MINUTES FOR 339TH MEETING OF REGISTRATION BOARD HELD ON 6TH AUGUST, 2024 TO 8TH AUGUST, 2024

DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX,
CHAK SHEHZAD, PARK ROAD,
---------ISLAMABAD ---------

339th meeting of Registration Board was held on 6th to 8th August, 2024 in theCommittee 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.	Member
7.	Mr. Imranullah Khan, Senior Drug Analyst. Rep of Director DIL, Govt. of KP	Member
8.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o NFS, Islamabad	Member
9.	Mr. Asad Abrar, Director, DTL, Govt. of Punjab	Member
10.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
11.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore	Co-opted Member
12.	Dr. Qurban Ali, Ex-Director General, NVL, Veterinary Expert	Co-opted Member
13.	Mr. Sadaat Ali Khan, Deputy Director, Rep. of Director,MD&MC Division	Member

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

Item No. I. Confirmation of Minutes of 336th meeting of Registration Board.

336th meeting of Registration Board was held on 4th June, 2024 to 6th June, 2024. Accordingly, draft minutes of the 336th meeting of Registration Board were prepared and circulated among the members through email on 2nd July, 2024 for their perusal / approval / comments (if any). Chairman Registration Board in 337th meeting of Registration Board held on 28th June, 2024 has requested to all members to comment (if any) on the minutes of 336th meeting of RB within three days. Accordingly, members were requested to comment till 05th July, 2024 (1100 am). Minutes of 336th meeting of RB stand approved.

Submitted for confirmation / vetting by the Registration Board, please.

Decision: Registration Board noted the information and unanimously confirmed minutes of 336th meeting of Registration Board.

Item No. II. Confirmation of Minutes of 337th meeting of Registration Board.

337th meeting of Registration Board was held on 28th June, 2024. Accordingly, draft minutes of the 337th meeting of Registration Board were prepared and circulated among the members through email on 19th July, 2024 for their perusal / approval / comments (if any). As per direction of Chairman Registration Board members were requested to respond by 22nd July, 2024 at (10:00 am), as case with direction of LHC, Lahore was also on agenda item. No comments from any member received till 22nd July, 2024. Hence minutes of 337th meeting of RB stand approved.

Submitted for confirmation / vetting by the Registration Board, please.

Decision: Registration Board noted the information and unanimously confirmed minutes of 337th meeting of Registration Board.

Item No. III. Confirmation of Minutes of 338th meeting of Registration Board.

338th meeting of Registration Board was held on 4th July, 2024. Accordingly, draft minutes of the 338th meeting of Registration Board were prepared and circulated among the members through email on 08th July, 2024 for their perusal / approval / comments (if any). As per direction members were requested to comment by 08th July, 2024 (1530 Hrs). Mr. Muhammad Aslam, Member, M/o Law & Justice, Islamabad through WhatsApp group of Registration Board commented as "Agreed". Rest of the members did not comment. Hence minutes of 338th meeting of RB stand approved.

Submitted for confirmation / vetting by the Registration Board, please.

Decision: Registration Board noted the information and unanimously confirmed minutes of 338th meeting of Registration Board.

Item No. I Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

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

Total Cases: 1570

Performance of Division of Pharmaceutical Evaluation & Registration

PERFORMANCE OF PE&R DIVISION
PERFORMANCE STATISTICS OF PE&R FROM 01-01-2023 TO 31-12-2023

Table I:

1.	**Total No. of Registration Applications Presented before Reg. Board**	8041
2.	**Total No. of Registrations Issued**	6202
3.	**Total No. of Post Registration Variation Applications Processed**	3761
4.	**Total No. Renewal Cases Processed**	19929

Table II:

S/N	Category	No. of Registered Products
1.	Total No. of Registrations Issued (**Human-Local**)	3304
2.	Total No. of Registrations Issued (**Human-Import**)	137
3.	Total No. of Registrations Issued (**Vet-Local**)	1096
4.	Total No. of Registrations Issued (**Vet-Import**)	53
5.	Total No. of Registrations Issued (**Human/Vet-Export**)	1612
Total		**6202**

Table III:

No. of Registered Products															
S/N	**Section**	**Attribute/ Activity**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Total**
1.	**Local Manufacturing Registration-I**	Issuance of Registration	102	97	171	80	37	27	194	168	106	39	40	177	1238
2.	**Local Manufacturing Registration-II**	Issuance of Registration	240	156	207	94	145	103	122	225	171	244	142	217	2066
3.	**Local Manufacturing-I&V-I (Vet)**	Issuance of Registration	42	42	87	79	104	137	170	50	74	117	01	193	1096
4.	**Import Drug Registration-I&V-I (Vet)**	Issuance of Registration	-	01	-	01	0	01	02	13	01	25	02	07	53
5.	**Import Drug Registration-I&V-II (Human)**	Issuance of Registration	04	07	11	12	12	10	12	18	20	14	04	13	137
6.	**Export Purpose Registration**	Issuance of Registration	106	181	112	140	130	140	0	211	129	197	130	136	1612
Total			494	484	588	406	428	418	500	685	501	636	319	743	**6202**
No. of PRV Cases Processed															
S/N	**Section**	**Attribute/ Activity**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Total**
1.	**Post Registration Variation-I**	Variation in registered drugs	23	302	119	-	149	197	0	244	221	64	303	192	1814
2.	**Post Registration Variation-II**	Variation in registered drugs	166	02	197	210	197	211	30	98	127	127	24	24	1413

3.	**Import & Vet-I (Veterinary)**	Variation in registered drugs	43	88	-	-	0	40	0	69	0	0	52	0	292
4.	**Import & Vet-II (Human)**	Variation in registered drugs	36	42	-	-	0	47	0	71	0	0	46	00	242
Total			268	434	316	210	346	495	30	482	348	191	425	216	**3761**

Pharmaceuticals Evaluation Cell (PEC)

Total Number of Registration Board Meetings	**07 (M- 324, M-326, M-327, M-329, M-330, M-331 & M-333)**

Number of Registration Applications Presented Before Board	**M-324**	**M-326**	**M-327**	**M-329**	**M-330**	**M-331**	**M-333**	**Total**
	1414	1154	678	1290	1140	1679	686	**8041**

Renewal of Registration (RRR)

Total No. of Cases received and processed for entry in database	**15185**
Total No. of Cases placed before Registration Board/ Renewal Sub-Committee	**444**
Total No. of Renewal confirmations from various quarters	**4300 (approx.)**

PERFORMANCE STATISTICS OF PE&R FROM 01-01-2024 TO 31-07-2024

Table I:

1.	**Total No. of Registration Applications Presented before Reg. Board**	4838
2.	**Total No. of Registrations Issued**	2657
3.	**Total No. of Post Registration Variation Applications Processed**	3761
4.	**Total No. Renewal Cases Processed**	11677

Table II:

S/N	**Category**	**No. of Registered Products**
1.	Total No. of Registrations Issued (**Human-Local**)	788
2.	Total No. of Registrations Issued (**Human-Import**)	42
3.	Total No. of Registrations Issued (**Vet-Local**)	731
4.	Total No. of Registrations Issued (**Vet-Import**)	65
5.	Total No. of Registrations Issued (**Human/Vet-Export**)	1031
Total		**2657**

Table III:

No. of Registered Products											**Miscellaneous Tasks**
S/N	**Section**	**Attribute/ Activity**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Total**	
1.	**Local Manufacturing Registration-I**	Issuance of Registration	84	86	-	-	09	12	21	212	i. Correspondence with Provincial Drug Inspectors / DTL / Hospitals / DHA / FBR Other Divisions of **145** cases along with **82** firms. ii. Processed cases for issuance of recommendation to

											Controlled Drugs Division for quota allocation of controlled drug substances for product development and stability determination of **03** firms. iii. Furthermore, there are number of cases received also from I&E Section for which status was confirmed for issuance of NOC for personal use.
2.	**Local Manufacturing Registration-II**	Issuance of Registration	277	128	02	-	101	17	51	576	i. Correspondence with Provincial Drug Inspectors / DTL / Hospitals / DHA / FBR Other Divisions of **731** cases. ii. Attestation of registration letters of **51** products for export purpose. iii. Processed cases for capacity assessment inspection of testing and manufacturing facility of **25** contract manufacturers. iv. Processed cases for issuance of recommendation to Controlled Drugs Division for quota allocation of controlled drug substances for product development and stability determination of **05** firms. v. Furthermore, there are number of cases received also from I&E Section for which status was confirmed for issuance of NOC for personal use.
3.	**Local Manufacturing-I&V-I (Vet)**	Issuance of Registration	165	42	118	-	189	112	105	731	i. Correspondence with Provincial Drug Inspectors / DTL / Hospitals / DHA / FBR

											Other Divisions of **731** cases. ii. Attestation of registration letters of **51** products for export purpose. iii. Processed cases for capacity assessment inspection of testing and manufacturing facility of **25** contract manufacturers. iv. Processed cases for issuance of recommendation to Controlled Drugs Division for quota allocation of controlled drug substances for product development and stability determination of **05** firms. v. Furthermore, there are number of cases received also from I&E Section for which status was confirmed for issuance of NOC for personal use.
4.	**Import Drug Registration-I&V-I (Vet)**	Issuance of Registration	03	04	07	09	22	04	16	65	--
5.	**Import Drug Registration-I&V-II (Human)**	Issuance of Registration	12	04	-	01	13	06	06	42	--
6.	**Export Purpose Registration**	Issuance of Registration	285	-	175	-	294	207	70	1031	--
Total			826	264	302	10	628	358	269	**2657**	--

No. of PRV Cases Processed

S/N	Section	Attribute/ Activity	Jan	Feb	Mar	Apr	May	June	July	Total
1.	**Post Registration Variation-I**	Variation in registered drugs	28	206	121	-	156	50	110	671
2.	**Post Registration Variation-II**	Variation in registered drugs	68	65	59	-	241	66	158	657
3.	**Import & Vet-I (Veterinary)**	Variation in registered drugs	56	-	42	-	16	-	-	114
4.	**Import & Vet-II (Human)**	Variation in registered drugs	40	-	75	-	17	-	-	132
Total			192	271	297	-	430	116	268	**1574**

Pharmaceuticals Evaluation Cell (PEC)

Total Number of Registration Board Meetings	05 (M- 334, M-335, M-336, M-337 & M-339)					
Number of Registration Applications Presented Before Board	**M-334**	**M-335**	**M-336**	**M-337**	**M-339**	**Total**
	135	657	2032	445	1569	**4838**
Renewal of Registration (RRR)						
Total No. of Cases received and processed for entry in database	**7000**					
Total No. of Cases placed before Registration Board/ Renewal Sub-Committee	**677**					
Total No. of Renewal confirmations from various quarters	**4000 (approx.)**					

Above mentioned performance of PE&R Division was presented before the Registration Board and the Board acknowledged and appreciated the efforts of all the officers of PE&R Division. The Board admired the continuous rising performance of the PE&R Division due to extraordinary efforts of the officers and staff of the Division. The Board after thorough deliberations, recommended that above performance report be presented before the Authority for its perusal and issuance of appreciation letters and honoraria to the officers of PE&R Division.

Case No. 1: Submission of replies of deferred applications of Form-5 and Form-5A of Human Drugs

The dead line for submission of Form-5 and Form-5A of Human Drugs was 07th March, 2019. Thereafter, Form-5F (CTD) was implemented. Registration Board observed that firms are submitting replies of applications of Form-5 and Form-5A of Human Drugs deferred in various registration board meetings after lapse of long time which is creating hurdle in reducing the pendency of current registration applications. The Board deliberated the matter in details and decided that replies of applications of Form-5 and Form-5A of Human Drugs deferred in various Registration Board meetings shall be submitted in R&I section of DRAP till 31st December, 2024. Replies of such applications submitted after said date shall not be entertained and all such applications shall be considered as disposed off and the applicant firm may submit fresh application on Form-5F which will be considered on its turn in queue of Form 5F. The Board further directed to issue a circular to stakeholders for information and compliance of the decision.

Case No. 2: Stability data submitted for applications applied on Form 5/5D.

