Awan)	Proposed Name: <b>MOXER 400mg/250ml INFUSION</b> Each vial 250ml contains: Moxifloxacin as hydrochloride 400 mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Moxiget 400mg/250ml Infusion Pack Size(s): 1's-As per SRO Previous Approval: Moxigen 400mg/250ml Infusion "320"
	<b>Evaluation Remarks:</b> Application may be deleted since it is firm has applied same formulation in another application of tracking ID "NZ4-R7A-628S" presented in instant meeting.	
	<b>Decision:</b> Rejected .	
138	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Bio-Mark Pharmaceuticals (Pvt.) Ltd.,</b> Plot No. 527, Sundar Industrial Estate, Lahore- PAKISTAN., 000863 Tracking ID: (WGY-2UY-RWPR, 2024-05-21) Fee Paid: 75000.0 Paid Date: 2024-05-03 (Ammar Ashraf Awan)	Proposed Name: <b>ONDANSETRON-4MG/ 5ML SYRUP</b> Each 5ml contains: Ondansetron (as Ondansetron HCl) .....4mg United States Pharmacopeia RRA Status: ZOFTRAN oral Syrup is USFDA approved Me Too Status: DYSIT oral Syrup By Wimits Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-317 By the Name of ONDATRO SYRUP 4mg/5ml
	<b>Evaluation Remarks:</b> ..	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
139	<b>Macter International Limited</b> E-40/A,S.I.T.E.,Karachi-Pakistan ( <b>000641</b> ) Contract Manufacturing <b>CSH Pharmaceuticals (Pvt.) Ltd.,</b> 32-Km, Ferozepur Road, Lahore – Pakistan , 000737 Tracking ID: (WLM-P27-6V1S, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2023-12-13 (Ammar Ashraf Awan)	Proposed Name: <b>Co-Amoxi Drops 62.50mg</b> When reconstituted as directed Each ml contains: Amoxicillin as trihydrate USP.....50mg Clavulanic acid as Potassium salt BP.....12.5mg Product Complies USP Specifications. United States Pharmacopeia RRA Status: Augmentin Drops 62.50mg (US FDA Approved) Me Too Status: Amclav Drops 62.50mg (Manufactured by: Getz Pharma, Pakistan) Pack Size(s): 10ml, 20ml -As per SRO Previous Approval: Fortecin oral powder for infants drops 62.50mg/ml of The Searle Company Limited (Approved in 331st M
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
140	<b>sanofi-aventis Pakistan Limited</b> Plot 23, Sector 22, Korangi Industrial Area, ( <b>000007</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited,</b> P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan, 000038 Tracking ID: (WPD-9YR-Z8EY, 2024-05-24) Fee Paid: 75000.0 Paid Date: 2024-05-07 (Ammar Ashraf Awan)	Proposed Name: <b>Emjard M Tablets 5mg/1000mg</b> Each film coated tablet contains:Empagliflozin.....5mgMetformin hydrochloride.....1000mg  RRA Status: Synjardy tablets (USFDA Approved) Me Too Status: Empagen-M Tablet 5/1000mg by Ferozsons Laboratories Limited (Reg # 105543) Pack Size(s): 14's-As per SRO,28's-As per SRO Previous Approval: Empagen-M 5mg/1000mg Tablets, 296th Meeting minutes

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
141	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma</b> , Plot No, 44-45-B Korangi Creek Road Karachi, 000351 Tracking ID: (XQ4-7WW-BL2V, 2024-02-26) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Dolazen DS</b> Each Orally disintegrating Tablet contains: Olanzapine.....5mg United States Pharmacopeia RRA Status: Zyprexa Velotab 5mg Me Too Status: Zyprexa Zydis Tablet 5mg Pack Size(s): 10's-As per SRO Previous Approval: Olagen ODT Tablet 5mg, 331 DRB Meeting
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
142	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (XV6-WMJ-XBY3, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Ammar Ashraf Awan)	Proposed Name: <b>FLOPIN 100mg/5mg TABLET</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglutamic Acid .....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Trevia R2 (5/100mg) by M/s Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: Flopin 5/100 mg Tablet, 333
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
143	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore (000688) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.,</b> 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (X1N-UY4-AEV9, 2024-02-23) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Ammar Ashraf Awan)	Proposed Name: <b>Dexifen Infusion 600mg/100ml</b> Each 100ml of solution contains: Ibuprofen.....600mg As per Innovators Specification RRA Status: Ibuoprofen B. Braun Infusion 600mg/100ml HPRA approved Me Too Status: Ubrof Infusion 600mg/100ml of M/s Sami Pharma , Karachi (Reg.No. 105263) Pack Size(s): 100ml-As per SRO Previous Approval: Exifin Infusion 600mg/100ml
	<b>Evaluation Remarks:</b> The reference of previously approved product is of Exifin Infusion 600mg/100ml approved in 331st meeting of Registration Board.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
144	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (X4G-N4N-A1SE, 2024-05-29) Fee Paid: 75000.0 Paid Date: 2024-05-22 (Ammar Ashraf Awan)	Proposed Name: <b>Nebivia Tablets 2.5mg</b> Each film coated tablet contains Nebivolol Hydrochloride Eq. to Nebivolol.....2.5mg As per Innovators Specification RRA Status: BYSTOLIC 2.5mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA. Me Too Status: Nebix 2.5mg Tablets of M/s Highnoon Laboratories Ltd. Pack Size(s): 10's, 14's, 30's -As per SRO Previous Approval: “Nebita 2.5mg Tablets” of M/s Ferozsons Laboratories Limited, approved in 329th Meeting of Registrat
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved .	
145	<b>Winthrox Laboratories Pvt. Ltd</b> K-219-A, SITE, Super Highway Phase II, Karachi ( <b>000807</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK , 000610 Tracking ID: (Y63-L3T-7Y53, 2024-04-15) Fee Paid: 75000.0 Paid Date: 2024-02-13 (Ammar Ashraf Awan)	Proposed Name: <b>Esonip Tablet 20mg/500mg</b> Each Modified release Tablet contains: Esomeprazole (as Magnesium Trihydrate) as IR .....20mg Naproxen(as Enteric Coated Core) .....500mg ( As per Innovators Specifications) As per Innovators Specification RRA Status: Vimovo Tablet by Horizon Pharma USA Me Too Status: Eznepo MR Tablet 500 20mg (Reg# 117966) by Wnsfeild Pharma Pack Size(s): 30s-As per SRO Previous Approval: Esonyp DR Tablet 20mg/500mg 324th DRB Meeting dated 24th - 26th January 2023

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	
146	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Wezen Pharmaceuticals,</b> Plot No. 23 & 24 S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (ZMY-561-E1XH, 2024-02-07) Fee Paid: 75000.0 Paid Date: 2024-01-18 (Ammar Ashraf Awan)	Proposed Name: <b>TRELGO 100mg TABLET</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....100mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA approved Me Too Status: Trelaglip 100 mg tablet Manufacturer: M/s The Searle Company Pack Size(s): As Per SRO-As per SRO Previous Approval: TABLET TRELLA 100 MG, 331
	<b>Evaluation Remarks:</b> ..	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
147	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (ZUN-H3L-19E6, 2024-02-23) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Esszole 40mg Dry powder Injection</b> Each vial Contains:Esomeprazole Sodium eq. to Esomeprazole = 40mg As per Innovators Specification RRA Status: MHRA Me Too Status: Nexum 40mg vial Pack Size(s): as per DPC-As per SRO Previous Approval: Esozium 40mg dry powder vial 327th meeting
	<b>Evaluation Remarks:</b> Reference of previously approved product is of Ezole 40mg injection approved in 327th meeting of Registration Board.	
	<b>Decision:</b> Approved	
148	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (ZZS-V99-3H6Y, 2024-02-23) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Ammar Ashraf Awan)	Proposed Name: <b>Citolit Injection 1gm/4ml</b> Each 4ml Contains: Citicoline as sodium= 1gm As per Innovators Specification RRA Status: AIFA approved Me Too Status: Citolin 1000mg/4ml Pack Size(s): 1's-As per SRO Previous Approval: Maykoline 1gm/4ml 323rd Meeting
	<b>Evaluation Remarks:</b> Reference of previously approved product is of C-Coline Injection approved in 323rd meeting of Registration Board.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
149	<b>Valor Pharmaceuticals</b> Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad (000496) Contract Manufacturing <b>M/S Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat - Rawalpindi, 000911 Tracking ID: (127-ZUW-HEMJ, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-11-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Dorival 500mg Injection</b> Each Vial Contains: Doripenem monohydrate eq. to doripenem.... 500mg (JP Specifications) Any Other RRA Status: Finibax Infusion 0.5gm PMDA JAPAN Approved Me Too Status: Dorinem Injection by ICI Pharma Pack Size(s): 1's-As per SRO Previous Approval: Dorigen 500mg Injection in M-316
	<b>Evaluation Remarks:</b> Japanese Pharmacopoeia specifications	
	<b>Decision:</b> Approved .	
150	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. , 000882 Tracking ID: (16Z-3Y3-5BXJ, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trella 50mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 66.5mg equivalent to Trelagliptin ..... 50 mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
151	<b>Valor Pharmaceuticals</b> Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad (000496) Contract Manufacturing <b>M/S Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat - Rawalpindi, 000911 Tracking ID: (19N-V2W-88N2, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-11-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Imival 250mg Injection</b> Each Vial Contains: Imipenem (as monohydrate)....250mg Cilastatin (as Sodium).....250mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Cilapen 250mg Injection by Bosh Pharmaceuticals having registration number 048490 Pack Size(s): 1's-As per SRO Previous Approval: Cilagen 250mg Injection IV by M-330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
152	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( 000655) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (1R2-WXD-7639, 2024-05-09) Fee Paid: 75000.0 Paid Date: 2024-04-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Empolin-M XR Tablets 12.5mg/1000mg</b> Each film coated tablet contains Empagliflozin.....12.5mg (as Immediate Release Coating) Metformin HCl.....1000mg (as Extended Release Core) As per Innovators Specification RRA Status: SYNJARDY XR 12.5mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Diampa-M XR Tablets 12.5mg/1000mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's , 28's -As per SRO Previous Approval: "Empagen-M XR Tablets 12.5/1000mg" of M/s Ferozsons Laboratories Limited, approved in 296th Meeting
	<b>Evaluation Remarks:</b>	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
153	<b>Valor Pharmaceuticals</b> Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad (000496) Contract Manufacturing <b>M/S Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat - Rawalpindi, 000911 Tracking ID: (2G4-2WW-WV1A, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-11-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Imival 500mg Injection</b> Each Vial Contains: Imipenem (as monohydrate).....500mg Cilastatin (as sodium).....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cilapen 500mg Injection by Bosh Pharmaceuticals having registration number 048491 Pack Size(s): 1's-As per SRO Previous Approval: Biocilas 500/500mg Injection IV in M-330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
154	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (2QE-Z6X-BEUX, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tegit 60mg Tablet</b> Each film coated tablet contains: Ticagrelor ... 60mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Anplag 60mg Tablet Pharmevo (Pvt) Ltd Pack Size(s): As Per SRO-As per SRO Previous Approval: Tigawin Tablet 60mg, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
155	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (2UJ-TT3-2BU2, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tecor 60mg Tablet</b> Each film coated tablet contains: Ticagrelor ... 60mg British Pharmacopeia RRA Status: UK MHRA Me Too Status: Anplag 60mg Tablet Pharmevo (Pvt) Ltd Reg. No.93105 Pack Size(s): As per SRO-As per SRO Previous Approval: Tigawin 60mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
156	<b>Trigon Pharmaceuticals (Private) Ltd</b> 8-k.m thokar raiwind road Lahore (000342) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore. , 000951 Tracking ID: (49V-MHQ-X3HN, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>IMASTIN 1000MG INJECTION</b> Each vial Contains: Imipenem as Monohydrate (USP)..... 500mg Cilastatin as Sodium (USP)..... 500mg (Product complies USP Specs) United States Pharmacopeia RRA Status: Approved by USFDA Me Too Status: CILENEM INJECTION 1000mg BY GENIX PHARMA Pack Size(s): 1's-As per SRO Previous Approval: DRB Meeting, 323rd. Nemcil 1g Injection
	<b>Evaluation Remarks:</b> Nemcil 500mg/500mg Injection approved in 323 RB meeting	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
157	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (3TN-8M8-SL73, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>obbitta 10mg Tablet</b> Each Film Coated Tablet Contains: Obeticholic Acid.....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Ocafib 10mg tablet by M/s Sami pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: B-Kolic Tablet 10mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
158	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610) Contract Manufacturing <b>Winbrains Research Laboratories,</b> Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK., 000725 Tracking ID: (44J-A5Y-UBXH, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Lakzol 1% Cream</b> Each Gm Contains: Luliconazole...10 mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Lunaz 1% Cream, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
159	<b>Trigon Pharmaceuticals (Private) Ltd</b> 8-k.m thokar raiwind road Lahore (000342) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore. , 000951 Tracking ID: (4A7-33Q-5VN4, 2024-01-22) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Mynoma 500mg Injection</b> Each vial contains:- Meropenem (as trihydrate).....500mg (Blended with sodium carbonate) (Product complies USP Specs) United States Pharmacopeia RRA Status: Approved by USFDA Me Too Status: OIVER INJECTION 500mg by Genix Pharma Pack Size(s): 1's-As per SRO Previous Approval: DRB Meeting, 323rd. Merfenum 500mg Injection
	<b>Evaluation Remarks:</b> Ropen (Meropenem) 500mg injection approved in 323rd RB meeting.	