Registration Board in its **320th** meeting considered the case of "Applications submitted on Form 5 / 5-D requiring submission of stability data" and decided as under:

"Registration Board deliberated the matter in detail and observed that these applications are pending for submission of stability data/product development data by the applicants since many years. Keeping in view the pendency, the Board deliberated the matter in detail and also took opinion of PPMA and then decided that the firms shall initiate the product development and stability studies of submitted applications and intimate to Pharmaceutical Evaluation Cell (PEC) regarding procurement of raw material, initiation of product development and initiation of stability studies, by 31st December 2022. For all those applications for which Pharmaceutical Evaluation Cell will not receive any intimation regarding initiation of product development and stability studies, will be placed before the Board for decision"

The above decision of the Board was notified vide letter No. No. 320-DRB/ 2022(PE&R) dated 17-10-2022. Later, Pakistan Pharmaceutical Manufacturer's Association through its Chairman (North) vide its letter No. PPMNAM-03312022 dated 30-12-2022 requested for Extension in Time for Submission of Stability Data of Form 5/5D.

Registration Board in its 324th meeting considered the request of PPMA and decided as under:

"Registration Board while considering the above cited request of PPMA reiterated that that the numerous applications are pending for submission of stability data/product development data by the applicants since many years causing by an un due backlog for the PE&R Division. Board also discussed that previously, opinion of PPMA was also taken while giving an opportunity to the firms to submit an intimation regarding initiation of product development & stability studies had been given to firms for submission of any had already been given a time period till by 31st December 2022. Keeping in view the above deliberation Board decided to refer the case to Authority for seeking guidance regarding timelines for submission of Stability Data of Form 5 / Form 5-D Files."

The matter was placed before the Authority in its 161st meeting held on 5-6 April, 2023 and the Authority decided as follow:
"The Authority noted that the numerous applications are pending for submission of stability data/product development data by the applicants since many years resulting in an un due backlog for the PE&R & BE&R Division. The applicants had failed to submit the requisite data after lapse of agreed deadline. Accordingly, the Authority advised the Registration Board to dispose of the cases on merit."

As per available record, a list of stability data submitted till 31st December, 2022 was placed before the Board in its 329th meeting and the Board decided as under:

"Registration Board discussed the decision of Authority in detail and after through deliberations decided in line with decision of the Authority to consider only those registration applications for which stability study data has been submitted till 31st December, 2022. Stability study data shall be processed as per its queue. Registration Board further decided that all those registration applications requiring stability study data (applied on Form5/Form 5D) for which the requite data has not been submitted till 31st December, 2022, shall be considered as disposed off and the applicant firms shall submit its product development and stability data on Form-5F which will be considered on its turn in queue of Form 5F."

It is submitted that various firm have submitted stability data after 31st December 2022 keeping in view the previous decision of registration Board taken in its 320th meeting held on 29th -31st August 2022. However, the matter was finally decided by Registration Board in its 329th meeting held on 6th to 8th June, 2023.
The matter was placed before the authority and the Authority in its 184th meeting held on 26th June, 2024 decided as follow:
"The Authority decided that only those registration applications shall be considered by the Registration Board for which stability data has been submitted by the pharmaceutical firm on or before 30th June, 2023."
As per available record, a list of stability data submitted till 30th June, 2023 is as follow:

S.No.	Name and Address of Manufacturer	Brand Name	Generic Name	Date of Submission of stability data (yyyymmdd)
1	M/s Wilshire Labs Pvt Ltd, 124/1, Qaid-e-azam Industrial Estate, kot lakhpat, lahore	Diamant-M 12.5/1000 mg tablet	Empagliflozin Metformin Hcl	20200115
2	M/s Wilshire Labs Pvt Ltd, 124/1, Qaid-e-azam Industrial Estate, kot lakhpat, lahore	Kanlif-M 150/500 mg Tablet	Canagliflozin Metformin Hcl	20200807
3	M/s Wilshire Labs Pvt Ltd, 124/1, Qaid-e-azam Industrial Estate, kot lakhpat, lahore	Kanlif-M 150/1000 mg Tablet	Canagliflozin Metformin Hcl	20200807

4	M/s Wilshire Labs Pvt Ltd, 124/1, Qaid-e-azam Industrial Estate, kot lakhpat, lahore	Depawil-M XR 5/500 mg Tablet	Dapagliflozin Metformin	20200922
5	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Maxvir 100/400 mg Tablet	Sofosbuvir Velpatasvir	20210318
6	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Davir 60mg Tablet	Daclatasvir	20210318
7	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Sofos 400mg Tablet	Sofosbuvir	20210318
8	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Silosyn 4mg Capsule	Silodosin	20210712
9	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Silosyn 8mg Capsule	Silodosin	20210712
10	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Ivaset-M 50/5 mg Tablet	Metoprolol Tartrate Ivabradine Hcl	20210806
11	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Ivaset-M 50/7.5 mg Tablet	Metoprolol Tartrate Ivabradine Hcl	20210806
12	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Nebival 5/80 mg Tablet	Nebivolol Valsartan	20211004
13	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Rizaptan 10mg Tablet	Rizatriptan	20211117
14	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Nesmet 12.5/500 mg Tablet	Alogliptin Metformin Hcl	20211217
15	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Nesmet 12.5/1000 mg Tablet	Alogliptin Metformin Hcl	20211217
16	M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Danzo 30mg Capsule	Dexlansoprazole	20211223
17	M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Danzo 60mg Capsule	Dexlansoprazole	20211223
18	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 5mg Tablet	Vortioxetine	20220103
19	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 10mg Tablet	Vortioxetine	20220103
20	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 15mg Tablet	Vortioxetine	20220103

21	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 20mg Tablet	Vortioxetine	20220103
22	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Baclo 5mg/5ml Syrup	Baclofen	20220104
23	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Canaloz 300mg Tablet	Canagliflozin	20220119
24	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glipan 25/5 mg Tablet	Empagliflozin Linagliptin	20220119
25	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 200mg Tablet	Eslicarbazepine Acetate	20220125
26	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 400mg Tablet	Eslicarbazepine Acetate	20220125
27	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 600mg Tablet	Eslicarbazepine Acetate	20220125
28	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 800mg Tablet	Eslicarbazepine Acetate	20220125
29	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Megron 50mg Tablet	Mirabegron	20220131
30	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Megron 25mg Tablet	Mirabegron	20220131
31	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Letrum 5mg Tablet	Linagliptin	20220209
32	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Pentadol 50mg Tablet	Tapentadol	20220216
33	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Pentadol 100mg Tablet	Tapentadol	20220216
34	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Meltog 25mg Tablet	Agomelatine	20220304
35	M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Dexprazole 30mg Capsule	Dexlansoprazole	20220317
36	M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Dexprazole 60mg Capsule	Dexlansoprazole	20220317
37	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Jexma 5mg Tablet	Vortioxetine	20220401
38	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ludil Opthalmic Solution 0.02%	Netarsudil	20220401

39	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK	Esonap 500/20 mg Tablet	Naproxen Esomeprazole	20220405
40	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Combito Opthalmic Suspension	Brinzolamide Brimonidine	20220411
41	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly 25mg Tablet	Empagliflozin	20220415
42	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly 10mg Tablet	Empagliflozin	20220415
43	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Auron Tablets 25mg	Mirabegron	20220423
44	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutrol 75mg Tablets	Tapentadol As Hcl	20220429
45	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Swiflo 4mg Capsule	Silodosin	20220509
46	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Swiflo 8mg Capsule	Silodosin	20220509
47	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Axhert 50/500 mg Tablet	Sitagliptin Metformin Hcl	20220509
48	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Etorid 90mg Tablet	Etoricoxib	20220519
49	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Etorid 120mg Tablet	Etoricoxib	20220519
50	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Darimac 15mg Tablet	Darifenacin Hydrobromide	20220519
51	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Darimac 7.5mg Tablet	Darifenacin Hydrobromide	20220519
52	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Gabra 25mg ER tablet	Mirabegron	20220519
53	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifo Met Tablet 5/1000mg	Dapagliflozin Propanediol Metformin Hcl	20220519
54	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifo Met Tablet 5/850mg	Dapagliflozin Propanediol Metformin Hcl	20220519
55	M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Lansodex 60mg Capsule	Dexlansoprazole	20220528

56	M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Lansodex 30mg Capsule	Dexlansoprazole	20220528
57	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore	Mycosin 125mg Tablet	Terbinafine Hcl	20220607
58	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Xempo 5/1000 mg Tablet	Empagliflozin Metformin	20220608
59	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore	Dezole 30mg Capsules	Dexlansoprazole	20220613
60	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore	Dezole 60mg Capsules	Dexlansoprazole	20220613
61	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutolv 30mg Tablet	Tolvaptan	20220617
62	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutolv 15mg Tablet	Tolvaptan	20220617
63	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Ticol 90mg Tablet	Ticagrelor	20220620
64	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Emglif-M XR Tablet 10mg/1000mg	Empagliflozin Metformin	20220623
65	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Emglif-M XR Tablet 25mg/1000mg	Empagliflozin Metformin	20220623
66	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Rajumat 50/500mg XR Tablet	Sitagliptin Metformin	20220623
67	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Rajumat 50/1000mg XR Tablet	Sitagliptin Metformin	20220623
68	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ocaliva/Obit/Chico Tablet 10mg	Obeticholic Acid	20220627
69	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ocaliva/Obit/Chico Tablet 5mg	Obeticholic Acid	20220627
70	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Prelin CR tablet 82.5mg	pregabalin	20220629
71	M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Y-Nil capsule 60mg	Orlistat	20220704
72	M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Y-Nil capsule 120mg	Orlistat	20220704
73	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Empilig 10/5mg Tablet	Empagliflozin Linagliptin	20220706
74	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Empilig 25/5mg Tablet	Empagliflozin Linagliptin	20220706
75	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin 10mg Tablet	Empagliflozin	20220707

76	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin 25mg Tablet	Empagliflozin	20220707
77	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Dapzin 10mg Tablet	Dapagliflozin	20220707
78	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	VasNeb 5/80mg tablet	Nebivolol Valsartan	20220707
79	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 80mg	Lurasidone HCl	20220718
80	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 40mg	Lurasidone HCl	20220718
81	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 20mg	Lurasidone HCl	20220718
82	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 60mg	Lurasidone HCl	20220718
83	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Angiclor 90mg Tablet	Ticagrelor	20220719
84	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	EM-Met 12.5/1000mg tablet	Metformin HCl Empagliflozin	20220720
85	M/s Dynatis Pakistan (Pvt) Ltd. Plot No.710 Sundar Industrial Estate, Lahore.	Begrem Tablet 25mg	Mirabegron	20220725
86	M/s Dynatis Pakistan (Pvt) Ltd. Plot No.710 Sundar Industrial Estate, Lahore.	Begrem Tablet 50mg	Mirabegron	20220725
87	M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli tablet 5mg	Dapagliflozin	20220802
88	M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli tablet 10mg	Dapagliflozin	20220802
89	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Azilsan 40mg Tablet	Azilsartan Medoxomil	20220815
90	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Esoprox 375/20mg Tablet	Esomeprazole Magnesium	20220815
91	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	Trifort DS 75/650 mg Tablet	Tramadol Paracetamol	20220815
92	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Velamer-C 0.8g Sachet	Savelamer Carbonate	20220825
93	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Velamer-C 2.4g Sachet	Savelamer Carbonate	20220825
94	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Esoprox 500/20mg Tablet	Naproxen Esomeprazole	20220907
95	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Lorsin 10mg Tablets	Lorcaserin HCl	20220907
96	M/s Mcolson Research Laboratories Pvt Ltd.	Mcbriet 534 mg tablet	Pirfenidone	20220908

	26 km Lahore-Sheikhupura Road, Sheikhupura			
97	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mcbriet 267 mg tablet	Pirfenidone	20220908
98	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mcbriet 801 mg tablet	Pirfenidone	20220908
99	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Winovir 400mg tablet	Sofosbuvir	20220913
100	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Gvia-S tablet 50/10mg	Sitagliptin Simvastatin	20220922
101	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Gvia-S tablet 100/20mg	Sitagliptin Simvastatin	20220922
102	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Brinzol Ophthalmic Suspension 10mg+2mg	Brinzolamide Brimonidine Tartrate	20220923
103	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutaxo 5/80mg tablet	Nebivolol Valsartan	20220926
104	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 10mg tablets	Apremilast	20220927
105	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 20mg tablets	Apremilast	20220930
106	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Prelin CR tablet 165mg	pregabalin	20221003
107	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Molta Tablet 665mg	Paracetamol	20221006
108	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Motais Ointment 0.1%	Mometasone Furate	20221006
109	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Tafilu ophthalmic solution 0.0015%	Tafluprost	20221007
110	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Prelin CR tablet 330mg	pregabalin	20221007
111	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 30mg tablets	Apremilast	20221010
112	M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli 5/1000mg tablet	Dapagliflozin Metformin Hcl	20221011
113	M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli 5/850mg tablet	Dapagliflozin Metformin Hcl	20221011
114	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Roflubar 500mcg Tablet	Roflumilast	20221012

115	M/s Winthrox Laboratories	Lanso 30mg capsule	Deslansoprazole	20221013
116	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 5mg Tablet	Ertugliflozin	20221026
117	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 15mg Tablet	Ertugliflozin	20221026
118	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 97+103mg tablet	Sacubitril Valsartan	20221030
119	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 49+51mg tablet	Sacubitril Valsartan	20221030
120	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 24+26mg tablet	Sacubitril Valsartan	20221030
121	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	D-Flozin 5mg Tablet	Dapagliflozin	20221101
122	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	D-Flozin 10mg Tablet	Dapagliflozin	20221101
123	M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Karangi Industiral Area, Karachi.	Lina 5mg Tablet	Linagliptin	20221103
124	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Sunny D Tablet 30,000 IU	Vitamin D3	20221104
125	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Aczo gel 5%	Dapsone	20221107
126	M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Tamsolid 0.4mg	Tamsulosin HCl SR Pellet 2%	20221114
127	M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Tamsolid 0.8mg	Tamsulosin HCl SR Pellet 2%	20221114
128	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Trapeze Plus XR 100/1000 mg Tablet	Sitagliptin Metformin	20221116
129	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neuhal Cream 0.05%	Halobetasol Propionate Ointment 0.05% w/w	20221118
130	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Nupreced 200mcg/2ml inejction	Dexmedetomide	20221118
131	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Gluta Dry powder Vial inj.	Glutathione	20221118
132	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Dipos Gel 5%	Dapsone	20221118
133	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Idyll 20mg tabelts	Vortioxetine	20221121
134	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Idyll 10mg tabelts	Vortioxetine	20221121

135	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Solif-T MR 0.4+6mg	Tamsulosin Hydrochloride Solifenacin succinate	20221122
136	M/s Pharma Lord, 12km, Lahore Road, Layyah	Dlans 30mg capsule	Dexlansoprazole	20221124
137	M/s Pharma Lord, 12km, Lahore Road, Layyah	Dlans 60mg capsule	Dexlansoprazole	20221124
138	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Otoxel otic Solution	ciprofloxacin as HCl Fluocinolone Acetonide	20221128
139	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Valoglif 10mg tablet	Empagliflozin	20221129
140	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	Cagrelor 90mg tablet	Ticagrelor	20221205
141	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Flexia 120mg tablet	Etroricoxib	20221206
142	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Flexia 90mg tablet	Etroricoxib	20221206
143	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Valoglif 25mg tablet	Empagliflozin	20221206
144	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Izolol Eye Drops 1%+0.5%	Brinzolamide Timolol	20221209
145	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusit 5/100 mg Tablet	Ertugliflozin Sitagliptin	20221210
146	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusit 15/100 mg Tablet	Ertugliflozin Sitagliptin	20221210
147	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Zenwo 5mg tablet	Dapagliflozin	20221212
148	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Dexoloc Capsule 30mh	Dexlansoprazole	20221212
149	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 10mg	Rizatriptan	20221219
150	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 5mg	Rizatriptan	20221219
151	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 7.5/500 mg Tablet	Ertugliflozin Metformin	20221220
152	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 2.5/500 mg Tablet	Ertugliflozin Metformin	20221220
153	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 2.5/1000 mg Tablet	Ertugliflozin Metformin	20221220
154	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 7.5/1000 mg Tablet	Ertugliflozin Metformin	20221220

155	M/s Sami Pharmaceuticals (Pvt) Ltd, F-95, Off.Hub River Road, S.I.T.E Karachi	Elinjec 500mg /10ml injection	Ferric Carboxymaltose	20221222
156	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Valsa 24/26mg Tablets	Sacubitril Valsartan	20221223
157	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Valsa 49/51mg Tablets	Sacubitril Valsartan	20221223
158	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Tacvo 90mg tablets	Ticagrelor	20221223
159	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Linavo 5mg tablts	Liagliptin	20221223
160	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Empaglin 25mg /5mg tablet	Empagliflozin Linagliptin	20221226
161	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Empaglin 10mg /5mg tablet	Empagliflozin Linagliptin	20221226
162	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Lina 5mg Tablet	Linagliptin	20221227
163	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Revonap 375/20mg tablet	Naproxen Esomeprazole	20221227
164	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Revonap 500/20mg tablet	Naproxen Esomeprazole	20221227
165	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Zenwo 10mg tablet	Dapagliflozin	20221228
166	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Xab tablets 2.5mg	Apixaban	20221228
167	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Xab tablets 5mg	Apixaban	20221228
168	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	wencuval 97+103mg tablet	Sacubitril Valsartan	20221228
169	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 12.5/1000mg tablet	Empagliflozin Metformin	20221229
170	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 5/1000mg tablet	Empagliflozin Metformin	20221229
171	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 5/500mg tablet	Empagliflozin Metformin	20221229
172	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 12.5/500mg tablet	Empagliflozin Metformin	20221229
173	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 10/500mg tablets	Dapaglifozin Metformin HCl	20221229

174	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 10/1000mg tablets	Dapaglifozin Metformin HCl	20221229
175	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 5/1000mg tablets	Dapaglifozin Metformin HCl	20221229
176	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 5/500mg tablets	Dapaglifozin Metformin HCl	20221229
177	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Emplina 10/5mg tablet	Empaglifozin Linagliptin	20221229
178	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Emplina 25/5mg tablet	Empaglifozin Linagliptin	20221229
179	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo 5mg tablet	Dapagliflozin	20221229
180	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo 10mg tablet	Dapagliflozin	20221229
181	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Rexira 1mg tablet	Brexpiprazole	20221229
182	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Rexira 2mg tablet	Brexpiprazole	20221229
183	M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem 25mg tablets	Empagliflozin	20221229
184	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Dapxin 5mg tablet	Dapagliflozin	20221229
185	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Dapxin 10mg tablet	Dapagliflozin	20221229
186	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin 10mg tablet	Empagliflozin	20221229
187	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin 25mg tablet	Empagliflozin	20221229
188	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin-M 5/500mg tablet	Metformin HCl Empagliflozin	20221229
189	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin-M 12.5/1000mg tablet	Metformin HCl Empagliflozin	20221229
190	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Noxilant 60mg capsule	Deslansoprazole	20221229
191	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Noxilant 30mg capsule	Deslansoprazole	20221229

192	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 375mg tablet	Ranolazine	20221230
193	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 500mg tablet	Ranolazine	20221230
194	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 750mg tablet	Ranolazine	20221230
195	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Denset 2mg tablet	Dienogest	20221230
196	M/s Genetic Pharmaceuticals (Pvt) Ltd, 539-A, Sundar Industrial Estate, Rawind, Lahore	Trint 10mg tablet	Vortioxetine	20221230
197	M/s Genetic Pharmaceuticals (Pvt) Ltd, 539-A, Sundar Industrial Estate, Rawind, Lahore	Trint 20mg tablet	Vortioxetine	20221230
198	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dorisol injection 250mg	Doripenem Monohydrate	20221230
199	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dorisol injection 500mg	Doripenem Monohydrate	20221230
200	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Linamet 2.5/1000mg tablet	Linagliptin Metfromin HCl	20230102
201	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Linamet 2.5/850mg tablet	Linagliptin Metfromin HCl	20230102
202	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Linamet 2.5/500mg tablet	Linagliptin Metfromin HCl	20230102
203	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Prelin CR tablet 330mg	Pregabalin	20230106
204	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Eyecef Ophthalmic solution	Alcaftadine	20230116
205	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad	Danso 30mg capsule	Dexlansoprazole	20230119
206	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad	Danso 60mg capsule	Dexlansoprazole	20230119
207	M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Vortox Tablet 10mg	Vortioxetine Hydrobromide	20230123
208	M/s Semos Pharmaceuticals (Pvt) Ltd,	Vortox Tablet 20mg	Vortioxetine Hydrobromide	20230123

	Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.			
209	M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Luras Tablets 40mg	Lurasidone HCl	20230123
210	M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Luras Tablets 80mg	Lurasidone HCl	20230123
211	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glipin tablet 6.25mg	Alogliptin Benzonate	20230123
212	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glipin tablet 12.5mg	Alogliptin Benzonate	20230123
213	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Rascod Sachet 10mg	Racecadotril	20230123
214	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Picrol Cream 1%	Pimecrolimus	20230123
215	M/s AGP Limited. B-23, S.I.T.E. Karachi	Emoglip 10/5mg tablet	Empagliflozin Linagliptin	20230126
216	M/s AGP Limited. B-23, S.I.T.E. Karachi	Emoglip 25/5mg tablet	Empagliflozin Linagliptin	20230126
217	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 5mg Tablet	Ertugliflozin	20230127
218	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 15mg Tablet	Ertugliflozin	20230127
219	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusita 5/100 mg Tablet	Ertugliflozin Sitagliptin	20230127
220	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusita 15/100 mg Tablet	Ertugliflozin Sitagliptin	20230127
221	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Glifmet 5/1000mg tablet	Empagliflozin Metformin	20230203
222	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Duzall Tablets 50mg	Sainamide	20230207
223	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Duzall Tablets 100mg	Sainamide	20230207
224	M/s High-Q Pharmaceuticls, 224/23 Korangi Industrial Area, Karachi	Vinovo 500/20mg Tablet	Napraoxen Esomeprazole as Magnesium	20230213
225	M/s High-Q Pharmaceuticls, 224/23 Korangi Industrial Area, Karachi	Vinovo 375/20mg Tablet	Napraoxen Esomeprazole as Magnesium	20230213
226	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Letrum-M 2.5/500mg Tablet	Linagliptin Metformin	20230216
227	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Letrum-M 2.5/850mg Tablet	Linagliptin Metformin	20230216
228	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Letrum-M 2.5/1000mg Tablet	Linagliptin Metformin	20230216

229	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly Met tablet 12.5mg +1000mg	Empagliflozin Metformin HCl	20230222
230	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly Met tablet 12.5mg +500mg	Empagliflozin Metformin HCl	20230222
231	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Kandina8+2.5mg tablet	Candesartan Amlodipine	20230224
232	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Kandina8+5mg tablet	Candesartan Amlodipine	20230224
233	M/s Fahmier Pharma (Pvt) Ltd., 26-Km-Lahore- Jarawala Road, main stop Mandianwala Tehsil Sharaqpur Sharif, District, Sheikhupura	Dexomir-30mg capsule	Dexlansoprazole	20230224
234	M/s Fahmier Pharma (Pvt) Ltd., 26-Km-Lahore- Jarawala Road, main stop Mandianwala Tehsil Sharaqpur Sharif, District, Sheikhupura	Dexomir-60mg capsule	Dexlansoprazole	20230224
235	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Carbiz 200mg tablet	Eslicarbazepine Acetate	20230227
236	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Matine 25mg tablet	Agomelatine	20230227
237	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Velsar 49/51mg Tablet	Sacubitril Valsartan	20230227
238	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Cardilol XR capsule 20mg	Carvedilol Phosphate	20230227
239	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Fludip-M XR 10/1000mg Tablet	Dapagliflozin Metformin	20230227
240	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Fludip-M XR 5/1000 mg Tablet	Dapagliflozin Metformin Hcl	20230227
241	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore	Britam 10mg tablet	Brivaracetam	20230227
242	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore	Britam 25mg tablet	Brivaracetam	20230227
243	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore	Britam 50mg tablet	Brivaracetam	20230227
244	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore	Britam 75mg tablet	Brivaracetam	20230227
245	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore	Britam 100mg tablet	Brivaracetam	20230227
246	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Asinap 5mg Tablet	Asenapine	20230301
247	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Asinap 10mg Tablet	Asenapine	20230301