	<b>Decision:</b> Approved .	
160	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( 000655) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (5LD-5S9-JVQ3, 2024-05-16) Fee Paid: 75000.0 Paid Date: 2024-04-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Empolin-M XR Tablets 25mg/1000mg</b> Each film coated tablet contains Empagliflozin.....25mg (as Immediate Release Coating) Metformin HCl.....1000mg (as Extended Release Core) As per Innovators Specification RRA Status: SYNJARDY XR 25mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Diampa-M XR Tablets 25mg/1000mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's -As per SRO Previous Approval: "Empagen-M XR Tablets 25/1000mg" of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
161	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK., 000644 Tracking ID: (5Q6-JJ3-GVDH, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-03 (Dr. Muhammad Haseeb Tariq)	Proposed Name: <b>Bempid 180mg Tablet</b> Each film coated tablet contains: Bempedoic Acid ..... 180 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: PDM 180mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
162	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat. , 000882 Tracking ID: (5WZ-ZL9-SGPH, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhammad Haseeb Tariq)	Proposed Name: <b>Trella 50mg Tablet</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....50mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan approved Zafatek® Me Too Status: Treptin 50mg Tablet, by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
163	<b>sanofi-aventis Pakistan Limited</b> Plot 23, Sector 22, Korangi Industrial Area, (000007) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan, 000038 Tracking ID: (5Y9-QWW-TUW2, 2024-05-14) Fee Paid: 75000.0 Paid Date: 2024-05-07 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Emjard M Tablets 12.5mg/500mg</b> Each film coated tablet contains:Empagliflozin.....12.5mgMetformin Hydrochloride.....500mg  RRA Status: Synjardy tablets (USFDA Approved) Me Too Status: Empagen-M Tablet 12.5/500mg by Ferozsons Laboratories Limited (Reg # 105544) Pack Size(s): 14's-As per SRO,28's-As per SRO Previous Approval: Empagen-M Tablet 12.5mg/500mg, 296th Meeting minutes
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
164	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (6EX-YVU-V2H6, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Verozen 10mg Tablet</b> Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan approved Me Too Status: Vonseca 10mg tablet by M/s Tabros, Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Verozen 10mg Tablet, DRB 322
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
165	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. <b>(000790)</b> Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> Plot No. 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (6QR-4QQ-6M7R, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>CEFZECT 2.5GM INJECTION</b> Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Zavicefta Injection by Pfizer (Reg No. 106848) Pack Size(s): As Per SRO-As per SRO Previous Approval: CEFZECT 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
166	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. <b>(000951)</b> Contract Manufacturing <b>Wnsfeild Pharmaceuticals,</b> Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (72H-YM5-ZJWV, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Vorxet 20mg Tablet</b> Each film coated tablet contains; Vortioxetine hydrobromide equivalent to Vortioxetine.....20mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Vorneu 20mg tablet M/s Hilton Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Vortex 20mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
167	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals</b> , 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (72Y-RMX-W39Q, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>BEMPID 180MG TABLET</b> Each Film Coated Tablet Contains: Bempedoic Acid.....180mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: N/A Pack Size(s): As Per SRO-As per SRO Previous Approval: PDM 180 mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
168	<b>The Searle Company Limited</b> Karachi (000016) Contract Manufacturing <b>M/s. Stallion Pharmaceuticals</b> , Plot # 581 – Sundar Industrial Estate, Raiwind Road Lahore., 000783 Tracking ID: (76P-L7A-EP3H, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-04-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>MEROMAX 500mg Injection</b> Each vial contains: Meropenem (as Trihydrate) .....500mg (Blended with Sodium Carbonate) United States Pharmacopeia RRA Status: Approved by USFDA, with the name of: Merrem 500mg IV by Astrazeneca Me Too Status: Merostin 500mg Injection M/s Stallion Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per DPC-As per SRO Previous Approval: Romero 500mg Injection, Drug Registration Board Meeting Number 312
	<b>Evaluation Remarks:</b> MOPEN Injection 500mg approved in 312 RB meeting.	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
169	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (7NN-NUL-NH54, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Vorxet 10mg Tablet</b> Each film coated tablet contains; Vortioxetine hydrobromide equivalent to Vortioxetine.....10mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Vorneu 10mg tablet Reg. No. 107777 M/s Hilton Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Vortex 10mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
170	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Bio-Mark Pharmaceuticals (Pvt.) Ltd.</b> , Plot No. 527, Sundar Industrial Estate, Lahore- PAKISTAN., 000863 Tracking ID: (7XR-V83-AY9W, 2024-05-14) Fee Paid: 75000.0 Paid Date: 2024-05-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>DESLORATADINE-0.5MG/ ML SYRUP</b> Each ml contains: Desloratadine.....0.5mg As per Innovators Specification RRA Status: NEO-CLARITYN oral Syrup is USFDA approved Me Too Status: DELERGIA oral Syrup By PharmeVo (Pvt.) Ltd. Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-297 VARIDINE SYRUP

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
171	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (88G-GVN-NY57, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-05 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Cefzect 2.5gm Injection</b> Each vial Contains: Ceftazidime (as pentahydrate).....2000mg Avibactam (as sodium salt).....500mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Zavicefta Injection by Pfizer (Reg No. 106848) Pack Size(s): As per SRO-As per SRO Previous Approval: CEFZECT 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
172	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore., 000951 Tracking ID: (898-TW7-E7YS, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Meropenem 1gm Injection</b> Each vial contains:- Meropenem (as trihydrate).....1gm (Blended with sodium carbonate) (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ropen Injection of Macter International Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Ropen 1g Injection, DRB 323rd Meeting
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
173	<b>SIMZ PHARMACEUTICALS PVT LTD</b> 574-575 SUNDAR INDUSTRIAL ESTATE LAHORE (000762) Contract Manufacturing <b>M/s Bio Mark Pharmaceuticals</b> , Plot No. 527, Sundar Industrial Estate, Lahore, 000863 Tracking ID: (8AX-ME9-6XTV, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Simtron</b> Each 5ml contains: Ondansetron (as Hydrochloride Dihydrate).....4mg United States Pharmacopeia RRA Status: Zofran Syrup by GSK USFDA Approved Me Too Status: Zofran Syrup by GSK Pack Size(s): 1s-As per SRO Previous Approval: Apron 4mg/5ml Syrup , 316 meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
174	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (8HE-MUT-M34H, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Levcart 1gm Injection</b> Each 5ml ampoule Contains: Levocarnitine ..... 1gm As per Innovators Specification RRA Status: Carnitor 1gm/5ml Injection USFDA approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Pack Size(s): As Per SRO-As per SRO Previous Approval: L-Carta 1gm injection, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
175	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (8MU-5R1-VXGL, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 10mg Tablet</b> Each Film Coated Tablet Contains: Obeticholic Acid.....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Ocafib 10mg film-coated tablet of M/s Sami pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 10mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
176	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (8VA-3SR-XXW1, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Azzota 80mg Tablet</b> Each tablet contains: Azilsartan Medoxomil (as Potassium) .....80mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Azilta 80mg Tablet, DRB 326 Pack Size(s): As per SRO-As per SRO Previous Approval: Azilta 80mg Tablet, DRB 326
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
177	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610) Contract Manufacturing <b>Winbrains Research Laboratories</b> , Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK., 000725 Tracking ID: (987-US6-ETG1, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Monexi Eye Drops</b> Each ml contains: Moxifloxacin HCl as Moxifloxacin .....5mg (0.5%) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Azlox ophthalmic solution 2900 Minutes of 331st Meeting of Registration Board held on 31st Oct – 2nd Nov, 2023 Alza Pharmaceuticals 081625 Pack Size(s): As per SRO-As per SRO Previous Approval: Monexi Eye Drops, DRB 331
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
178	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat. , 000882 Tracking ID: (A1X-UJB-2T13, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Dexxlo 60mg Capsule</b> Each capsule contains: Dexlansoprazole (as dual delayed release pellets).....60mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: DEXZEN 60mg Capsule, DRB 330
	<b>Evaluation Remarks:</b> .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
179	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. <b>(000790)</b> Contract Manufacturing <b>M/s Welmark pharmaceuticals</b> , Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar., 000614 Tracking ID: (A3Q-LLN-LXQW, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tenfo 25mg Tablet</b> Each film-coated tablet contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide .....25mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Tenofovir Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109 Pack Size(s): As Per SRO-As per SRO Previous Approval: Teno 25mg Tablet, DRB 324
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
180	<b>Onyx Pharmaceuticals</b> 30-A small Industrial Estate mansehra <b>(000440)</b> Contract Manufacturing <b>Bio-Mark Pharmaceuticals</b> , Plot # 527, Sundar Industrial Estate, Lahore, 000863 Tracking ID: (A4E-6X7-PNQX, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-05-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Ozonex 20mg capsule</b> Each capsule contains: Omeprazole (as enteric coated pelettes).....20mg United States Pharmacopeia RRA Status: Risek Capsules by Getz Pharma Me Too Status: Risek Capsule by Getz Pharma Pack Size(s): 14 & 28's-As per SRO Previous Approval: Gosoft 20mg Capsule (Meeting no. 329)
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
181	<b>Valor Pharmaceuticals</b> Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad (000496) Contract Manufacturing <b>M/S Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat - Rawalpindi, 000911 Tracking ID: (A7S-EWT-JT7D, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-11-06 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Acetoval 10mg/ml Infusion</b> Each Vial Contains: Paracetamol.....10mg/ml solution for infusion As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Provas Infusion by Sami Pharmaceuticals having registration number 050650 Pack Size(s): 1 x 100ml-As per SRO Previous Approval: Actogen 100ml Vial in M-330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved with following label claim:Each vial contains: Paracetamol.....1g/100mlRegistration Board further decided that registration letter will be issued after submission of 75,000/- fee for correction / revision of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
182	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. , 000644 Tracking ID: (ABT-JLU-2DY7, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Bemdi 180mg Tablet</b> Each film coated tablet contains: Bempedoic Acid ..... 180 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As Per SRO-As per SRO Previous Approval: PDM 180 mg Tablet, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
183	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK ( <b>000610</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot no. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (AEV-PL9-5V2Y, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trella 100mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 133mg equivalent to Trelagliptin ..... 100mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
184	<b>The Searle Company Limited</b> Karachi ( <b>000016</b> ) Contract Manufacturing <b>M/s. Stallion Pharmaceuticals</b> , Plot # 581 – Sundar Industrial Estate, Raiwind Road Lahore., 000783 Tracking ID: (AJ1-J15-GHSY, 2024-01-23) Fee Paid: 75000.0 Paid Date: 2023-04-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>MEROMAX 1000mg Injection</b> Each vial contains: Meropenem (as Trihydrate) .....1000mg (Blended with Sodium Carbonate) United States Pharmacopeia RRA Status: Approved by USFDA, with the name of: Merrem 1000mg IV by Astrazeneca Me Too Status: Merostin 1000mg Injection M/s Stallion Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per DPC-As per SRO Previous Approval: Romero 1000mg Injection, Drug Registration Board Meeting Number 312



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> MOPEN Injection 1g approved in 312 RB meeting	
	<b>Decision:</b> Approved .	