248	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Glifmet 12.5/1000mg tabelt	Empagliflozin Metformin	20230303
249	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 14mg tablet	Semaglutide	20230320
250	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Onset 4mg Tablet	Ondansetron	20230321
251	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Onset 8mg Tablet	Ondansetron	20230321
252	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Cefspan Max Suspension 500mg/5ml	Cefixime	20230324
253	M/s S.J. & G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E Karachi	Ates-P 200mg/500mg tablet	Ibuprofen Paracetamol	20230330
254	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Colistim injection 2MIU	Colistimethate Sodium	20230330
255	M/s Hiranis Pharmaceuticals (Pvt) Ltd, Plot No.E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi	safcort tablet	Deflazacort	20230403
256	M/s Hiranis Pharmaceuticals (Pvt) Ltd, Plot No.E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi	Glucort S.R Tablet 5mg	Beclomethasone Dipropionate	20230403
257	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dapoglin 10mg tablet	Dapagliflozin	20230410
258	M/s Amarant Pharmaceuticals (Pvt) Ltd. 158, D.Tore, Gadap road, Super Highway, Karachi	Bricetam Tablet 10mg	Brivaracetam	20230411
259	M/s Amarant Pharmaceuticals (Pvt) Ltd. 158, D.Tore, Gadap road, Super Highway, Karachi	Bricetam Tablet 10mg	Brivaracetam	20230411
260	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin-M 5/1000mg Tablet	Empagliflozin Metformin	20230420
261	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin-M 12.5/1000mg Tablet	Empagliflozin Metformin	20230420
262	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Sacval tablet 49mg +51mg	Sacubitril Valsartan	20230427
263	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Sacval tablet 24mg +26mg	Sacubitril Valsartan	20230427

264	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Sacval tablet 97mg +103mg	Sacubitril Valsartan	20230427
265	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Fludip-M XR 5mg/500mg	Dapagliflozin Metformin	20230428
266	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Fludip-M XR 10mg/500mg	Dapagliflozin Metformin	20230428
267	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 10mg	Rizatriptan	20230505
268	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 5mg	Rizatriptan	20230505
269	M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate Gadoon Amazai, District Swabi.	Dexlansip Capsule 30mg	Dexlansoprazole	20230505
270	M/s Hisun Pharmaceuticals Industries, 37-A, R-2 Industrial Estate Gadoon Amazai, District Swabi.	Dexlansip Capsule 60mg	Dexlansoprazole	20230505
271	M/s Zeta Pharmaceuticals, 494-A, Sunder Industrial Estate, Raiwind Road, Lahore.	Zempa M 5/500mg tablet	Empagliflozin Metformin	20230509
272	M/s Zeta Pharmaceuticals, 494-A, Sunder Industrial Estate, Raiwind Road, Lahore.	Zempa M 12.5/1000mg tablet	Empagliflozin Metformin	20230509
273	M/s Zeta Pharmaceuticals, 494-A, Sunder Industrial Estate, Raiwind Road, Lahore.	Zelanso capsule 30mg	Dexlansoprazole	20230509
274	M/s Zeta Pharmaceuticals, 494-A, Sunder Industrial Estate, Raiwind Road, Lahore.	Zelanso capsule 60mg	Dexlansoprazole	20230509
275	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Mirabron XR 50mg tablet	Mirabegron	20230512
276	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan	Zeegab Oral Solution	Pregabalin	20230512
277	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Glifmet 12.5/850mg tablet	Empagliflozin Metformin	20230529
278	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Glifmet 12.5/500mg tablet	Empagliflozin Metformin	20230529
279	M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Canazin 100mg Tablet	Canagliflozin	20230529
280	M/s Barrett Hodgson pakistan Pvt Ltd. F/423, SITE, Karachi	Oclozine Ophthalmic solution 0.24%	Cetrizine	20230601

281	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Mirabron XR 25mg tablet	Mirabegron	20230602
282	M/s Amarant Pharmaceuticals (Pvt) Ltd. 158, D.Tore, Gadap road, Super Highway, Karachi	Bricetam Tablet 75mg & 100mg Tablet & 50mg Tablet	Brivaracetam	20230612

Delibrations: Registaration Board discussed the compliance of decision of Authority in detail along with the presented list. The Board also directed the division to revisit the list in consultation with the observers/representatives of the PPMA and Pharma Buerue during the days of current meeting of the Board so that list could be updated with minimum omissions/errors. Acordingly as per received evidence, list was updated as presented above.

Decision: Registration Board, in compliance to the decision of 184th meeting of Authority decided to endorse the above list of registration applications for whome stability study data has been submitted till 30th June, 2023. Stability study data shall be processed as per the dates mentioned in the last column of the table. Registration Board further decided that all those registration applications requiring stability study data (applied on Form5/Form 5D) for which the requisite data has not been submitted till 30th June, 2023, shall be considered as disposed off and the applicant firms may apply afresh on Form-5F which will be considered on its turn in queue of Form 5F.

Agenda of Mr. Ammar Ashraf Awan

Case no.: 01 Applications submitted on Form 5F by way of self-manufacturing

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited.** **Plot No. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	Hudson Pharma Private Limited. **Address:** D-93, North Western Industrial Zone, Port Qasim, Karachi, Sindh 75020, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 4-April-2022 based on inspection conducted on 07-October-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 30-08-2016 specifying plastic ampoules section (BFS Technology).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 27128 dated 26-09-2022
	Details of fee submitted	Rs.75000/- dated 13-09-2022
	The proposed proprietary name / brand name	**Ipradow-S Inhalation Solution 0.5/2.5 mg 2.5m**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Contains: Ipratropium Bromide…0.5mg Salbutamol Sulphate …… 3mg eq. to Sulbutamol Base …… 2.5mg
	Pharmacotherapeutic Group of (API)	Salbutamol and Ipratropium bromide for obstructive airway disease ATC code: R03A L02
	Pharmaceutical form of applied drug	Nebuliser Solution Clear colourless sterile solution, filled in LDPE ampoule, free from any external particles.
	Reference to Finished product specifications	USP
	Proposed Pack size	Pack Size:5x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Combihale respules by Hudson Pharma Private Limited (Reg.#090971)
	Name and address of API manufacturer.	**Ipratropium:** Olon S.p.A. Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy. **Salbtamol:** Cipla Limited-Patalganga, Plot No.A-33, A-42, A-2 Patalganga Industrial Area, District-Raigad (Maharashtra), INDIA.

Remarks of Evaluator:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.3**	Details of product manufactured in the plastic ampoules section (BFS Technology) of M/s Hudson pharma shall be submitted.	Submitted
2.	**1.5.2**	Label claim in terms of complete salt form of Ipratropium shall be submitted i.e., Ipratropium bromide as monohydrate.	Firm has submitted revised label claim as under: Each ampoule contains: Ipratropium Bromide ……0.5mg (as 0.5218mg Ipratropium Bromide monohydrate) Salbutamol Sulfate……..3.0125mg eq. To Salbutamol base 2.5mg
3.	**1.6.5**	Valid DML/GMP certificate shall be submitted for the M/s Via Livelli, 1 26852 Casaletto Lodigiano (Frazione Mairano) (LO), Italy.	Submitted
4.	**3.2.S.4**	• Clarification shall be submitted regarding the claimed specifications for Ipratropium bromide by drug substance manufacturer, whether it is USP, BP, Ph. Eur. or IP.	We (Hudson Pharma Private Limited) are following BP specs. However, Drug substance manufacturer is performing testing as per mentioned Pharmacopoeial specifications i.e. USP, BP and IP depend on

			vendor requirements. Which is enclosed for your reference.
		• Drug substance details submitted in section 3.2.S for Ipratropium is from M/s Olon S.p.A whereas COAs, have been submitted from M/s Sifavitor. Justification shall be submitted in this regard.	
	Firm has submitted following justification from M/s Olon s.p.a: "Infa Group Spa and its affiliates Labochim Spa and Sifavitor Srl have been acquired in May 2016 by Olon Spa. Beginning January 1st, 2017 Labochim Spa and Sifavitor Srl will be merged by incorporation into Olon Spa All the documents including, but not limited to: Certificate of Analysis, Label, Invoice, Packing List will be retaining the Brand Name, Logo, Plant Address of Labochim and Sifavitor in order to facilitate the change process. The layout of each document is available and will be supplied upon request. The Manufacturing Licenses and the GMP certificates will be available reissued in the new name Olon Spa within first quarter of 2017. All DMFs and CEPs will be promptly updated and submitted to the Regulatory Authorities in order to reflect the name change."		
5.	**3.2.P.1**	Submitted master formulation shall be justified for quantities of Ipratropium bromide and Salbutamol sulphate per batch, with reference to the equivalency factors of salt forms. Submitted master formulation shall declare the contents of Ipratropium bromide in terms of Ipratropium bromide as monohydrate.	Submitted
6.	**3.2.P.2.1**	Submitted formulation development data declares the use of Ipratropium bromide anhydrous form, whereas Innovator drug product has used Ipratropium bromide monohydrate form. Justification shall be submitted in this regard.	There is a typographical error in part P.2 (PD report). Basically it is Ipratropium bromide monohydrate instead of Ipratropium bromide anhydrous form.
7.	**3.2.P.2.2.1**	Justification shall be submitted for not including test of sterility, particulate matter and Uniformity of dosage units in the Pharmaceutical equivalence studies.	Not submitted
8.	**3.2.P.3.2**	Details of sterilization procedure adopted for the applied formulation shall be submitted.	Sterilization procedure is carried out through 3 step filtration
9.	**3.2.P.5.1**	• Justification shall be submitted for not including test of Leachables and Net fill weight, with reference to USP general chapter <5>.	• Firm has submitted general "Container qualification studies for LDPE" and "Analytical report for the Leachability testing for plastic packaging" • USP general chapter <1664> recommends testing the final drug product for leachables

10.	**3.2.P.6**	• Date of manufacturing of working standards is subsequent to the date of batch release of drug product. • Justification shall be submitted for use of BP grade working standard of Ipratropium Bromide for analysis of drug product as per USP monograph.	• Not submitted • The testing methods for Ipratropium Bromide raw material are outlined in the British Pharmacopoeia (BP), whereas the testing procedures for the finished drug product are specified in the United States Pharmacopeia (USP). To standardize the working standard for drug product testing, a BP grade reference standard is utilized. The acceptance of both BP and USP standards ensures compatibility and compliance throughout the manufacturing process.
11.	**3.2.P.8.3**	• Justification for not performing tests of "Leachable", "Net fill weight" & "Water Loss" during drug product stability studies, with reference to USP general chapter <5>. • Justification shall be submitted for not performing stability studies as per conditions recommended for semi-permeable containers by ICH Q1 guidelines. • As per submitted analytical record chromatographic conditions and concentration of standard and sample solution applied for the Assay test during stability studies are not as per the recommendations of USP monograph of "Ipratropium Bromide and Albuterol Sulfate Inhalation Solution". Justification shall be submitted in this regard.	• Firm has referred to general report of "Analytical report for the Leachability testing for plastic packaging" while USP general chapter <1664> recommends testing the final drug product for leachables. • Firm has submitted water loss studies performed during stability studies on basis of initial weight of filled ampoules, whereas submitted drug product specifications does not include any limits for filled weight of ampoules. • Kindly note that the stability studies as per guideline of ICH Q1 for semi permeable condition is submitted wherein chromatographic conditions and concentration of standard and sample solution applied for assay test are as per the recommendations of USP monograph of Ipratropium Bromide and Albuterol Sulfate Inhalation Solution.

Decision: Approved. Firm shall submit full fee of registration for revision of stability studies data, before issuance of registration letter.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals Pvt Ltd** **Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**

	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 28769 dated 11-10-2022
	Details of fee submitted	Rs.30,000/- dated 22-09-2022
	The proposed proprietary name / brand name	**Dipof 12/25 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Olanzapine…..12mg Fluoxetine as HCl……25mg
	Pharmacotherapeutic Group of (API)	Fluoxetine HCl: TCA class of Anti-depressants ATC code: N06CA03 Olanzapine: Second generation Antipsychotic ATC code: N05AH03
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Flupine Capsule 12/25mg of Winthrox Labs (Pvt) Ltd
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC^{II}:		
Decision: Approved.		
3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt. Ltd. 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23867 dated 31-08-2021
	Details of fee submitted	Rs.30,000/- dated 07-06-2021
	The proposed proprietary name / brand name	**Mfor-Sita Plus Tablet JPL 50/500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Sitagliptin as Phosphatemonohydrate…50mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Sita-Met tablet of M/s CCL.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC^{II}:		
Decision: Approved		
4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 24076 dated 01-09-2021
	Details of fee submitted	Rs.30,000/- dated 07-06-2021
	The proposed proprietary name / brand name	**Mfor-Sita Plus Tablet JPL 50/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Sitagliptin as Phosphate…50mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Sita-Met tablet of M/s CCL.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's response
1.	Submit valid GMP certificate of Drug substance manufacturer	Submitted
2.	Submit latest GMP inspection report of drug product manufacturer conducted within last three years.	Submitted
3.	Submit drug substance analytical method verification studies performed by drug product manufacturer.	Submitted

Decision: Approved.		
5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 24077 dated 01-09-2021

	Details of fee submitted	Rs.30,000/- dated 07-06-2021
	The proposed proprietary name / brand name	**J-Pride 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Glimepiride…2mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Getryl tablet of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore**
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 24078 dated 01-09-2021
	Details of fee submitted	Rs.30,000/- dated 07-06-2021
	The proposed proprietary name / brand name	**J-Pride 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Glimepiride…4mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Getryl tablet of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14385 dated 08-06-2023
	Details of fee submitted	Rs.30,000/- dated 25-05-2023

	The proposed proprietary name / brand name	**Clindacure 1% Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Clindamycin as Phosphate…10mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Clinagel gel of M/s GSK
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Medicaids Pakistan (pvt) Ltd.** **Plot No 10, Sector-27 Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	**M/s Medicaids Pakistan (pvt) Ltd.** **Plot No 10, Sector-27 Korangi Industrial Area, Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7390 dated 14-03-2023
	Details of fee submitted	Rs.30,000/- dated 23-01-2023
	The proposed proprietary name / brand name	**Kraze 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	A-Mycin Tablets 500 mg of M/s Alen Pharmaceuticals (Pvt.) Ltd
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16409 dated 27-06-2023
	Details of fee submitted	Rs.30,000/- dated 30-03-2023

	The proposed proprietary name / brand name	**Glimpa 5/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals** **Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16408 dated 27-06-2023
	Details of fee submitted	Rs.30,000/- dated 30-03-2023
	The proposed proprietary name / brand name	**Glimpa 5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	
2.	**3.2.S.1.3**	Declaration of solubility of Empagliflozin in water as "practically insoluble" shall be justified with reference to the innovator drug product literature.	
3.	**3.2.S.4**	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer.	
4.	**3.2.P.2.2.1**	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	
5.	**3.2.P.5.3**	Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g.,	

		using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	
6.	**3.2.P.5.4**	Justification shall be submitted for not performing test of "Uniformity of dosage unit" by way of content uniformity.	
7.	**3.2.P.8.3**	• Clearance certificate issued by DRAP I&E office shall be submitted for evidence of import of Empagliflozin issued in name of M/s Weatherfolds form which firm has cited borrowing of API.	

Decision: Registration Board deferred the applications of Glimpa 5/25 mg Tablet & Glimpa 5/10 mg Tablet for submission of reply of above cited shortcomings.

11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd.** **Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14206 dated 07-06-2023
	Details of fee submitted	Rs.30,000/- dated 18-05-2023
	The proposed proprietary name / brand name	**Vonopro 20mg Tablet**
	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd.** **Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14206 dated 07-06-2023
	Details of fee submitted	Rs.30,000/- dated 18-05-2023
	The proposed proprietary name / brand name	**Vonopro 10mg Tablet**

	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	
2.	**3.2.S.1**	Submitted CAS number is not of Vonoprazan fumarate	
3.	**3.2.S.4**	Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.	
4	**3.2.P.5**	• Reference shall be submitted for the adopted dissolution parameters. • Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	
5.	**3.2.P.8.3**	Following shall be submitted: • Document confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted • Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.	

Decision: Registration Board deferred the applications of Vonopro 20mg Tablet & Vonopro 10mg Tablet for submission of reply of above cited shortcomings.

13.	**Name, address of Applcant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9675 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 30-08-2022
	The proposed proprietary name / brand name	**Vocinza 10mg Tablet**

	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited.** **F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9676 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 30-08-2022
	The proposed proprietary name / brand name	**Vocinza 20mg Tablet**
	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.5.2**	Submitted claim shall be elaborated for the dosage form as "film coated", as per innovator drug product along with submission of relevant fee.	
2.	**1.5.6**	Relevant information shall be submitted for the reference of drug product specifications.	
3.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	
6.	**3.2.S.4**	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.	
7.	**3.2.S.4.4**	COA relevant batch of drug substance, used for manufacturing of drug product stability batches, shall be submitted.	
8.	**3.2.P.1**	Justification shall be submitted for not including fumaric acid in the composition of applied product, as used by the innovator drug product.	

9.	**3.2.P.2.2.1**	Justification shall be submitted for not including sampling time point of "15 minutes" in the performance of CDP studies, as recommended by the relevant guidelines.	
10.	**3.2.P.5**	• Reference shall be submitted for the adopted dissolution parameters. • Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	
11.	**3.2.P.8.3**	Following shall be submitted: • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.	

Decision: Registration Board deferred the applications of Vocinza 10mg Tablet & Vocinza 20mg Tablet for submission of reply of above cited shortcomings.

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9824 dated 12-04-2023
	Details of fee submitted	Rs.30,000/- dated 17-03-2023
	The proposed proprietary name / brand name	**Empazin M XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg as Immediate Release Coating Metformin HCl…1000mg as Extended Release Core
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications
16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals.** **Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals.

		Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9825 dated 12-04-2023
	Details of fee submitted	Rs.30,000/- dated 17-03-2023
	The proposed proprietary name / brand name	**Empazin M XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg as Immediate Release Coating Metformin HCl…1000mg as Extended Release Core
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.5.1**	Justification shall be submitted for not including test of content uniformity for Empagliflozin in drug product specifications.	Firm has submitted revised drug product specifications.
2.	**3.2.P.5.3**	Complete analytical method verification studies shall be submitted including details of sample and standard preparation for each parameters along with method of analysis.	Submitted
3.	**3.2.P.8.3**	• Documents confirming procurement of drug substance approved by DRAP I&E Office shall be submitted. • Submit analytical record for the drug product stability studies	Submitted.

Decision: Registration Board approved the applications of Empazin M XR 25/1000 mg Tablet & Empazin M XR 12.5/1000 mg Tablet.

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited. Plot No. 384, Sundar Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. Plot No. 384, Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12722 dated 23-05-2023

	Details of fee submitted	Rs.30,000/- dated 30-03-2023
	The proposed proprietary name / brand name	**Ipratropium Bromide Nebuliser Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Single 2ml Unit Dose Vial Contains: Ipratropium Bromide…500mcg
	Pharmacotherapeutic Group of (API)	Anticholinergics
	The status in reference regulatory authorities	Approved by HPRA of Ireland
	For generic drugs (me-too status)	Atem Nebuliser Solution of M/s Cheisi
	Proposed Pack size & Price	5 vials x 2ml: As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3**	Clarification shall be submitted regarding the section in which applied formulation will be manufactured.	Firm has referred to the letter dated 24-06-2019, issued by Secretary CLB, declaring issuance of DML for following sections: • LVP (General section • SVP (General) section • Ophthalmic (General) section
4.	**3.2.P.8.3**	Following shall be submitted: • Documents confirming procurement of drug substance approved by DRAP I&E Office shall be submitted. • Stability study data of 6th month time point.	• Firm ha submitted commercial invoice for Ipratropium bromide dated 15-09-22. • 6th month stability data submitted.

Decision: Approved.

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13646 dated 01-06-2023
	Details of fee submitted	Rs.75,000/- dated 20-02-2023
	The proposed proprietary name / brand name	**Ertulix-S 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. To Ertugliflozin…5mg Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…100mg
	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor

	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 12721 dated 23-05-2023
	Details of fee submitted	Rs.75,000/- dated 21-02-2023
	The proposed proprietary name / brand name	**Ertulix-S 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. To Ertugliflozin…15mg Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…100mg
	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	Submitted
2.	**3.2.S.4**	• Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product. • Drug substance analytical method verification studies shall be submitted from drug product manufacturer. • COA of Ertugliflozin-LGA, from M/s Helix does not include performance of test of "LPGA content". Justification shall be submitted in this regard. • As per submitted analytical record of drug substance analysis of Ertugliflozin-LPGA, it is evident that the chromatographic conditions declared in drug substance analytical method	

		submitted in section 3.2.S3, have not been followed. Justification shall be submitted in this regard.	
3.	**3.2.S.5**	• The submitted Drug substance analytical procedure recommends the use of working standard of "Ertugliflozin L-pyrogulatmic acid" for Assay & related substances test, whereas the COA of working standard of "Ertugliflozin" has been submitted. • Submitted COA of Ertugliflozin declares that "it complies with USP specifications", while no USP monograph is available for Ertugliflozin. Justification shall be submitted in this regard.	
4.	**3.2.S.7.3**	Long term stability conditions on the submitted stability report of Sitagliptin Phosphate appears to be overwritten/modified. Clarification shall be submitted from drug substance manufacturer regarding the conditions on which stability studies have been performed.	
5.	**3.2.P.3.3**	Dispensed quantity of Ertugliflozin-LPGA in trial batch manufacturing shall be justified against the label claim for Ertugliflozin.	
6.	**3.2.P.6**	COA of reference standard/working standard used for analysis of drug product stability studies, shall be submitted.	
7.	**3.2.P.8.3**	• Justification shall be submitted for the potency of working standard applied for calculation of Assay results of drug substance during stability studies, considering the values of potency reported in the COA of working standard. • Documents confirming procurement of drug substance shall be submitted.	

Decision: Registration Board deferred the applications of Ertulix-S 5/100 mg Tablet & Ertulix-S 15/100 mg Tablet for submission of rely of above cited shortcomings.

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd.** **Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6026 dated 03-03-2023
	Details of fee submitted	Rs.30,000/- dated 16-02-2023
	The proposed proprietary name / brand name	**Sacupro 24/26 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg (As Sacubitril Valsartan sodium salt complex)

	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech Pvt. Ltd.** **Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech Pvt. Ltd. Plot No. FD-49-A8 ,FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6027 dated 03-03-2023
	Details of fee submitted	Rs.30,000/- dated 16-02-2023
	The proposed proprietary name / brand name	**Sacupro 49/51 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg (As Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.S.4**	➢ Drug substance manufacturer has not included test of Sodium content in the drug substance specifications. Justification shall be submitted din this regard. ➢ Justification shall be submitted for not including the following tests in drug substance specifications as recommended by innovator product literature: • Assay of Co-crystal. • Calcium and Chloride content. ➢ Justification shall be submitted for variation in analytical method for Assay test from that proposed by the drug substance manufacturer. ➢ Analytical method for the Assay test of Co-crystal complex shall be submitted. ➢ Analytical method verification studies shall be submitted from M.s Pinnacle Biotech.	

2.	**3.2.S.5**	➢ Justification shall be submitted for applying Co-crystal complex as reference standard instead of the individual drug components.	
3.	**3.2.P.2.2.1**	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	
4.	**3.2.P.5.2**	Justification shall be submitted for variation in dissolution parameters i.e., apparatus, rpm and time limit from that recommended by innovator drug product literature.	
5.	**1.6.5**	• Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	
6.	**3.2.P.8.3**	• Stability studies data of 6th month time point shall be submitted. • Justification shall be submitted for the potency of working standard applied for calculation of Assay results of drug substance during stability studies, considering the values of "Water content" and "Sodium content" reported in the COA of working standard. • Documents confirming procurement of drug substance shall be submitted.	
7.	**3.2.R.1**	• Complete batch manufacturing record of drug product stability batches shall be submitted.	

Decision: Registration Board deferred the applications of Sacupro 24/26 mg Tablet & Sacupro 49/51 mg Tablet for submission of reply of above cited shortcomings.

22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 10767 dated 28-04-2023
	Details of fee submitted	Rs.30,000/- dated 06-03-2023
	The proposed proprietary name / brand name	**Iyal 0.2% Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Sodium hyaluronate…2mg
	Pharmacotherapeutic Group of (API)	Anionic, non-sulfated glycosaminoglycan
	The status in reference regulatory authorities	Hylo-Forte Approved by TGA of Australia (Approved aa medical device)
	For generic drugs (me-too status)	Hylo 0.2% of M/ Helix Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.5.9**	Evidence of approval of applied formulation as drug in any of the reference regulatory authority adopted by Registration Board in its 275th meeting, shall be submitted since submitted reference product has been approved by TGA Australia, as Medical device.	Firm has referred to Hylo-Forte manufactured by Ursapharm Germany, but the reference could not be verified form the official website.
2.	**3.2.P.8.3**	• Stability studies data of 6th month time point.	Submitted.

Decision: Approved.

23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 8492 dated 28-03-2023
	Details of fee submitted	Rs.75,000/- dated 13-02-2023
	The proposed proprietary name / brand name	**Vonapp-A 100/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Aspirin…100mg Vonoprazan as Fumarate…10mg
	Pharmacotherapeutic Group of (API)	Analgesic/proton pump inhibitor
	The status in reference regulatory authorities	Approved by PMDA of Japan
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	• Valid DML/GMP certificate of the drug substance manufacturer of Aspirin shall be submitted.	Submitted
2.	**3.2.P.8.3**	• Stability studies data of 6th month time point.	Submitted

Decision: Approved.