185	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (000610) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK., 000644 Tracking ID: (ARB-ALN-3SD6, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 10mg Tablet</b> Each film coated tablet contains: Obeticholic Acid .....10 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Ocafib 10mg tablet by M/s Sami pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 10mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
186	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (AVD-3GX-LUZ2, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Bempid 180mg Tablet</b> Each film coated tablet contains: Bempedoic Acid ..... 180 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: PDM 180 mg Tablet, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
187	<b>Sapient Pharma</b> 123/S Quaid E Azam Industrial Estate Kot Lakhpat (000207) Contract Manufacturing <b>Bio-Mark Pharmaceuticals,</b> 527 Sundar Industrial Estate, Lahore, 000863 Tracking ID: (B9Q-9BA-VJ83, 2024-01-11) Fee Paid: 75000.0 Paid Date: 2023-12-12 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Samplozin 25mg tablet</b> Each film coated tablet contains:Empagliflozin .....25mg  RRA Status: Jardiance Tablet by Boehringer Ingelheim Me Too Status: Diampa Tablets by GETZ Pharma Pack Size(s): 14 & 28's-As per SRO Previous Approval: EmpMark 25mg Tablet (Meeting 331st)
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
188	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wallace Pharma Evolutions,</b> Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore., 000951 Tracking ID: (BYX-SQ2-9SLR, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tazocin 4.5gm Injection</b> Each Vial Contains: Piperacillin As Sodium .....4g, Tazobactam as Sodium .. .....500mg  RRA Status: USFDA Approved Me Too Status: Zosyn 4.5gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As per SRO-As per SRO Previous Approval: TAZOCIN 4.5gm Injection, DRB 331

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
189	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (D3R-A7L-DJ77, 2024-05-03) Fee Paid: 75000.0 Paid Date: 2024-04-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Devona Tablets 5mg</b> Each film coated tablet contains Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin .....5mg As per Innovators Specification RRA Status: FARXIGA 5mg Tablets of AstraZeneca Pharmaceuticals LP Wilmington, DE 19850 approved by USFDA. Me Too Status: Dapwiz 5mg Tablets of M/s Pharmevo Pvt Ltd. – Karachi. Pack Size(s): 10's-As per SRO Previous Approval: “Dekardi Tablets 5mg” of M/s Ferozsons Laboratories Limited, approved in 320th Meeting of Registrati
	<b>Evaluation Remarks:</b> Dakardi 5mg tablet approved in 320 RB meeting	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
190	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (D3X-MJ8-MUXA, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>BEMPID 180MG TABLET</b> Each Film Coated Tablet Contains: Bempedoic Acid.....180mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: PDM 180 mg Tablet, DRB 331 Meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
191	<b>SIMZ PHARMACEUTICALS PVT LTD</b> 574-575 SUNDAR INDUSTRIAL ESTATE LAHORE (000762) Contract Manufacturing <b>M/s Bio Mark Pharmaceuticals</b> , Plot No. 527, Sundar Industrial Estate, Lahore, 000863 Tracking ID: (D67-341-61P5, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>SIMLORAT</b> Each ml contains: Desloratadine.....0.5mg Manufacturer Specification RRA Status: NEO-Clarityn Marketing Authorization holder: MSD Regulatory Authority: AEMPS Me Too Status: Desora 0.5mg/5ml Syrup by M/s Continental Pharma Pack Size(s): 30ml,60ml,90ml,120ml-As per SRO Previous Approval: Varidine Syrup, 297 meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
192	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore., 000951 Tracking ID: (D9Y-HSQ-9P2G, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tazocin 2.25gm Injection</b> Each Vial Contains: Piperacillin as Sodium.....2000mg, Tazobactam as Sodium.....250mg  RRA Status: USFDA Approved Me Too Status: Zosyn 2.25gm INJECTION of M/s Regent Laboratories Reg# 070759 Pack Size(s): As per SRO-As per SRO Previous Approval: TAZOCIN 2.25gm Injection, DRB 331
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
193	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat. , 000882 Tracking ID: (DUT-TDB-ZNS6, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Dexxlo 30mg Capsule</b> Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....30MG (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: DEXZEN 30mg Capsule, DRB 330
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
194	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Wnsfeild Pharmaceuticals,</b> Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar., 000610 Tracking ID: (DWU-G9H-R7Y1, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>L-Carta 1gm injection</b> Each Ampoule (5mL) Contains:Levocarnitine.....1000mg  RRA Status: USFDA approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Shamco traders Pack Size(s): As Per SRO-As per SRO Previous Approval: L-Carta 1gm injection, DRB 331
	<b>Evaluation Remarks:</b> L-Carta 1gm injection approved in 331 RB meeting.	
	<b>Decision:</b> Approved .	
195	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Winbrains Research Laboratories,</b> Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK., 000725 Tracking ID: (DVP-8PQ-LBJH, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Monexi Eye Drops</b> Each ml contains: Moxifloxacin HCl as Moxifloxacin .....5mg (0.5%) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Azlox ophthalmic solution by Alza Pharmaceuticals 081625 Pack Size(s): As per SRO-As per SRO Previous Approval: Monexi 5mg/ml eye drops, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
196	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572) Contract Manufacturing <b>Bio-Labs (Pvt)Ltd</b> , Plot No.145 Industrial Triangle Kahuta Road Islamabd, 000296 Tracking ID: (EM8-SG1-LDWP, 2024-05-13) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Colifix 34mg Injection</b> Each Vial Contains: Colistimethate Sodium (1MIU) eq. to 34mg Colistin Base Activity) United States Pharmacopeia RRA Status: MHRA APPROVED Me Too Status: Colistin Injection (Pharmasol (PVT)Ltd Pack Size(s): 1's-As per SRO Previous Approval: 330 meeting
	<b>Evaluation Remarks:</b> Nextcraft 1MIU Injection IV approved in 330 RB meeting	
	<b>Decision:</b> Approved .	
197	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (GE2-7QP-BGAE, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Appoxi 2.5mg Tablet</b> Each film coated tablet contains: Apixaban .....2.5 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: ABAXIL 2.5 mg Tablets (Reg # 104678) M/s Saffron Pharmaceuticals (Pvt) Ltd. Pack Size(s): As per SRO-As per SRO Previous Approval: Axnap 2.5mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
198	<b>SIMZ PHARMACEUTICALS PVT LTD</b> 574-575 SUNDAR INDUSTRIAL ESTATE LAHORE (000762) Contract Manufacturing <b>Bio Mark Pharmaceuticals.,</b> Plot No. 527, Sundar Industrial Estate, Lahore, 000863 Tracking ID: (GP3-N1N-TUMJ, 2024-01-31) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Omepza</b> Each Sachet Contains: Omeprazole.....40mg Sodium Bicarbonate.....1680mg As per Innovators Specification RRA Status: Zegerid Immediate powder for oral soln (SANTARUS, Inc.) Me Too Status: FFAST 40mg/1680mg Sachet Pack Size(s): 1s, 2s, 5s-As per SRO Previous Approval: 307minutes of meeting, FFAST 40mg/1680mg sachet
	<b>Evaluation Remarks:</b> Faast 40mg/1680mg Sachet for oral suspension approved in 307 RB meeting	
	<b>Decision:</b> Approved .	
199	<b>AUSPEC PHARMACEUTICALS PVT LTD</b> 21, Km, Raiwind Road, Lahore. (000964) Contract Manufacturing <b>Aulton Pharmaceuticals.,</b> 12-Km, Raiwand Road, Lahore., 000828 Tracking ID: (H6M-6Z5-LRXT, 2024-05-09) Fee Paid: 75000.0 Paid Date: 2024-02-06 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Cephine 250mg Injection</b> Each vial contains: Ceftriaxone sodium (USP) equivalent to ceftriaxone .....250mg United States Pharmacopeia RRA Status: Rocephin 250mg Powder for Solution for Injection by Roche Products Limited, UK Me Too Status: Droncef Injection 250mg by Seraph Pharmaceutical, Islamabad Pack Size(s): 1's/ As per SRO / DP-As per SRO Previous Approval: Ceftrix 250 mg Injection, 333rd meeting of registration board
	<b>Evaluation Remarks:</b> Ceftrix 250 mg Injection IM, approved in 333 RB meeting. However firm has applied for IV Injection.	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Deferred Registration Board decided to consider this application on its turn since the applied product is not cross referred to previous approval by Registration Board.	