24.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road,

		Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 9673 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 04-04-2023
	The proposed proprietary name / brand name	**Linkotrex 250mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Lincomycin HCl Monohydrate Eq. to Lincomycin…….250mg
	Pharmacotherapeutic Group of (API)	Antibiotics
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Limera syrup of M/s Helix Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	• Relevant information shall be submitted. • Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
2.	**3.2.S.4.1**	• Limits for Assay test shall be elaborated as per BP monograph. • Standard preparation given in Assay method submitted by M/s Wimits Pharmaceuticals is different from that recommended by BP monograph	Firm has submitted revised analytical procedure as per BP monograph.
3.	**3.2.P.5.2**	Submitted analytical method does not include the details of the calculation formula for the results of Assay test.	Revised analytical procedure submitted.

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

25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14718 dated 12-06-2023
	Details of fee submitted	Rs.30,000/- dated 06-04-2023
	The proposed proprietary name / brand name	**Dibian-Met 5/500 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14711 dated 12-06-2023
	Details of fee submitted	Rs.30,000/- dated 06-04-2023
	The proposed proprietary name / brand name	**Dibian-Met 5/100 mg Tablet**
	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)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
2.	**3.2.S.1.3**	Declaration of solubility of Empagliflozin in water as "practically insoluble" shall be justified with reference to the innovator drug product literature.	Firm has submitted a "Statement letter" from M/s Fuxin Long Rui as under: "We Fuxin Long Rui Pharmaceutical Co., Ltd. (123000, Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province, China) guarantee that Empagliflozin has a certain degree of hydrophobicity, and its solubility in water and buffer solution is relatively small. During the

			dissolution process, particle aggregation is prone to occur, which further prolongs the dissolution time of the sample, reduces solubility, and causes the detection results to fluctuate at the edge of the limit. Therefore, the limit was slightly relaxed at that time. Later, during the testing process, we paid attention to removing agglomerated particles from the sample, ensuring that the solubility limit of the sample in water was consistent with the innovator drug product literature. At present, the COA specification for the product has been revised, but DMF has not been updated in a timely manner, resulting in inconsistency between the both. We will submit the updated files immediately."

Decision: Registration Board approved the applications of Dibian-Met 5/500 mg Tablet & Dibian-Met 5/100 mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

27.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13517 dated 31-05-2023
	Details of fee submitted	Rs.75,000/- dated 26-04-2023
	The proposed proprietary name / brand name	**Emel 10/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin……10mg Linagliptin……5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**

	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13516 dated 31-05-2023
	Details of fee submitted	Rs.75,000/- dated 26-04-2023
	The proposed proprietary name / brand name	**Emel 25/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin……25mg Linagliptin……5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
2.	**3.2.S.4.4**	Submitted COA of Linagliptin from both drug product and drug substance manufacturer does not confirm "Enantiomeric purity". Justification shall be submitted in this regard.	Firm has submitted COA of Linagliptin from drug substance manufacturer declaring test of S-enantiomer.
3.	**3.2.P.8.3**	• Clearance certificate issued by DRAP I&E office shall be submitted for evidence of import of Linagliptin.	Firm has submitted license to import Linagliptin , issued by DRAP I&E office dated 26-05-2022.

Decision: Registration Board approved the applications of Emel 10/5 mg Tablet & Emel 25/5 mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5910 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 30-11-2022

	The proposed proprietary name / brand name	**L-Empamet XR 12.5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg (as immediate release layer) Linagliptin…2.5mg (as immediate release layer) Metformin HCl …1000mg (as extended Release core)
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.1**	Differential fee of Rs. 45,000/- shall be submitted since applied formulation has yet not been registered in Pakistan	Submitted
2.	**3.2.S.5**	COA of reference/working standards used for analysis of drug substance by Ms Bio-Mark shall be submitted.	Submitted
3.	**3.2.P.2.2.1**	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	Firm has submitted Pharmaceutical equivalence and CDP studies against the reference product.
4.	**3.2.P.5.3**	Specificity of UV spectrophotometric method of Dissolution test for Metformin HCl shall be established with respect to the absorbance of Empagliflozin & Linagliptin in the sample solution.	Submitted

Decision: Approved.

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals.** **Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14714 dated 12-06-2023
	Details of fee submitted	Rs.30,000/- dated 02-06-2023
	The proposed proprietary name / brand name	**Empaglif-M 12.5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:**

		Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met tablet of M/s Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted.
2.	**3.2.P.8.3**	Documents confirming import of drug substance attested by DRAP I&E office shall be submitted.	Submitted.

Decision: Approved.

31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited.** **Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7393 dated 14-03-2023
	Details of fee submitted	Rs.30,000/- dated 01-03-2023
	The proposed proprietary name / brand name	**Vono 10mg Tablet**
	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
32.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited.** **Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7394 dated 14-03-2023
	Details of fee submitted	Rs.30,000/- dated 01-03-2023
	The proposed proprietary name / brand name	**Vono 20mg Tablet**
	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)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.S.4**	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer.	Submitted
2.	**3.2.S.4.4**	Name of drug substance manufacturer declared on COA from M.s PharmEvo is different form that declared in section 1.6.5 & 3.2.S.2.1	There was a typographical error in the name of the API Manufacturer in the COA of PharmEvo. Revised COA submitted
3.	**3.2.S.5**	COA of reference/working standard used for analysis of drug substances by M/s PharmEvo shall be submitted.	Submitted
4.	**3.2.S.7.3**	Long term stability studies data shall be submitted as per Zone IV conditions till claimed shelf life.	Submitted

Decision: Registration Board approved the applications of Vono 10mg Tablet & Vono 20mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13520 dated 31-05-2023
	Details of fee submitted	Rs.30,000/- dated 24-02-2023
	The proposed proprietary name / brand name	**Glulina-E 5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…10mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.

		A10BD19
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.P.8.3**	Documents confirming import of drug substance shall be submitted.	Submitted.
2.	**2.3.R**	Complete batch manufacturing record of drug product stability batches shall be submitted.	Submitted.

Decision: Approved.

34.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuticals.** **Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13529 dated 31-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-05-2023
	The proposed proprietary name / brand name	**Dia-EL 5/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…25mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD19
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals
35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuticals.** **Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13530 dated 31-05-2023
	Details of fee submitted	Rs.30,000/- dated 10-05-2023
	The proposed proprietary name / brand name	**Dia-EL 5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…10mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD19
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of Linagliptin shall be submitted.	Submitted
2.	**2.3.R**	Complete batch manufacturing record of drug product stability batches shall be submitted.	Submitted

Decision: Registration Board approved the applications of Dia-EL 5/25 mg Tablet & Dia-EL 5/10 mg Tablet.

36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6368 dated 06-03-2023
	Details of fee submitted	Rs.30,000/- dated 13-12-2022
	The proposed proprietary name / brand name	**Empac-M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin……12.5mg Metformin HCl……500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	In-house specs

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA Approved.
37.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6366 dated 06-03-2023
	Details of fee submitted	Rs.30,000/- dated 13-12-2022
	The proposed proprietary name / brand name	**Empac-M 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin……5mg Metformin HCl……500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	In-house specs
38.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6367 dated 06-03-2023
	Details of fee submitted	Rs.30,000/- dated 13-12-2022
	The proposed proprietary name / brand name	**Empac-M 5/850 mg Tablet**
	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)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	In-house specs
Evaluation by PEC[II]:		

Sr.#	Section#	Observation	Firm's response
1.	**1.3.4**	Latest GMP inspection report of the drug product manufacturer, conducted within last three years shall be submitted,	
2.	**1.5.2**	Strength of each drug substance shall be specified.	
3.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	
4.	**3.2.S.1.3**	Declaration of solubility of Empagliflozin in water as "Freely soluble" shall be justified with reference to the innovator drug product literature.	
5.	**3.2.S.4.4**	Submit drug substance specifications, analytical procedure and analytical method verification studies from the drug product manufacturer.	
6.	**3.2.S.5**	COA of reference/working standard used for analysis of drug substances by M/s Le Mendoza shall be submitted.	
7.	**3.2.S.7.3**	• Drug substance stability studies shall be signed and stamped from the drug substance manufacturer. • Limits for assay test of Empagliflozin are different between submitted stability studies and COA.	
8.	**3.2.P.2.2.1**	• Result of comparative dissolution profile studies for each drug substance shall be declared separately. • Submitted results of comparative dissolution profile shall be justified against the solubility profile of applied formulation in the innovator drug product literature. • Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	
9.	**3.2.P.3.5**	Submitted process validation protocol does not include details for coating stage. Submitted process validation protocol does not include dissolution test	
10.	**3.2.P.5.1**	Justification shall be submitted for not including test of content uniformity for Empagliflozin in drug product specifications.	
11.	**3.2.P.5.2**	• Justification shall be submitted for adopting different dissolution parameter for Empagliflozin from that recommended by innovator drug product. • Justification shall be submitted for adopting different dissolution parameter for Metformin from that recommended by innovator drug product. • Justification shall be submitted for performing Dissolution test separately for each drug substance whereas innovator drug product literature has recommended simultaneous analysis of dissolution of both drug substances.	

	12.	**3.2.P.5.3**	• Complete analytical method validation studies including parameters of specificity, linearity, precision and robustness shall be submitted. • Specificity of UV spectrophotometric method of Dissolution test for Metformin HCl shall be established with respect to the absorbance of Empagliflozin in the sample solution.	
	13.	**3.2.P.6**	COA of reference/working standard used for analysis of drug product stability batches by M/s Le Mendoza shall be submitted.	
	14.	**3.2.P.8.3**	Following shall be submitted: • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Compete batch manufacturing record of stability batches. • System generated chromatograms and spectrums since submitted chromatograms are extracted images wherein neither time of analysis nor the wavelength applied for analysis is revealed.	

Decision: Registration Board deferred the applications of Empac-M 12.5/500 mg Tablet, Empac-M 5/500 mg Tablet & Empac-M 5/850 mg Tablet for submission of reply to above cited shortcomings.

39.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5907 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 25/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03

	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6411 dated 07-03-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 10/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…10mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met XR Tab of M/s Hilton Pharma Pvt Ltd
41.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7388 dated 14-03-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 12.5/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg

	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
42.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals.** **5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5908 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 10-01-2023
	The proposed proprietary name / brand name	**Voreta Plus XR Tablet 5/1000 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
Evaluation by PEC[II]:		
Decision: Registration Board approved the applications of Voreta Plus XR Tablet 25/1000 mg, Voreta Plus XR Tablet 10/1000 mg, Voreta Plus XR Tablet 10/1000 mg & Voreta Plus XR Tablet 12.5/1000 mg.		
43.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Highnoon Laboratories Ltd.** **17.5 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7170 dated 13-03-2023
	Details of fee submitted	Rs.30,000/- dated 17-02-2023
	The proposed proprietary name / brand name	**Emplina 5/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…25mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD19

	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals
44.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7169 dated 13-03-2023
	Details of fee submitted	Rs.30,000/- dated 17-02-2023
	The proposed proprietary name / brand name	**Emplina 5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…10mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD19
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	Empagliflozin is slightly soluble in water as per literature US FDA and EMA, there was an error in DMF from drug substance manufacturer. Corrected section of DMF is submitted.