200	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (HLU-8WB-AJZU, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Verozen 20mg Tablet</b> Each Film Coated Tablet Contains: Vonoprazan as Fumarate.....20mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan approved Me Too Status: Vonseca 20mg tablet by M/s Tabros, Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Verozen 20mg Tablet, DRB 322
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
201	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat, 000882 Tracking ID: (HPW-DJN-X7ZJ, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trelgo 50mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 66.5mg equivalent to Trelagliptin ..... 50 mg As per Innovators Specification RRA Status: PMDA approved Zafatek® Me Too Status: Treptin Tablet, Wezen Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
202	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (HT7-47B-6DAM, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 5mg Tablet</b> Each film coated tablet contains: Obeticholic Acid ..... 5 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 5mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
203	<b>Sarco Chemicals Industries</b> 17-Km. Lahore Road Multan (000203) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd</b> , Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore, 000789 Tracking ID: (HU5-S63-853J, 2024-05-15) Fee Paid: 75000.0 Paid Date: 2024-04-30 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Ketomit 30mg/ml Injection</b> Each ml contains: Ketorolac tromethamine .....30mg United States Pharmacopeia RRA Status: Toradol 30mg /ml injection M/s Roche Ltd. MHRA Approved Me Too Status: Toradol 30mg/ml injection M/s Barrett Hodgson Pakistan (Pvt.)Ltd Reg.#015000 Pack Size(s): 5x1ml As per SRO-As per SRO Previous Approval: Vintera injection, 320th meeting
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
204	<b>Wenovo Pharmaceuticals</b> Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (000790) Contract Manufacturing <b>M/s Weather Folds Pharmaceuticals,</b> 69/2, Phase-II, Industrial Area, Hattar., 000644 Tracking ID: (J58-DQS-TPY6, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-19 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>obbitta 5mg Tablet</b> Each Film Coated Tablet Contains: Obeticholic Acid.....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA approved Me Too Status: Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112710 Pack Size(s): As Per SRO-As per SRO Previous Approval: B-Kolic Tablet 5mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
205	<b>Onyx Pharmaceuticals</b> 30-A small Industrial Estate mansehra (000440) Contract Manufacturing <b>Bio-Mark Pharmaceuticals,</b> 527 Sundar Industrial Estate, Lahore, 000863 Tracking ID: (JTT-JVW-P5SW, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-03-07 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Indazole 40mg Capsule</b> Each Capsule contains: Esomeprazole (as enteric coated pelletes).....40mg United States Pharmacopeia RRA Status: Nexium Capsules by Novartis Me Too Status: Nexium Capsules by Novartis Pack Size(s): 14 & 28's-As per SRO Previous Approval: Staesso 40mg Capsule (Meeting no. 329)
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
206	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wallace Pharma Evolutions,</b> Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore., 000951 Tracking ID: (JZN-WT4-YZEX, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Meronem 500mg Injection</b> Each vial contains:- Meropenem (as trihydrate).....500mg (Blended with sodium carbonate) (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ropen Injection of Macter International Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: Ropen 500mg Injection, DRB 323rd Meeting
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
207	<b>SIMZ PHARMACEUTICALS PVT LTD</b> 574-575 SUNDAR INDUSTRIAL ESTATE LAHORE (000762) Contract Manufacturing <b>M/s Bio Mark Pharmaceuticals,</b> Plot No. 527, Sundar Industrial Estate, Lahore, 000863 Tracking ID: (L4U-785-JVM3, 2023-12-28) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Omepra</b> Each Sachet Contains: Omeprazole.....20mg Sodium Bicarbonate.....1680mg As per Innovators Specificatio RRA Status: Zegerid ® Powder for Oral Suspension by Santarus, Inc., is Approved in USFDA Me Too Status: Mep-Insta 20/1680mg Sachet (Bio-Mark Pharmaceuticals) Pack Size(s): As per SRO-As per SRO Previous Approval: "FAAST 20mg/1680mg Sachet ,307 th meeting
	<b>Evaluation Remarks:</b> Faast 20mg/1680mg Sachet for oral suspension approved in 307 RB meeting.	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
208	<b>Reliance Pharma</b> Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan ( <b>000724</b> ) Contract Manufacturing <b>Global Pharmaceuticals (Pvt) Ltd.,</b> Plot # 204- 205 Industrial Triangle, Kahuta Road, Islamabad- Pakistan., 000417 Tracking ID: (LJ5-65R-H8X7, 2023-12-29) Fee Paid: 75000.0 Paid Date: 2023-11-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Relem 2g Injection IV</b> Each vial contains: Meropenem trihydrate Eq. to meropenem.....2gm (blended with sodium carbonate) United States Pharmacopeia RRA Status: HPRA Ireland Me Too Status: Not Available Pack Size(s): 1 vial-As per SRO Previous Approval: Product Name: Merem 2g Injection. Discussed in 331 Registration Board Meeting with positive remarks
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
209	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura ( <b>000976</b> ) Contract Manufacturing <b>M/s May &amp; Baker (Pvt.) Ltd.,</b> 45 Km, Dina Nath, Multan Road, Lahore., 000953 Tracking ID: (LZJ-WB6-TMV3, 2024-01-24) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Atlas-D 5mg/ml injection</b> Each ml Contains: Vitamin D3 = 5mg As per Innovators Specification RRA Status: Approved by ANSM of France Me Too Status: D-Trees Injection of Sami Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: V-Drop 5mg/ml Injection in 323 RB meeting

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> V-Drop 5mg/ml Injection, approved in 323 RB meeting	
	<b>Decision:</b> Approved	
210	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Welmark Pharmaceuticals</b> , Plot NO. 122, Block-B, Phase-V, Industrial Estate, Hattar, KPK. , 000614 Tracking ID: (M3D-M1U-7L6U, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tenfo 25mg Tablet</b> Each film-coated tablet contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide .....25mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Tenofoviride Tablet 25mg by M/s. Getz pharma ., Reg. No. 093109 Pack Size(s): As per SRO-As per SRO Previous Approval: Teno 25mg Tablet, DRB 324
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
211	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeld Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (MBY-T8G-VUHG, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>L-Carta 1gm Injection</b> Each 5ml ampoule Contains: Levocarnitine ..... 1gm As per Innovators Specification RRA Status: Carnitor 1gm/5ml Injection USFDA approved Me Too Status: LEKARNITIN 1gm/5ml ampoule Reg. No. 093928 Shamco traders Pack Size(s): As per SRO-As per SRO Previous Approval: L-Carta 1gm injection, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
212	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. , 000882 Tracking ID: (MNQ-8HD-4AA9, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Dexxlo 30mg Capsule</b> Each capsule contains: Dexlansoprazole (as dual delayed release pellets).....30mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: DEXZEN 30mg Capsule, DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
213	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (MQS-6VV-8WBB, 2024-05-03) Fee Paid: 75000.0 Paid Date: 2024-04-01 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>FLOPIN 100MG/15mg Tablet</b> Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate .....100mg Erugliflozin as L-pyroglutamic Acid .....15mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Trevia R2 (15/100mg) 14 Tablets By GetZ Pharma Pack Size(s): As per SRO-As per SRO Previous Approval: Flopin Tablet, by Weather Folds Pharma, DRB 333
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
214	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (MR6-M6P-TLB2, 2024-05-08) Fee Paid: 75000.0 Paid Date: 2024-04-03 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Empolin-M XR Tablets 5mg/1000mg</b> Each film coated tablet contains Empagliflozin.....5mg (as Immediate Release Coating) Metformin HCl.....1000mg (as Extended Release Core) As per Innovators Specification RRA Status: SYNJARDY XR 5mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Diampa-M XR Tablets 5mg/1000mg of M/s Getz Pharma Pakistan (Pvt.) Ltd. Pack Size(s): 14's , 28's -As per SRO Previous Approval: "Empagen-M XR Tablets 5/1000mg" of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
215	<b>Bio-Next Pharmaceuticals</b> plot no 50 street no S-10 RCCI Rawat (000910) Contract Manufacturing <b>Bio-Labs (Pvt) Ltd.,</b> Plot 145, Industrial Trangle, Kahuta Road Is;a,abad, 000296 Tracking ID: (N4R-4NG-9Z2A, 2024-01-22) Fee Paid: 75000.0 Paid Date: 2022-10-26 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Ferritose</b> Each ml contains: iron as ferric carboxymaltose 50mg As per Innovators Specificatio RRA Status: Injectafer Injection 50mg/ml MHRA UK Me Too Status: FCM Injection Genix Pharma Pack Size(s): 10ml-Controlled Previous Approval: MaltEvo Injection (PharamEvo) , 331 DRB
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
216	<b>Sapient Pharma</b> 123/S Quaid E Azam Industrial Estate Kot Lakhpat (000207) Contract Manufacturing <b>Bio-Mark Pharmaceuticals,</b> 527 Sundar Industrial Estate, Lahore, 000863 Tracking ID: (N78-ZUV-8JQN, 2023-12-28) Fee Paid: 75000.0 Paid Date: 2023-12-12 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Samplozin 10mg Tablet</b> Each film coated tablet contains: Empagliflozin.....10mg Any Other RRA Status: Jardiance Tablet by Boehringer Ingelheim Me Too Status: Diampa Tablets by GETZ Pharma Pack Size(s): 14 & 28's-As per SRO Previous Approval: EmpMark 10mg Tablet (Meeting 331st)
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
217	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (NMD-G44-HZTJ, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Azzota 40mg Tablet</b> Each tablet contains: Azilsartan Medoxomil (as Potassium) .....40mg As per Innovators Specification RRA Status: EMA Approved Me Too Status: Zelwist 40mg Tablet, by Wnsfeild Pharmaceuticals, Reg No. Pack Size(s): As per SRO-As per SRO Previous Approval: Azilta 40mg Tablet, DRB 326
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
218	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block- A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (NYM-61B-WUNA, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Monexi Eye Drops</b> Each mL Contains: Moxifloxacin (USP).....5mg (0.5%) (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Azlox ophthalmic solution by Alza Pharmaceuticals 081625 Pack Size(s): As per SRO-As per SRO Previous Approval: Esonyp 20/375mg DR Tablet, DRB 324
	<b>Evaluation Remarks:</b> Monexi 5mg/5ml eye drops approved in 331 RB meeting, However the contract manufacturer specified in uploaded module 1 is Winbrains Research Laboratories while that mentioned in eapp is M/s Wnsfield	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved Registration Board further decided that firm shall submit applicable fee for correction on the name and address of contract manufacturer before issuance of Registration letter.	
219	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat. , 000882 Tracking ID: (P3L-2P7-4WVQ, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trella 100mg Tablet</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....100mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA Japan approved Zafatek® Me Too Status: Treptin 100mg Tablet, by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b> .	
	<b>Decision:</b> Approved .	