Decision: Registration Board approved the applications of Emplina 5/25 mg Tablet & Emplina 5/10 mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

45.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9202 dated 05-04-2023
	Details of fee submitted	Rs.30,000/- dated 19-12-2022
	The proposed proprietary name / brand name	**Empaglif-M 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……..…. 12.5mg Metformin HCl …...1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	**Brand Name:** Xenglu-Met Tab of M/s Hilton Pharma Pvt Ltd
46.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5903 dated 02-03-2023
	Details of fee submitted	Rs.30,000/- dated 19-12-2022
	The proposed proprietary name / brand name	**Empaglif-M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. …. 12.5mg Metformin HCl…...500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs
47.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dyson Research Laboratories Pvt. Ltd. 28 km Ferozepur Road Lahore**
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt. Ltd. 28 km Ferozepur Road Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5807 dated 01-03-2023
	Details of fee submitted	Rs.30,000/- dated 19-12-2022
	The proposed proprietary name / brand name	**Empaglif-M 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin ……. …. 5mg Metformin HCl…...500mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	Reference to Finished product specifications	Innovator's Specs

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.3.4**	➢ Latest GMP inspection report of the drug product manufacturer, conducted within last three years shall be submitted,	Copy of inspection report dated 03-11-2022 concludes satisfactory level of compliance.
2.	**1.6.5**	➢ Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl shall be submitted.	Submitted
3.	**3.2.S.1.3**	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	The solubility of Empagliflozin is practically insoluble in water as per manufacturer`s certificate of analysis. Moreover, we comply with manufacture's certificate of analysis (COA). The Board was intimated regarding the declaration from drug substance manufacturer of Empagliflozin in other cases regarding solubility profile submitted
4.	**3.2.S.4**	➢ Submit drug substance analytical procedure of Empagliflozin from drug substance manufacturer. ➢ Justification shall be submitted for declaring specifications of Metformin HCl as " In-House" in section 3.2.S.4.1	Submitted. Metformin HCl is already verified on HPLC as per United States Pharmacopeia (USP) monograph. Moreover, specifications, analytical method and analytical method verification (AMV) I submitted.
5.	**3.2.P.3.2**	Innovator drug product literature states as under: "To combine the low amount of Empagliflozin with the relatively high quantity of metformin hydrochloride, a	To combine the low amount of Empagliflozin with relatively high quantity of Metformin HCl geometric mixing of Empagliflozin with Metformin

			wet granulation process with granulation liquid containing Empagliflozin was chosen." • In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozin with binder solution. Justification shall be submitted in this regard.	HCl is performed to ensure the homogeneous mixing of Empagliflozin. Moreover, we commit that manufacturing of commercial batches are according to innovator and submit stability data to Drug Regulatory Authority of Pakistan (DRAP) after charged on stability.
		3.2.P.5.2	• Justification shall be submitted for adopting UV Spectrophotometric method for Assay test of Metformin HCl in drug product.	We have validated the drug product method for both API`s as per ICH Q2R1 Guidelines i.e. Empagliflozin by HPLC Metformin HCl by UV We have performed specificity parameter by making placebo and there is no interference observed during method Validation. Empagliflozin is not detectable due to its lowest concentration (0.05ppm) with respect to Metformin HCl (10ppm), that`s why Metformin HCl determination is on UV.

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

48.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 2609 dated 27-01-2023
	Details of fee submitted	Rs.75,000/- dated 08-12-2022
	The proposed proprietary name / brand name	**Trivesta-M XR 10/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)……10mg Linagliptin (Immediate Release)…….5mg Metformin HCl (Extended Release)……1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specifications
49.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**

	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 2610 dated 27-01-2023
	Details of fee submitted	Rs.75,000/- dated 08-12-2022
	The proposed proprietary name / brand name	**Trivesta-M XR 25/5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)……25mg Linagliptin (Immediate Release)…….5mg Metformin HCl (Extended Release)……1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specifications
50.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 2608 dated 27-01-2023
	Details of fee submitted	Rs.75,000/- dated 08-12-2022
	The proposed proprietary name / brand name	**Trivesta-M XR 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Empagliflozin (Immediate Release)……5mg Linagliptin (Immediate Release)…….2.5mg Metformin HCl (Extended Release)……1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specifications
51.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Wilshire Laboratories Private Limited 124/1 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 2386 dated 25-01-2023
	Details of fee submitted	Rs.75,000/- dated 08-12-2022
	The proposed proprietary name / brand name	**Trivesta-M XR 12.5/2.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Empagliflozin (Immediate Release) …. 12.5mg Linagliptin (Immediate Release) ...…… 2.5mg Metformin HCl (Extended Release) ….1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specifications

Evaluation by PEC[II]:

Section#	Observations	Firm's response
1.6.5	Copy of Valid GMP certificate for M/s Fuxin Long Rui, issued by relevant regulatory authority shall be submitted.	Submitted
3.2.S.4	Copies of the Drug substance specifications and analytical procedures & analytical method verification studies used for routine testing of the Drug substance /Active Pharmaceutical Ingredients by Drug Product manufacturer is required.	Submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Justification shall be submitted for the proposed limits of "NMT 1.0%" for the test of "Enantiomer content (S-Isomer content) in Linagliptin by the drug substance manufacturer. • As per innovator drug product literature review the "S-isomer" is controlled as an impurity. While referring to the declared limit from drug substance manufacturer for "S-Isomer", the limit for the "Total impurities" as "NMT 1.0%" shall be justified.	• Submitted • The limit of Total impurities is NMT 1.0% mentioned on COA of drug substance manufacturer and same is given in the testing method.
3.2.P.1	• Justification shall be submitted for proposed Quantity/tablet of Empagliflozin and Linagliptin against the label claim.	• Our product is designed and developed as per innovator in which two mentioned APIs (Empagliflozin and Linagliptin) are incorporated in the coating stage on

		the extended released core of Metformin HCl. As in the case of coating process there was process related loss was observed which was estimated to round about 8% to 10% during developmental stage. When the trials were concluded with 10% excess the shared Stability batches were manufactured and stability studies conducted as per shared record.
3.2.P.2	• Justification shall be submitted for not performing tests of water content, uniformity of content, microbial purity and arginine content in Pharmaceutical equivalence studies as recommended by the innovator product literature review from reference regulatory authorities. • Details shall be submitted for the dissolution parameters applied for the performance of CDP studies. • Complete analytical record shall be submitted for the performance of the Pharmaceutical equivalence & CDP studies.	• As per the testing method and COAs of Drug Product uniformity of dosage unit has been conducted by Content Uniformity (CU) method for Linagliptin and Empagliflozin and by weight variation for Metformin HCl.
3.2.P.3.4	• In contrary to the recommendations of innovator product literature, "particle size" of Empagliflozin & Linagliptin has not been identified as Critical Quality Attribute.	• Due to non-availability of Particle size analyzer, particle size is not identified in Critical Quality attribute during development. But as the formulation was based exactly as per recommendation of USFDA the dissolution specifications has been adequately attained with the provided APIs.
3.2.P.5.3	• Concentrations (in mg/ml) applied for the performance of Linearity and Accuracy parameter shall be justified against the standard and sample concentrations of each drug substance declared in the drug product analytical procedure for Assay test. • Limits of 90-110% for the performance of accuracy parameter shall be justified.	• Submitted. • There was a typographic error in the report of testing Method validation & the revised corrected report is being submitted
3.2.P.5.4	The copies of complete analysis of trial batches shall be provided.	Submitted
3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
3.2.P.8.3	• Complete raw data sheets for the performance of Assay & Dissolution test during stability studies shall be submitted, wherein	Submitted

	details of standard weight, sample weight, dilution preparation and calculation formula applied for the results shall have been included. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
2.3.R	• Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation. • Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin & Linagliptin at in process stage of active coating. • Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin and Linagliptin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing. • Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.	• In case of Metformin HCl to be coated with APIs it is more preferable to seal coat the metformin HCl core tablet to protect during the long run of two APIs coating plus and upper color coating layer. Otherwise breakage of edges may be resulted. To avoid this situation seal coating is incorporated. • As the in-process testing and formulation locking was done during initial trial developmental stage then on the basis of passed trials these shared stability batches were manufactured therefore at these stability trial batch this in-process testing of API coating was not performed.

Decision: Registration Board approved the applications of Trivesta-M XR 10/5/1000 mg Tablet, Trivesta-M XR 25/5/1000 mg Tablet, Trivesta-M XR 5/2.5/1000 mg Tablet & Trivesta-M XR 12.5/2.5/1000mg Tablet. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

Case no.: 01 Applications of new DML/section

CLB in its 292nd meeting held on 04-10-2023 approved the "Ear/Eye drops-II (general) section" in name of M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan

52.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25893 dated 26-10-2023
	Details of fee submitted	Rs.75,000/- dated 16-10-2023

	The proposed proprietary name / brand name	**Rabedo 2% Opthalmic Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Opthalmic Suspension Contains: Rebamipide…20mg
	Pharmacotherapeutic Group of (API)	Enhances the production of mucin A02BX14
	The status in reference regulatory authorities	Mucosta approved by PMDA of Japan
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC[II]:		
Decision: Approved.		
53.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25894 dated 26-10-2023
	Details of fee submitted	Rs.75,000/- dated 16-10-2023
	The proposed proprietary name / brand name	**Ibrom 0.09% Opthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Bromfenac Sodium Hydrate Eq. to Bromfenac…0.9mg
	Pharmacotherapeutic Group of (API)	Nonsteroidal anti-inflammatory drugs (NSAIDs).
	The status in reference regulatory authorities	XIBROM approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC[II]:		
Decision: Approved.		
54.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21900 dated 05-09-2023
	Details of fee submitted	Rs.75,000/- dated 22-06-2023
	The proposed proprietary name / brand name	**Vyzulto 0.024% w/v Opthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Latanoprostene Bunod…0.24mg

	Pharmacotherapeutic Group of (API)	Prostaglandin F receptor agonist, Antiglaucoma.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC[II]:		
Decision: Approved.		

CLB in its 292nd meeting held on 04-10-2023 approved the "Dry powder for inhalation section" in name of M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan

55.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 24784 dated 11-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-08-2023
	The proposed proprietary name / brand name	**Tropeez 18mcg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: 22.5mcg of Tiotropium Bromide Monohydrate Eq. to Tiotropium……18mcg The delivered dose (the dose that leaves the mouthpiece of the device) is 10 microgram tiotropium per actuation
	Pharmacotherapeutic Group of (API)	Anticholinergics
	The status in reference regulatory authorities	Approved by HPRA of Ireland
	For generic drugs (me-too status)	
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC[II]:		
Decision: Approved.		

Case no.: 02 Deferred cases

56.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seatle Pvt Ltd. 45 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 33020 dated 17-11-2022
	Details of fee submitted	Rs.75,000/- dated 12-10-2022
	The proposed proprietary name / brand name	**Tamdow-S 6/0.4 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vesomni Tablet by M/s Astellas Pharma Ltd., EMA Approved.
	For generic drugs (me-too status)	Tamsolin -S by M/s Getz Pharma
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 04- 01-2022.
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt. Ltd Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Solifenacin Succinate & Tamsulosin HCl is not present in Pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6

		months Tamsulosin HCL Batches: (8000173-039(A), 8000173-045(A), 8000173-046(A)) Solifenacin Succinate Batches: (8000173-039(B), 8000173-045(B), 8000173-046(B))
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence and CDP Studies data in three dissolution mediums of pH 1.2, 4.5 & 6.8 has been submitted against the Tamsolin-S tablet pf M/s Getz Pharma
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd. Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India		
API Lot No.	Tamsulosin HCl: AT0018-002 Solifenacin Succinate: AT0019-003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21L133	21M294	--
Batch Size	110,000 tab	110,000 tab	--
Manufacturing Date	11-2021	12-2021	--
Date of Initiation	29-12-2021	20-01-2022	--
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision of 336th meeting: Deferred for submission of reply to below cited shortcomings, to which firm has replied detailed as under:

Remarks of Evaluator(Ammar):

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosine HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	• Polyethylene oxide is being used by API to provide modified drug release • Since, pellets are semifinished dosage form therefore the dissolution has not been performed however it has been done only in finished product. • Revised COAs submitted. • As per drug substance manufacturer; "Since we are supplying semi-finished material to customer to make the further process, and release pattern will only be proven once it is converted in to finished dosage form. Hence, we have not mentioned in any of our document" In USP, *Granules are often the precursors used in tablet compression or capsule filling. Although this application represents a pharmaceutical intermediate and not a final dosage form.*
3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	As per innovator; Vesomni 6 mg/0.4 mg modified release tablets Each tablet contains 6 mg Solifenacin succinate and 0.4 mg Tamsulosin hydrochloride corresponding to 4.5 mg Solifenacin and

		0.37mg Tamsulosin respectively. We have mentioned above statement of innovator as; Each bilayer modified release tablet contains: Tamsulosin HCl …….. 0.4mg (Corresponding to 0.37mg of Tamsulosin base) Solifenacin Succinate……6.0mg (Corresponding to 4.5mg of Solifenacin base) (As per Innovator's specifications)
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	• In CDP, release above 85% was achieved at 12th Hour, i-e ranges 93% to 100% in all the three mediums for Tamsulosin HCl therefore next time points were skipped.
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	As per USP general Chapter <1092>: "For immediate-release capsule or tablet formulations, Apparatus 1 (Baskets) at 50-100rpm or Apparatus 2 (paddles) at 50 or 75 rpm are used commonly. Other agitation speeds are acceptable with appropriate justification. If justified, 100 rpm may be used with Apparatus 2, especially for extended release dosage forms". In reference, Tamsulosin HCl capsules USP monograph is using Apparatus II with 100 rpm. So we also adopted the said condition during dissolution development studies.
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	Submitted
	• Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	During drug substance analysis, Assay results were found above 100% therefore dispensed quantity for both API's is 100%. In case of potency below 100%, dispensed quantity of API is adjusted to ensure complete delivery of dose to patients.