220	<b>Valor Pharmaceuticals</b> Plot No 124/A, Industrial Triangle, Kahuta Road, Islamabad (000496) Contract Manufacturing <b>M/S Biogen Life sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (P7T-ASP-929G, 2024-01-18) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Atreval 10mg/ml Injection</b> Each 5ml Ampoule contains: Atracurium besylate.....50mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Efacurium Injection having registration number 069058 Pack Size(s): As per SRO-As per SRO Previous Approval: Atregen 10mg/ml Solution for Injection in M-331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
221	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeld Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (PJL-9ZY-8ZE7, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Prolide 1mg Tablet</b> Each Film Coated Tablet contains: Prucalopride as Succinate .....1mg (Product Complies Innovator's Specs) As per Innovators Specification RRA Status: EMAE approved Resolor® by Takeda Me Too Status: Prutide 1mg Tablet by Weather Folds Pack Size(s): As per SRO-As per SRO Previous Approval: Pruco 1mg Tablet , DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
222	<b>Semos Pharmaceuticals PVT LTD</b> Plot No.11, Sector 12-A North Karachi, Industrial Area, Karachi, Pakistan (000335) Contract Manufacturing <b>M/s Dew-Max Pharmaceuticals (Pvt) Ltd.,</b> Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad Pakistan, 000889 Tracking ID: (Q5W-PE4-9BYZ, 2024-05-09) Fee Paid: 75000.0 Paid Date: 2024-04-18 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Senum Injection 500mg</b> Each vial contains: Meropenem trihydrate USP eq. to Meropenem.....500 mg United States Pharmacopeia RRA Status: MERREM 500mg Injection Approved in USFDA Me Too Status: MOPEN Injection 500 mg(M/s Hilton Pharma) Pack Size(s): 1's-As per SRO Previous Approval: Dewnem 500mg Injection (Reg No: 110939), 312th Meeting of Registration Board
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
223	<b>Medizan Laboratories (Pvt) Ltd</b> Plot No.313 Industrial Triangle Kahuta Road Islamabad (000572) Contract Manufacturing <b>Bio-Labs (Pvt)Ltd</b> , Plot No.145 Industrial Triangle Kahuta Road Islamabd, 000296 Tracking ID: (Q7J-L6D-ZDY1, 2024-05-13) Fee Paid: 75000.0 Paid Date: 2024-04-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tigefix 50mg Injection</b> Each vial Contains: Tigecycline (Lyophilized Powder).....50mg United States Pharmacopeia RRA Status: Drugs@FDA: FDA-Approved Drugs Abbreviated New Drug Application (ANDA): 091620 Company: SANDOZ INC Me Too Status: Tygacil Wyeth Pakistan Limited Pack Size(s): 1's-As per SRO Previous Approval: 330 meeting
	<b>Evaluation Remarks:</b> Bactcil 50mg Injection IV approved in 330 RB meeting	
	<b>Decision:</b> Approved .	
224	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (Q6D-GJA-PA69, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Vonpin 10mg + 100mg Tablet</b> Each Tablet Contains: Aspirin as Enteric Coated Inner Core.....100mg Vonoprazan as fumarate (Outer Immediate Release Layer).....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical (Japan) Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Venospa 10/100mg Tablet, DRB 324
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
225	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. , 000882 Tracking ID: (QSV-TNS-EJ2P, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trella 100mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 133mg equivalent to Trelagliptin ..... 100mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 100mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
226	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeld Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (QVN-WNE-8U66, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Ricefo 30mg Sachet</b> Each Sachet Contains: Racecadotril.....30mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: UK MHRA Me Too Status: Hidrasec 30mg Sachet by M/s Abbot Laboratories (Pakistan) Ltd Pack Size(s): As per SRO-As per SRO Previous Approval: Raceka 30mg Sachet, DRB 324
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
227	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (QVT-RRG-18SR, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Cefzect 2.5gm Injection</b> Each Vial Contains: Ceftazidime as Pentahydrate.....2000mg Avibactam as Sodium Salt.....500mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Zavicefta Injection by Pfizer (Reg No. 106848) Pack Size(s): As per SRO-As per SRO Previous Approval: CEFZECT 2.5gm Injection, DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
228	<b>Vision Pharmaceuticals Pvt Ltd</b> Plot#22-23, Industrial Triangle, Kahuta Road, Islamabad. (000517) Contract Manufacturing <b>Global Pharmaceuticals (Pvt) Ltd.,</b> Plot # 204- 205 Industrial Triangle, Kahuta Road, Islamabad- Pakistan., 000417 Tracking ID: (RE2-WY1-2QGZ, 2023-12-07) Fee Paid: 75000.0 Paid Date: 2023-11-16 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Visopen 2g Injection IV</b> Each vial contains: Meropenem Trihydrate Eq. to Meropenem.....2gm (blended with sodium carbonate) United States Pharmacopeia RRA Status: HPRA Ireland Me Too Status: Merem 2g Injection by Global Pharmaceuticals Pvt. Ltd. Pack Size(s): 1's-As per SRO Previous Approval: Merem 2g Injection. Approved in 331 Registration Board Meeting Minutes.
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
229	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>M/s Biogen Life Sciences</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (RH6-8Y9-RWM4, 2024-01-24) Fee Paid: 75000.0 Paid Date: 2023-11-14 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Moxopine 400mg/250ml infusion</b> Each 250ml contains: Moxifloxacin (as hydrochloride)..... 400 mg (As Per Innovators Specifications) As per Innovators Specification RRA Status: Avelox 400mg/250ml Infusion, Bayer AG, Registered by Germany Me Too Status: Moxiget 400mg/250ml by Getz Pharma (P.V.T) Limited, reg.#050650 Pack Size(s): 1x1s-As per SRO Previous Approval: 320th meeting of Registration board
	<b>Evaluation Remarks:</b> MOXIGEN 400mg/250ml Solution for Infusion approved in 320 RB meeting.	
	<b>Decision:</b> Approved .	
230	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase II, Industrial Area, Hattar., 000644 Tracking ID: (RLD-1RE-62A5, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 5mg Tablet</b> Each Film Coated Tablet Contains: Obeticholic Acid.....5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 5 mg, DRB 331
	<b>Evaluation Remarks:</b>	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
231	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeld Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (RVB-LAV-HB61, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Esonepp 20mg/375mg Tablet</b> Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR ..... 20mg Naproxen as enteric coated core ..... 375mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Glomov 20/375mg tablet by M/s Global Pharmaceutical Pack Size(s): As per SRO-As per SRO Previous Approval: Esonyp 20/375mg DR Tablet, DRB 324
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
232	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. , 000644 Tracking ID: (T3B-B1Q-XAH6, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Apbox 2.5mg Tablet</b> Each film coated tablet contains: Apixaban .....2.5 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: ABAXIL 2.5 mg Tablets (Reg # 104678) Pack Size(s): As Per SRO-As per SRO Previous Approval: AXNAP 2.5mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
233	<b>Trigon Pharmaceuticals (Private) Ltd</b> 8-k.m thokar raiwind road Lahore (000342) Contract Manufacturing <b>Wallace Pharma Evolutions</b> , Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore. , 000951 Tracking ID: (T4B-W86-4AHU, 2023-12-27) Fee Paid: 75000.0 Paid Date: 2023-11-15 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Mynoma 1g Injection</b> Each vial contains:- Meropenem (as trihydrate).....1gm (Blended with sodium carbonate) (Product complies USP Specs) United States Pharmacopeia RRA Status: Approved by USFDA Me Too Status: OIVER INJECTION 1000mg by Genix Pharma Pack Size(s): 1's-As per SRO Previous Approval: DRB Meeting, 323rd. Merfenum 1000mg Injection
	<b>Evaluation Remarks:</b> Ropen 1g Injection, approved in 323 RB meeting.	
	<b>Decision:</b> Approved .	
234	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK., 000610 Tracking ID: (T8Q-Q6R-89BB, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Nebvo 20mg Tablet</b> Each uncoated tablet contains: Nebivolol (as HCl)..... 20mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Nabiz 20mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved .	
235	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>VARIANT PHARMACEUTICALS (PVT.) LTD,</b> PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN, 000914 Tracking ID: (TY8-DHG-5GP3, 2024-05-09) Fee Paid: 75000.0 Paid Date: 2023-11-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Pzol 40mg injection</b> Each Vial contains:Pantoprazole sodium eq. to Pantoprazole ..... 40 mg  RRA Status: PANTOPRAZOLE SODIUM (EQ. 40mg base/vial) by SANDOZ INC USFDA Approved Me Too Status: NEEGE40 mg Injection by Sami Pack Size(s): 1's-As per SRO Previous Approval: 312th
	<b>Evaluation Remarks:</b> PANTO 40mg IV Injection approved in 312 RB meeting	
	<b>Decision:</b> Approved .	
236	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (000574) Contract Manufacturing <b>M/s Wezen Pharmaceuticals,</b> Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (TYZ-JHS-VG25, 2024-05-07) Fee Paid: 75000.0 Paid Date: 2024-04-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>TRELGO 100MG TABLET</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....100mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PDMA Approved Me Too Status: Trelaglip 100 mg tablet by The Searle Company Pack Size(s): As Per SRO-As per SRO Previous Approval: TABLET TRELLA 100 MG , DRB 331st

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
237	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK ( <b>000610</b> ) Contract Manufacturing <b>Wezen Pharmaceuticals</b> , Plot no. 23 & 24, S-1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (U1R-EJR-1YXJ, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Trella 50mg Tablet</b> Each film coated tablet contains: Trelagliptin Succinate 66.5mg equivalent to Trelagliptin ..... 50 mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: Treptin Tablet by Wezen Pharmaceuticals Pack Size(s): As per SRO-As per SRO Previous Approval: Trella 50mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
238	<b>Evolution Pharmaceuticals (Pvt.) Ltd.</b> Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. ( <b>000867</b> ) Contract Manufacturing <b>M/s Swera Pharmaceuticals</b> , M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, RCCI-Rawat, Islamabad, 000867 Tracking ID: (UR5-JNS-5P9N, 2024-01-22) Fee Paid: 75000.0 Paid Date: 2023-11-07 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>IMO 40mg Injection</b> Each Vials contains ESOMEPRAZOLE SODIUM Eq. to ESOMEPRAZOLE.....40mg As per Innovators Specification RRA Status: Nexium I.V 40mg Injection, Manufactured by: AstraZeneca pharmaceutical LP, Wilmington, DE 19850 Me Too Status: Konzept 40mg Injection, Manufacturer:McOLSON Research Laboratories, Rawat Pack Size(s): 1,s-As per SRO Previous Approval: SEZRO 40mg Injection, Reg: 115274, NO.F.5-6/2022-REG-II(M-322)

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Evaluation Remarks:</b> Emozol 40mg Injection approved in 322 RB meeting	
	<b>Decision:</b> Approved .	
239	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan ( <b>000725</b> ) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase- V, Block-A, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (UYN-9W7-1GN5, 2024-01-24) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Tegit 90mg Tablet</b> Each film coated tablet contains: Ticagrelor ... 90mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Anplag 90mg Tablet Pharmevo (Pvt) Ltd Pack Size(s): As Per SRO-As per SRO Previous Approval: Tigawin Tablet 90mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
240	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (VGN-9Y8-XV4X, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Ricefo 10mg Sachet</b> Each Sachet Contains: Racecadotril.....10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: UK MHRA Me Too Status: Hidrasec 10mg Sachet by M/s Abbot Laboratories Pack Size(s): As per SRO-As per SRO Previous Approval: Raceka 10mg Sachet, DRB 324
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
241	<b>Winbrains Research Laboratories</b> Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (000725) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (VM3-PZR-5244, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-29 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Nevibo 20mg Tablet</b> Each uncoated tablet contains: Nebivolol (as HCl)..... 20mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As Per SRO-As per SRO Previous Approval: Nabiz 20mg Tablet, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
242	<b>Welwrd Pharmaceuticals</b> Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar ( <b>000574</b> ) Contract Manufacturing <b>M/s Wezen Pharmaceuticals</b> , Plot # 23 & 24, S- 1, RCCI, Industrial Estate, Rawat., 000882 Tracking ID: (VNY-4G9-T61N, 2024-05-07) Fee Paid: 75000.0 Paid Date: 2024-04-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>TRELGO 50MG TABLET</b> Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate.....50mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PDMA Approved Me Too Status: Trelaglip 50 mg tablet by The Searle Company Pack Size(s): As Per SRO-As per SRO Previous Approval: TABLET TRELLA 50 MG, DRB 331st
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
243	<b>Wnsfeild Pharmaceuticals</b> Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK ( <b>000610</b> ) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK., 000644 Tracking ID: (VNY-TNZ-DA5T, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-02 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 5mg Tablet</b> Each film coated tablet contains: Obeticholic Acid .....5mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112710 Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 5mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
244	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (WPQ-QRU-RTWL, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Prolide 2mg Tablet</b> Each Film Coated Tablet contains: Prucalopride as Succinate .....2mg (Product Complies Innovator's Specs) As per Innovators Specification RRA Status: EMAE approved Resolor® by Takeda Me Too Status: Prutide 2mg Tablet by Weather Folds Pack Size(s): As per SRO-As per SRO Previous Approval: Pruco 2mg Tablet, DRB 330
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
245	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Winbrains Research Laboratories</b> , Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK., 000725 Tracking ID: (XEY-A82-TQV4, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Lazkol 1% Cream</b> Each Gm Cream Contains: Luliconazole ...10 mg As per Innovators Specification RRA Status: PMDA Japan Me Too Status: N/A Pack Size(s): As per SRO-As per SRO Previous Approval: Lunaz 1% Cream, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
246	<b>Daneen Pharma Pvt Limited</b> plot no: 27 sunder industrial estate, sunder raiwind road, lahore ( <b>000688</b> ) Contract Manufacturing <b>Genix Pharma (Pvt.) Ltd.</b> , 44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan, 000351 Tracking ID: (XMN-9SL-G6R6, 2024-05-08) Fee Paid: 75000.0 Paid Date: 2024-04-05 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Daglox 200mg Film Coated Tablet</b> Each tablet contains: Elagolix Sodium 207.00 equivalent to Elagolix 200mg As per Innovators Specification RRA Status: ORLISSA 200mg TABLET Manufactured by AbbVie Inc. approved by USFDA Me Too Status: N/A Pack Size(s): 7's, 14's, 28's-As per SRO Previous Approval: Elox 200mg Tablet approved in 331st Registration Board Meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
247	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura ( <b>000976</b> ) Contract Manufacturing <b>M/s May &amp; Baker (Pvt) Ltd.</b> , 45 Km, Dina Nath, Multan Road, Lahore., 000953 Tracking ID: (Z4L-EQW-XDEZ, 2024-01-17) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Stermet 2MIU Injection</b> Each vial Contains: Colistimethate Sodium (2MIU) eq. to Colistin base activity = 68MG United States Pharmacopeia RRA Status: Approved by MHRA of UK Me Too Status: Colistim 2MIU Injection Pack Size(s): As per SRO-As per SRO Previous Approval: Colmate 2 MIU powder for injection in 324th meeting
	<b>Evaluation Remarks:</b> Colmate 2 MIU powder for injection, approved in 324 RB meeting	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
248	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (YD3-7ME-4MLV, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>L-Carta 1gm injection</b> Each Ampoule (5mL) Contains: Levocarnitine (USP) .....1000mg (Product complies USP Specs) United States Pharmacopeia RRA Status: UK MHRA Me Too Status: KEFEI INJECTION by RG Pharmaceuticals Pack Size(s): 1-As per SRO Previous Approval: L-Carta 1gm Injection, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
249	<b>Wallace Pharma Evolutions</b> Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (000951) Contract Manufacturing <b>Weather Folds Pharmaceuticals</b> , Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK, 000644 Tracking ID: (Z8U-MUN-UU81, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Obbitta 10mg Tablet</b> Each film coated tablet contains: Obeticholic Acid .....10 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Ocafib 10mg film-coated tablet of M/s Sami pharmaceuticals, Karachi Pack Size(s): As per SRO-As per SRO Previous Approval: B-Kolic Tablet 10 mg, DRB 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
250	<b>Welcome Pakistan Trading Pharma (Pvt) Ltd</b> Chakri Interchange, Gangawala (000987) Contract Manufacturing <b>Wnsfeild Pharmaceuticals</b> , Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. , 000610 Tracking ID: (ZR3-J4L-TMHN, 2024-01-19) Fee Paid: 75000.0 Paid Date: 2023-12-22 (Dr. Muhmmad Haseeb Tariq)	Proposed Name: <b>Esonepp 20mg/500mg Tablet</b> Each modified release tablet contains: Esomeprazole (as magnesium trihydrate) as IR.....20mg Naproxen as enteric coated core .....500mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Glomov 20/500mg tablet by M/s Global Pharmaceutical Pack Size(s): As per SRO-As per SRO Previous Approval: Esonyp 20/500mg DR Tablet, DRB 324
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved .	
251	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>M/s Biogen Life Sciences</b> , 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (15W-TEZ-V8PD, 2024-03-04) Fee Paid: 75000.0 Paid Date: 2023-11-14 (Salateen Waseem Philip)	Proposed Name: <b>Dpin Injection 5mg/ml</b> Each ml contains: Cholecalciferol.....5mg (As Per Innovators Specifications) As per Innovators Specification RRA Status: Cholecalciferol (5mg) injection (IM/ Oral) by M/s Bouchara Recordate Laboratories DE GAULLE GAL IMME Me Too Status: Novel-D Injection Oral/ I.M 5mg/ml ,DANAS Pharmaceuticals Islamabad Pack Size(s): 1x1s-As per SRO Previous Approval: 323
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
252	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (1QX-25X-Y9QY, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>COLESTI-1MIU INJECTION IV</b> each Vial Contains: Colistimethate Sodium.....1 MIU United States Pharmacopeia RRA Status: Colomycin 1 MIU (IU) Injection (MHRA Approved) Me Too Status: Colistimethate Injection 1 MIU By Mukhtar Enterprises Reg. No. 093937 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-297 By the Name of LISTIM INJECTION 1 MIU IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
253	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd,</b> 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (29N-P59-GYJG, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>Esszole 40mg capsule</b> Each Capsule contains: Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole = 40MG United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Nexum 40mg capsule Pack Size(s): as per DPC-As per SRO Previous Approval: 327
	<b>Evaluation Remarks:</b> Ref. Product: Ezole meeting:327	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
254	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (1RJ-RHR-MDPP, 2024-03-15) Fee Paid: 75000.0 Paid Date: 2024-03-13 (Salateen Waseem Philip)	Proposed Name: <b>Empolin-M Tablets 12.5mg/500mg</b> Each Film Coated Tablet Contains: Empagliflozin.....12.5mg Metformin HCl.....500mg As per Innovators Specification RRA Status: SYNJARDY 12.5mg/500mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Xenglu-Met 12.5mg/500mg Tablets Manufacturer: M/s Hilton Pharma Private Ltd. Karachi. Pack Size(s): 14's , 28's -As per SRO Previous Approval: “Empagen-M Tablets 12.5/500mg” of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of R
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
255	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Seraph Pharmaceuticals</b> , Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (1X8-8D3-Y2LS, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>SOLEXIME DS-200MG DRY SUSPENSION</b> Each 5ml of reconstituted suspension contains: Cefixime trihydrate equivalent to cefixime 200mg United States Pharmacopeia RRA Status: SUPRAX By Sanofi Limited , UK (Medicines and Healthcare products Regulatory Agency (MHRA) of UK.) Me Too Status: Trispan 200MG/5ML Dry Suspension By Seraph Pharmaceutical, Islamabad Reg. No.: 086231 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-317 By the Name of BRIAR 200mg/5ml Suspension.
	<b>Evaluation Remarks:</b>	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
	<b>Decision:</b> Approved	
256	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd,</b> 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (2RH-V9G-DLVQ, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>Esszole 20mg capsule</b> Each Capsule contains: Esomeprazole magnesium trihydrate enteric coated pellets eq. to Esomeprazole = 20MG United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Nexum 20mg capsule Pack Size(s): as per DPC-As per SRO Previous Approval: 327
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
257	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>M/s Biogen Life Sciences,</b> 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (37X-D6J-HBZA, 2024-03-05) Fee Paid: 75000.0 Paid Date: 2023-11-14 (Salateen Waseem Philip)	Proposed Name: <b>Iropin Injection 100mg/5ml</b> Each 5ml contains: Iron (III) Hydroxide Sucrose Complex eq. to Elemental Iron.....100mg (B.P Specifications) British Pharmacopeia RRA Status: Venofer 20 mg iron /mL Vifor France 100-101 TerrasseBoieldieu Tour Franklin La Défense 8 92042 Paris Me Too Status: G-FER Injection 100mg/ 5ml Global Pharma Pack Size(s): 5x5s-As per SRO Previous Approval: 313th Meeting of Registration Board
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
258	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (3T4-1RD-QGB9, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>IMESTIN-500MG INJECTION IV</b> each vial contains: (Imipenem (as Monohydrate).....500mg + Cilastatin (as Sodium).....500mg) powder for solution for injection/ infusion United States Pharmacopeia RRA Status: USFDA Approved (Primaxin Injection 500mg) By Merck Inc USA Me Too Status: Cilapen-250mg Injection By Bosh Pharmaceuticals Reg. No.: 048491 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-330 By the Name of CILAGEN 500MG INJECTION IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
259	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (5D5-89R-5Z84, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>VONOCIT-10MG TABLETS</b> Each film coated tablet contains: Vonoprazan fumarate eq to Vonoprazan.....10mg As per Innovators Specification RRA Status: Takecab Tablet 10mg For Takeda Pharmaceutical (Japan PMDA Approved) Me Too Status: Vonozan Tablet 10mg By M/s Getz Pharma (Pvt.) Ltd Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of KALSEPH 10mg Tablet
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
260	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (5J7-99Z-5Q5B, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>Seftray-250mg Injection IM</b> Each vial contains (powder for reconstitution): Ceftriaxone (as sodium).....250mg  RRA Status: Ceftriaxone 250mg powder for solution for injection (MHRA Approved) Me Too Status: Droncef injection 250mg by Seraph Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-307 By the Name of SIXONE 250mg Injection (IM) on Contract Basis For Siam Pharma, ISB
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
261	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (5VT-3PQ-TWNU, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>VONOCIT-20MG TABLETS</b> Each film coated tablet contains: Vonoprazan fumarate eq to Vonoprazan.....20mg As per Innovators Specification RRA Status: Takecab Tablet 20mg For Takeda Pharmaceutical (Japan PMDA Approved) Me Too Status: Vonozan Tablet 20mg By M/s Getz Pharma (Pvt.) Ltd Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of KALSEPH 20mg Tablet
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
262	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (6ZA-QRH-JWQE, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>COMIPROL-40MG INJECTION IV</b> each Vial Contains: Esomeprazole as sodium.....40mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Nexum Injection By Getz Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-312 By the Name of ESOGEN INJECTION 40MG IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
263	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd,</b> 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (73W-17D-8DDE, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>Paingo 75mg/3ml solution for Injection</b> Each 3 ml contains: Diclofenac sodium-----75mg As per Innovators Specification RRA Status: EMA Me Too Status: Dicloran Injection Pack Size(s): as per DPC-As per SRO Previous Approval: 322
	<b>Evaluation Remarks:</b> Brand name: Fanak approved in 322 DRB meeting	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
264	<b>Jinnah Pharmaceuticals Pvt Ltd</b> 13 Km Lahore Road Multan (000578) Contract Manufacturing <b>ISLAM PHARMACEUTICALS, 7 KM</b> PASRUR ROAD SIALKOT PAKISTAN, 000885 Tracking ID: (7YN-NL9-LEM7, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Salateen Waseem Philip)	Proposed Name: <b>JACOBAL INJECTION 500mcg/ml</b> Each 1ml Contains Mecobalamin 500mcg  RRA Status: TEGMA JAPAN APPROVED Me Too Status: BIOCOBAL INECTION (SURGE LABORATORIES, 033385, Packing 1ml x10`s, Solution for Injection Pack Size(s): 1mlx10`s-As per SRO Previous Approval: DRB M-316
	<b>Evaluation Remarks:</b> Brand name mekobb approved in 316 DRB meeting	
	<b>Decision:</b> Approved	
265	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>M/s Seraph Pharmaceuticals, Plot# 210,</b> Industrial Triangle Kahuta road, Islamabad, Pakistan, 000860 Tracking ID: (824-PZP-EL4Z, 2024-03-05) Fee Paid: 75000.0 Paid Date: 2023-11-13 (Salateen Waseem Philip)	Proposed Name: <b>Odan 8mg/4ml</b> Each 4ml contains: Ondansetron as HCl Dihydrate.....8mg (USP Specifications) United States Pharmacopeia RRA Status: Zofran, Novartis, Zofran Injection is Approved in USFDA Me Too Status: Onset 8mg injection is DRAP Approved Pack Size(s): 1x1s-As per SRO Previous Approval: 330th Meeting of Registration Board
	<b>Evaluation Remarks:</b> RestOn Injection approved in 330 DRB meeting	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
266	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (8LQ-E8A-VJGN, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>SOLEXIME-400MG CAPSULES</b> Each capsule contains: Cefixime trihydrate eq. to cefixime 400mg Any Other RRA Status: SUPRAX By Lupin Limited , (FDA Approved) Me Too Status: Trispan-400mg Capsule By Seraph Pharmaceutical, Islamabad Reg. No.: 086236 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-317 By the Name of BRIAR 400mg Capsule.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
267	<b>Seraph Pharmaceutical</b> Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (9GN-8G9-WG62, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>ISOSER 20 MG SOFT GELATIN CAPSULE</b> Each soft gel capsule contains: Isotretinoin .....20mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Oratane Soft gel capsule Pack Size(s): 3x10's-As per SRO Previous Approval: Biotan Capsule "312"
	<b>Evaluation Remarks:</b> Brand Name Biotan approved in 312 DRB meeting	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
268	<b>Seraph Pharmaceutical</b> Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (9T6-RPS-NZR4, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>ISOSER 10 MG SOFT GELATIN CAPSULE</b> <b>psule</b> Each soft gel capsule contains: Isotretinoin .....10mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Oratane Soft gel capsule Pack Size(s): 3x10's-As per SRO Previous Approval: Biotan Capsule "312"
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
269	<b>Jinnah Pharmaceuticals Pvt Ltd</b> 13 Km Lahore Road Multan (000578) Contract Manufacturing <b>ISLAM PHARMACEUTICALS</b> , 7 KM PASRUR ROAD SIALKOT PAKISTAN, 000885 Tracking ID: (AX4-2UT-ZTW7, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-01-04 (Salateen Waseem Philip)	Proposed Name: <b>J-Setron Injection 8mg/4ml</b> Each ml contains Ondansetron (as hydrochloride dihydrate USP ---2mg  RRA Status: MHRA APPROVED (Teva Pharmaceuticals Hungary) Me Too Status: ONSET 8mg/4ml (Ondansetron (As Hydrochloride) Injection MS Pharmedic Laboratories. Pvt. Ltd. Reg No.0259996 Pack Size(s): 4ml x 1 Ampule-As per SRO Previous Approval: DRB M-316
	<b>Evaluation Remarks:</b> Brand name No-Vom approved in 316 DRB meeting	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
270	<b>Macter International Limited</b> E-40/A,S.I.T.E.,Karachi-Pakistan (000641) Contract Manufacturing <b>CSH Pharmaceuticals (Pvt.) Ltd.,</b> 32-Km, Ferozepur Road, Lahore – Pakistan , 000737 Tracking ID: (B5W-YQG-N1WJ, 2024-03-04) Fee Paid: 75000.0 Paid Date: 2023-12-13 (Salateen Waseem Philip)	Proposed Name: <b>Co-Amoxi BD Dry Suspension 457mg</b> Each 5ml contains: (after reconstitution) Amoxicillin Trihydrate Eq. to Amoxicillin.....400mg Potassium Clavulanate Eq. to Clavulanic Acid ..... 57mg USP Specifications.  RRA Status: Augmentin Dry Powder Suspension 457mg (US FDA Approved) Me Too Status: Amclav Dry Powder Suspension 457mg (Manufactured by: Getz Pharma, Pakistan) Pack Size(s): 35ml, 70ml, 140ml -As per SRO Previous Approval: Fortecin Dry Suspension 457mg/5ml of The Searle Company Limited (Approved in 331st Meeting Minutes)
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
271	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (000955) Contract Manufacturing <b>M/s Biogen Life Sciences,</b> 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (BJ7-M8T-4ZPD, 2024-03-04) Fee Paid: 75000.0 Paid Date: 2023-11-14 (Salateen Waseem Philip)	Proposed Name: <b>Ison 20mg Soft Gel Capsule</b> Each soft gel capsule contains: Isotretinoin.....20mg (BP Specifications) British Pharmacopeia RRA Status: Roacctane 20mg soft gel capsule by Roche Pharma AG Email-Barell- Str.1 D-79639 Greanzach- Wyhlen Germ Me Too Status: Isotretinoin basics by Alkaloida Chemical Company Zrt Pack Size(s): 3x10s-As per SRO Previous Approval: 312
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
272	<b>Fast Pharmaceuticals (Pvt) Ltd.</b> Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. <b>(000954)</b> Contract Manufacturing <b>Bio-Next Pharmaceuticals</b> , Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad, 000910 Tracking ID: (D3M-34Z-2QXU, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-01-29 (Salateen Waseem Philip)	Proposed Name: <b>Imifas</b> Each vial contains: Imipenem (as monohydrate) 500mg Cilastatin (as sodium) 500mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Cilapen Bosch Pharma Pack Size(s): 1 vial-Controlled Previous Approval: 331 Nawan Pharma
	<b>Evaluation Remarks:</b> Imcilaf 500mg IV Injection approved in 331 DRB meeting	
	<b>Decision:</b> Approved	
273	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura <b>(000976)</b> Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (ERP-LZN-XMSZ, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>Oramep 40mg dry powder vial</b> Each vial contains: (Dry powder for solution for IV injection) Omeprazole as sodium.....40mg  RRA Status: FDA Approved Me Too Status: Risek Injection Pack Size(s): as per DPC-As per SRO Previous Approval: 322 omebak 40mg dry powder vial
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
274	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (EZZ-3TN-J4QP, 2024-03-15) Fee Paid: 75000.0 Paid Date: 2024-03-13 (Salateen Waseem Philip)	Proposed Name: <b>Empolin-M Tablets 12.5mg/1000mg</b> Each Film Coated Tablet Contains: Empagliflozin.....12.5mg Metformin HCl.....1000mg As per Innovators Specification RRA Status: SYNJARDY 12.5mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Xenglu-Met 12.5mg/1000mg Tablets Manufacturer: M/s Hilton Pharma Private Ltd. Karachi. Pack Size(s): 14's , 28's -As per SRO Previous Approval: “Empagen-M Tablets 12.5/1000mg” of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
275	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (GZT-1NH-3238, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>Skintin-20mg Softgel Capsules</b> Each soft gel capsule Contains: Isotretinoin.....20mg British Pharmacopeia RRA Status: Isotretinoin 20mg Soft Capsule (MHRA Approve) Me Too Status: Oratane Capsule By Crystolite Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-312 By the Name of BIOTAN 20mg Capsule
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
276	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (H3A-EVR-Z3B4, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>ATURIUM-50MG/ 5ML SOLUTION FOR INFUSION/ INJECTION</b> each 5ml ampoule contains: Atracurium beyslate.....50mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Efacurim By Pharmedic Labs Reg. No. 069058 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of ATREGEN 50MG/ 5ML SOLUTION FOR INFUSION/ INJECTION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
277	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (JM4-MAZ-55X8, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>KALOPRID-1MG TABLETS</b> Each film coated tablet contains: Prucalopride succinate equivalent to Prucalopride.....1mg As per Innovators Specification RRA Status: Motegrity 1 mg Tablet By TAKEDA PHARMS USA, (FDA Approved) Me Too Status: Notogrity 1mg Tablet By Seraph Pharmaceutical Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of Notogrity 1mg tablet
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
278	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (J24-UBZ-T2VH, 2024-03-14) Fee Paid: 75000.0 Paid Date: 2024-03-13 (Salateen Waseem Philip)	Proposed Name: <b>Empolin-M Tablets 5mg/1000mg</b> Each Film Coated tablet Contains: Empagliflozin.....5mg Metformin HCl.....500mg As per Innovators Specification RRA Status: SYNJARDY 5mg/1000mg of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Xenglu-Met 5mg/1000mg Tablets Manufacturer: M/s Hilton Pharma Private Ltd. Karachi. Pack Size(s): 14's , 28's -As per SRO Previous Approval: "Empagen-M Tablets 5/1000mg" of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of Reg
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
279	<b>Winlet Pharmaceuticals (Pvt) Ltd.</b> 30-Km, Lahore Sargodha Raod, Sargodha ( <b>000874</b> ) Contract Manufacturing <b>M/s Biogen life sciences</b> , 8-km chakbeli road rawat Rawalpindi, 000911 Tracking ID: (MWA-SM6-X559, 2024-03-01) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>solowin</b> Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone.....250mg United States Pharmacopeia RRA Status: Solu-Cortef250mgInjections <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/009866s77s79lbl">https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/009866s77s79lbl</a> . Me Too Status: Hy-Cortizone Injection Pack Size(s): 1,s-Controlled Previous Approval: Succigen 250mg injection (M-307) reg. no. 109379
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
280	<b>Sarco Chemicals Industries</b> 17-Km. Lahore Road Multan (000203) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd</b> , Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore, 000789 Tracking ID: (N1D-1ZD-UU6P, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-11-07 (Salateen Waseem Philip)	Proposed Name: <b>Medzole 20mg/375mg Tablet</b> Each Modified release tablet contains: Naproxen.....375mg (Enteric coated core) Esomeprazole as magnesium trihydrate .....20mg(Immediate released coat) As per Innovators Specification RRA Status: Vimovo 375/20mg modified-release tablet M/s Grunenthal Ltd Me Too Status: Glomov 375mg/20mg Tablet M/s Gobal Registration# 109339 Pack Size(s): 1x10's, 2x10's, 3x10-As per SRO Previous Approval: Napsom 20/375 mg Tablet Approved in Meeting no. 331
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
281	<b>M/s Levon Pharmaceuticals</b> Plot ; 13.5 Sheikhpura Sharakpur Road ,Sheikhpura (000976) Contract Manufacturing <b>May &amp; Baker Pvt Ltd</b> , 45KM Dina Nath, Multan Road Lahore, 000953 Tracking ID: (NLR-LSL-MU7S, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2023-12-08 (Salateen Waseem Philip)	Proposed Name: <b>Vancocin Dry Powder Injection 500mg</b> Each vial Contains:Vancomycin Hydrochloride eq. to Vancomycin = 500mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Vancomycin injection 500mg Pack Size(s): as per DPC-As per SRO Previous Approval: vancomin 500mg Dry Powder for injection 324th meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
282	<b>Bosch Pharmaceuticals (Pvt) Ltd.</b> Plot No. 221-223, Sector-23, Korangi Industrial Area (000350) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd,</b> Plot No. 129, Sundar Industrial Estate Raiwind Road, Lahore, Pakistan, 000789 Tracking ID: (NPY-ESY-2UGS, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-09 (Salateen Waseem Philip)	Proposed Name: <b>Zerica CR Tablets 165mg</b> Each Film coated Extended Release Tablet contains: Pregabalin.....165mg Manufacturer Specification RRA Status: USFDA Me Too Status: - Pack Size(s): As per SRO-As per SRO Previous Approval: Gabal 165mg ER Tablets, 324th RB Meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
283	<b>Bosch Pharmaceuticals (Pvt) Ltd.</b> Plot No. 221-223, Sector-23, Korangi Industrial Area (000350) Contract Manufacturing <b>Wimits Pharmaceuticals (Pvt) Ltd,</b> Plot No. 129, Sundar Industrial Estate Raiwind Road, Lahore, Pakistan, 000789 Tracking ID: (NTZ-Z8S-18QP, 2024-03-14) Fee Paid: 75000.0 Paid Date: 2024-02-09 (Salateen Waseem Philip)	Proposed Name: <b>Zerica CR Tablets 82.5mg</b> Each Film coated Extended release Tablet contains : Pregabalin.....82.5mg Manufacturer Specification RRA Status: USFDA Me Too Status: - Pack Size(s): As per SRO-As per SRO Previous Approval: Gabal 82.5mg ER Tablets, 324th RB Meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
284	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (PJ6-28G-NU4B, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>LOZILID-600MG INFUSION</b> Each vial of 300ml Contains: Linezolid.....600mg As per Innovators Specification RRA Status: Zyvox IV (USFDA Approved) Me Too Status: Nezkil Infusion by Continental Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-320 By the Name of LINZOGEN 600MG/300ML SOLUTION FOR INFUSION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
285	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences,</b> 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (PJP-ZU5-ZVRD, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>DROCORT-100MG INJECTION</b> Each Vial Contains: Hydrocortisone sodium succinate eq. to. Hydrocortisone.....100mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone Injection By Global Pharma Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-307 By the Name of BIOCORT 100MG INJECTION
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
286	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (PM3-63X-HDWZ, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>DEFERID-250MG TABLETS</b> Each dispersible tablet contains: Deferasirox.....250mg European Pharmacopeia RRA Status: EXJADE By NOVARTIS (FDA Approved) Me Too Status: Dasirox Dispersible 250 mg Tablet By CCL Pharmaceutical, Lahore Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-322 By the Name of SERROX 250mg Tablet.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
287	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (R65-2GJ-GD5R, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>ZAPARINE-10MG TABLETS</b> Each film coated tablet contains: Cyclobenzaprine Hydrochloride eq. to cyclobenzaprine.....10mg United States Pharmacopeia RRA Status: FLEXERIL By Merck & Co. Inc., West Point, PA 19486, USA. For McNeil Consumer & Specialty Pharmaceuti Me Too Status: Eumytic 10mg Tablet By Atco Laboratories Reg. No.: 067274 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of Comforta 10mg Tablet.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
288	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (RQS-DW6-4NNR, 2024-03-19) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>KALOPRID-2MG TABLETS</b> Each film coated tablet contains: Prucalopride succinate equivalent to Prucalopride.....2mg As per Innovators Specification RRA Status: Motegrity 2mg Tablet By TAKEDA PHARMS USA, (FDA Approved) Me Too Status: Notogrity 2mg Tablet By Seraph Pharmaceutical Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of Notogrity 2mg tablet
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
289	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (TBN-YM2-U3VZ, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>DEFERID-500MG TABLETS</b> Each dispersible tablet contains: Deferasirox.....500mg European Pharmacopeia RRA Status: EXJADE By NOVARTIS (FDA Approved) Me Too Status: Dasirox Dispersible 500mg Tablet By CCL Pharmaceutical, Lahore Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-322 By the Name of SERROX 500mg Tablet.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
290	<b>Siam Pharmaceuticals</b> Plot No 217 Industrial Triangle Kahuta Road Islamabad (000711) Contract Manufacturing <b>SERAPH PHARMACEUTICAL</b> , Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan, 000860 Tracking ID: (TJT-3UH-NWML, 2024-03-01) Fee Paid: 75000.0 Paid Date: 2024-01-18 (Salateen Waseem Philip)	Proposed Name: <b>CARVO 1G INJECTION IV/IM</b> Each ampoule contains: Levocarnitine ..... 1g (USP Specs) United States Pharmacopeia RRA Status: Carnitor injection(Leadiant Biosciences)FDA Approved Drug. Me Too Status: Metacartin Injection 1g/5ml(Genome Pharma )Reg.No. 103770 Pack Size(s): As per SRO -As per SRO Previous Approval: 331 st meeting
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
291	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN., 000911 Tracking ID: (VM7-TJH-QT36, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>IMESTIN-250MG INJECTION IV</b> each Vial Contains Imipenem (as Monohydrate).....250mg + Cilastatin (as Sodium).....250mg Powder for solution for Injection/ Infusion United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Cilapen-250mg Injection By Bosh Pharmaceuticals Reg. No.: 048490 Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-330 By the Name of CILAGEN 250MG INJECTION IV
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
292	<b>BF Biosciences Limited</b> 5-KM Sundar Raiwind Road, Raiwind, Lahore ( <b>000655</b> ) Contract Manufacturing <b>Ferozsons Laboratories Limited</b> , P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan., 000038 Tracking ID: (UP9-YGP-S76B, 2024-03-14) Fee Paid: 75000.0 Paid Date: 2024-03-13 (Salateen Waseem Philip)	Proposed Name: <b>Empolin-M Tablets 5mg/500mg</b> Each Film Coated tablet Contains: Empagliflozin.....5mg Metformin HCl.....500mg As per Innovators Specification RRA Status: SYNJARDY of Boehringer Ingelheim Pharmaceutical approved by USFDA. Me Too Status: Product Name: Empozin-M 5mg/500mg Tablets Manufacturer: Ms. Macter International Limited-Karachi Pack Size(s): 10's, 14's, 28's, 30-As per SRO Previous Approval: "Empagen-M Tablets 5/500mg" of M/s Ferozsons Laboratories Limited, approved in 296th Meeting of Regi
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
293	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Seraph Pharmaceuticals</b> , Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (VMZ-ESZ-68MM, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>Seftray-500mg Injection IV</b> Each vial contains: Ceftriaxone (as sodium).....500mg United States Pharmacopeia RRA Status: Ceftriaxone 500mg powder for solution for injection (MHRA Approved) Me Too Status: Droncef injection 500mg by Seraph Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-317 By the Name of ACRUX 500mg Injection IV on Contract Basis For Carer Pharma, Rawat.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	



Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
294	<b>Seraph Pharmaceutical</b> Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (000860) Contract Manufacturing <b>Biogen Life Sciences</b> , 8-Km Chakbeli Road Rawat Rawalpindi -Pakistan, 000911 Tracking ID: (XRA-6NZ-S4UJ, 2024-03-18) Fee Paid: 75000.0 Paid Date: 2024-03-14 (Salateen Waseem Philip)	Proposed Name: <b>Lizobact 600mg/300ml Infusion</b> Each vial 300ml contains: Linezolid.....600 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Nezkil 600mg/300ml Infusion Pack Size(s): 1's-As per SRO Previous Approval: Linzogen "320"
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
295	<b>Solaris Life Sciences Private Limited</b> , Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals</b> , Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad- PAKISTAN., 000860 Tracking ID: (XAG-ZQP-GVAB, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>CARBOXI INJECTION 50mg/ml IV</b> Each ampoule of 10ml contains: Ferric carboxymaltose corresponding to 500mg elemental Iron.  RRA Status: Ferinject By Vifor Pharma UK Limited. Ferinject® Dispersion for Injection/ Infusion (USFDA) Me Too Status: Fercari By Hilton Pharma. Fercari Dispersion for Injection/ Infusion 50mg Iron/ ml 10ml Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-331 By the Name of IronInject Injection 10ml.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
296	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (XX2-L39-EWAY, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>Seftray-500mg Injection IM</b> Each vial contains: Ceftriaxone (as sodium).....500mg United States Pharmacopeia RRA Status: Ceftriaxone 500mg powder for solution for injection (MHRA Approved) Me Too Status: Droncef injection 500mg by Seraph Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-307 By the Name of SIXONE 500mg Injection (IM) on Contract Basis For Siam Pharma, ISB.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
297	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN., 000860 Tracking ID: (Z1E-46H-2487, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>Seftray-1GM Injection IV</b> Each vial contains: Ceftriaxone (as sodium).....1g United States Pharmacopeia RRA Status: Ceftriaxone 1g powder for solution for injection (MHRA Approved) Me Too Status: Droncef injection 1g by Seraph Pharmaceuticals Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-317 By the Name of ACRUX 1G Injection IV on Contract Basis For Carer Pharma, Rawat.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Sr. No	Name of Applicant, Manufacturer & FeeDetails	Product Info
298	<b>Pine Pharmaceuticals</b> Plot No, 40, S-4, Rawat Industrial Estate, Islamabad ( <b>000955</b> ) Contract Manufacturing <b>M/s Biogen Life Sciences,</b> 8-km, Chakbeli Road, Rawat, Rawalpindi, 000911 Tracking ID: (Z4H-GQ8-ER2N, 2024-03-04) Fee Paid: 75000.0 Paid Date: 2023-11-14 (Salateen Waseem Philip)	Proposed Name: <b>LNZO 600mg/300ml Infusion</b> Each 300 ml contains: Linezolid.....600mg (As per innovators specifications) As per Innovators Specification RRA Status: Registration Status = Pan Pharma UK Ltd Linezolid 2mg/ml Solution for Infusion Me Too Status: Nezkil 600mg/300ml by Continental Pharmaceuticals Pack Size(s): 1x1s-As per SRO Previous Approval: 320th meeting of Registration board
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	
299	<b>Solaris Life Sciences Private Limited,</b> Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, ( <b>000992</b> ) Contract Manufacturing <b>Seraph Pharmaceuticals,</b> Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad- PAKISTAN., 000860 Tracking ID: (XZ5-RZX-BWRA, 2024-03-13) Fee Paid: 75000.0 Paid Date: 2024-02-02 (Salateen Waseem Philip)	Proposed Name: <b>SOLDROP-D 7.5MG/ml Injection IM or Oral</b> Each ampoule contains: Cholecalciferol (3 00,000IU).....7.5mg British Pharmacopeia RRA Status: Xarenel® By Italfarmaco S.p.A. Regulatory Authority: Xarenel® Injection is Approved in AIFA of Italy Me Too Status: D Strong Injection 7.5mg (300,000IU) By Seraph Pharmaceutical Islamabad Pack Size(s): As Per SRO-As per SRO Previous Approval: DRB M-330 By the Name of D-Strong Injection 7.5 mg.
	<b>Evaluation Remarks:</b>	
	<b>Decision:</b> Approved	

Meeting ended with vote of thanks to and from the chair

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