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

57.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission	Dy.No 14530 dated 09-06-2023
	Details of fee submitted	Rs.225,000/- dated 21-03-2023
	The proposed proprietary name / brand name	**UFI-S 6/0.4 mmg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers
	Reference to Finished product specifications	Innovator

Decision of 336th meeting: Deferred for submission of reply to below cited shortcomings, to which firm has replied detailed as under:

Remarks of Evaluator(Ammar):

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosine HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	• Polyethylene oxide is being used by API to provide modified drug release • Since, pellets are semifinished dosage form therefore the dissolution has not been performed however it has been done only in finished product. • Revised COAs submitted. • As per drug substance manufacturer; "Since we are supplying semi-finished material to customer to make the further process, and release pattern will only be proven once it is converted in to finished dosage form. Hence, we have not mentioned in any of our document" In USP, *Granules are often the precursors used in tablet*

		compression or capsule filling. Although this application represents a pharmaceutical intermediate and not a final dosage form.
3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	As per innovator; Vesomni 6 mg/0.4 mg modified release tablets Each tablet contains 6 mg Solifenacin succinate and 0.4 mg Tamsulosin hydrochloride corresponding to 4.5 mg Solifenacin and 0.37mg Tamsulosin respectively. We have mentioned above statement of innovator as; Each bilayer modified release tablet contains: Tamsulosin HCl …….. 0.4mg (Corresponding to 0.37mg of Tamsulosin base) Solifenacin Succinate……6.0mg (Corresponding to 4.5mg of Solifenacin base) (As per Innovator's specifications)
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	• In CDP, release above 85% was achieved at 12th Hour, i-e ranges 93% to 100% in all the three mediums for Tamsulosin HCl therefore next time points were skipped.
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	As per USP general Chapter <1092>: "For immediate-release capsule or tablet formulations, Apparatus 1 (Baskets) at 50-100rpm or Apparatus 2 (paddles) at 50 or 75 rpm are used commonly. Other agitation speeds are acceptable with appropriate justification. If justified, 100 rpm may be used with Apparatus 2, especially for extended release dosage forms". In reference, Tamsulosin HCl capsules USP monograph is using Apparatus II with 100 rpm. So we also adopted the said condition during dissolution

		development studies.
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	Submitted
	• Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	During drug substance analysis, Assay results were found above 100% therefore dispensed quantity for both API's is 100%. In case of potency below 100%, dispensed quantity of API is adjusted to ensure complete delivery of dose to patients.

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

58.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020.
	Evidence of approval of manufacturing facility	Copy of GMP certificate issued on the basis of inspection conducted on 04-02-2020 declares availability of Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Dy. No. and date of submission & Details of fee submitted	Dy.No 23832 dated 23-08-2022 Rs.30,000/- dated 20-06-2022
	The proposed proprietary name / brand name	**Jargin Duo 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl …..500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trijardy by Boehringer Ingelheim Pharmaceuticals, Inc. is USFDA Approved.
	For generic drugs (me-too status)	Diampa-M 5/500 of M/s Getz pharma
	Name and address of API manufacturer.	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India.

		Empagliflozin M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module-III Drug Substance:	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Submitted for both drug substances as per Zone IV conditions
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established against the Diampa-M 12.55/500 of M/s Getz pharma along with CDP studies wherein values f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Metformin Hydrochloride** M/s Aarti Drugs Limited, Plot no. 211-213, Road no. 2, G.I.D.C., Sarigam Valsad, Gujarat India. **Empagliflozin** M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No. 15, Donghai 5th Avenue, Zhejiang Provinceal Chemical and medical Rw Materials Base Linhai Zone, Taizhou City, Zhejiang province, China.
API Lot No.	Metformin Hydrochloride: MEF/11020485
Description of Pack (Container closure system)	Alu Alu Blisters with aluminum foil
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	EGMF-12.5/500/T001	EGMF-12.5/500/T002	EGMF-12.5/500/T003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	10/2021	11/2021	11/2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of Evaluator:

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

Firm's response:

Section #	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of drug substance manufacturers, issued by relevant regulatory authority of country of origin.	Valid GMP certificate till 20-06-2026 issued by Food & Drugs Control Administration Gujarat, India has been submitted.
3.2.S.1.3	Justify the declaration of solubility of Empagliflozin as "Practically insoluble in water" with reference to the innovator drug product literature	It is a typographic error, Empagliflozin is slightly soluble in water.
3.2.S.4.1	Justify the variation in drug substance specifications between drug substance manufacturer and M/s Pharmedic laboratories for Empagliflozin	Firm has submitted revised drug substance specifications.
3.2.S.4.3	Analytical method verification studies of drug substances shall be submitted from M/s Pharmedic laboratories.	Submitted
3.2.S.4.4	• Submit COA of relevant batch of Metformin HCl & Empagliflozin used for preparation for	Firm has submitted COA of relevant batch drug substance. The submitted invoice

	drug product trial batches, from drug substance manufacturer. • Submitted COA of Empagliflozin form M./s Pharmedic Laboratories declare drug substance manufacturer as M/s Shanghai YST Pharma Co. Ltd, China whereas 3.2.S part has been submitted from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Justification shall be submitted in this regard.	attested by AD I&E Lahore dated 24-06-2021 is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd
3.2.S.7.3	Long term stability studies data of Empagliflozin shall be submitted till claimed shelf life as per Zone IV conditions.	Submitted
3.2.P.5.1	Justification shall be submitted for dissolution limits of 30 minutes with reference to the innovator drug product literature.	Firm has submitted revised drug product specifications.
3.2.P.5.4	Justification shall be submitted for not performing "Uniformity of Dosage Unit" test by way of "Content Uniformity" for Empagliflozin.	Firm has ubsmitted revised raw data sheets with performance of content uniformity test.
3.2.P.8.3	Submit following: • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of comemrial invoice no. YST21121 attested by AD I&E DRAP, Lahore dated 24-06-2021 for 181gm of Empagliflozin. The invoice is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. Data logger record submitted.

Decision of 336th meeting: Deferred for clarification regarding manufacturer of drug substance used for manufacturing of drug product stability batches since submitted copy of commercial invoice is from M/s Shanghai YST Pharma Co. Ltd, China while the COA of drug substance is from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd.

Firm's response: M/s Shanghai YST Pharma Co. Ltd, is importer of Zhejiang Tianyu Pharm. DMF is from Zheijinag Tianyu Pharm. Co., LTD

Decision: Approved.

59.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi-75700**
	Name, address of Manufacturing site.	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25272 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 17-08-2023
	The proposed proprietary name / brand name	**Vacutec 24/26mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril……..24.3mg Valsartan……..25.7mg

		(as Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Neprilysin Inhibitor (ARNI)
	Reference to Finished product specifications	Innovator Specifications.

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021
Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021 specifying Tablet general section
Proposed Pack size	7's,10's,14's,20's,28's & 30's
Proposed unit price	As per DPC and SRO.
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	Savesto 49/51mg Tablet by Getz Pharma Pakistan (Pvt.) Limited, Reg. No. 093111
Name and address of API manufacturer.	M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Savesto 100 Tablets 24/26mg Getz Pharmaceutical (Pvt.) Ltd. CDP has been performed against the comparator product that is Savesto 24/26mg Tablets Getz Pharmaceutical (Pvt.) Ltd., in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	12200-200303		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD012SECVALT02	22PD013SECVALT03	2PD014SECVALT04
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	04-2022	04-2022	04-2022

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by AD I&E DRAP,Karachi dated 10-06-2020 specifying 1Kg of Sacubitril+Valsartan
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision of 336th meeting: The case was deferred for submission of reply to below cited shortcomings, to which firm has now replied as detailed under:

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate for the drug substance manufacturer shall be submitted , issued by the relevant regulatory authority of country of origin.	Submitted.
2.	**2.3.R**	Dispensed quantity of drug substance for the manufacturing of trial batches shall be justified against the potency of drug substance determined in batch analysis.	Submitted.
3.	**3.2.P.5.1**	➢ Justification shall be submitted for the dissolution specifications of NLT Q in 45 minutes whereas Innovator drug product literature approved by USFDA recommends dissolution limits of "NLT Q in 25 minutes"	Firm has referred to the US FDA "Dissolution method" database.

Decision: Approved.

60.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi-75700**
	Name, address of Manufacturing site.	M/s. Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E.,Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25273 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 17-08-2023
	The proposed proprietary name / brand name	**Vacutec 49/51 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…48.6mg Valsartan…51.4mg (as Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Neprilysin Inhibitor (ARNI)
	Reference to Finished product specifications	Innovator Specifications.

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021
Evidence of approval of manufacturing facility	Firm has submitted copy of GMP Certificate based on inspection conducted on 11-10-2021 specifying Tablet general section
Proposed Pack size	7's,10's,14's,20's,28's & 30's
Proposed unit price	As per DPC and SRO.
The status in reference regulatory authorities	Approved by MHRA of UK
For generic drugs (me-too status)	Savesto 49/51mg Tablet by Getz Pharma Pakistan (Pvt.) Limited, Reg. No. 093111
Name and address of API manufacturer.	M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions as per Zone IV conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the comparator product that is Savesto 100 Tablets 49/51mg Getz Pharmaceutical (Pvt.) Ltd. CDP has been performed against the comparator product that is Savesto 49/51mg Tablets Getz Pharmaceutical (Pvt.) Ltd., in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	12210-211201		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22PD184SVALS01	22PD185SVALS02	22PD186SVALS03

Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	11-2022	11-2022	11-2022
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Reference of previous approval of applications with stability study data of the firm (if any)	--
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of drug import license no. K-712746664269 issued by AD I&E DRAP,Karachi dated 18-07-2022 specifying 3Kg of Sacubitril+Valsartan.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision of 336th meeting: The case was deferred for submission of reply to below cited shortcomings, to which firm has now replied as detailed under:

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate for the drug substance manufacturer shall be submitted , issued by the relevant regulatory authority of country of origin.	Submitted.
2.	**2.3.R**	Dispensed quantity of drug substance for the manufacturing of trial batches shall be justified against the potency of drug substance determined in batch analysis.	Submitted.
3.	**3.2.P.5.1**	➢ Justification shall be submitted for the dissolution specifications of NLT Q in 45 minutes whereas Innovator drug product literature approved by USFDA recommends dissolution limits of "NLT Q in 25 minutes"	Firm has referred to the US FDA "Dissolution method" database.

Decision: Approved.

61.	Name, address of Applicant / Marketing Authorization Holder	**M/s CCL Pharmaceuticals Pvt Ltd.** **62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	GMP status of the manufacturer	Last inspection report dated 18.06.2020 concluded good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Tablet section approval letter submitted from M. Horizon Helathcare Lahore (Ex Walt Danay)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 12728 dated 23-05-2023 Rs.75,000/- dated 30-11-2022
	The proposed proprietary name / brand name	**Maxflow-S 6/0.4 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Solifenacin Succinate(Immediate Release…….6.0mg Tamsulosin HCl (modified Release)…….0.4mg
	Pharmaceutical form of applied drug	film coated tablet.
	Pharmacotherapeutic Group of (API)	**Solifenacin Succinate**: Urologicals, Drugs for urinary frequency and incontinence **Tamsulosin HCl**: Adrenergic $_{\alpha 1}$-receptor antagonist
	Reference to Finished product specifications	As per innovator Specifications
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	Nexlitol Tablets 180mg approved by US-FDA
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	**Solifenacin Succinate:** M/s Optimus Drugs (Pvt.) Limited. Survey No. 239 & 240, Dothigudan (V), Pochampally (M), Yadadri, BhuvanagriIndia **Tamsulosin HCl:** M/s Symed Labs (Pvt) Ltd. Survey No, 353, Domadugu (Village), Jinnaram (Mandal),Medak (Dist) ,Telangana, INDIA.

Evaluation by PEC:

The applied product to be manufactured by M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore have already been approved by Registration Board in its 320th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
Manufacturer firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
Brand Name	Sinzon-S tablet 6.0/0.4mg

- M/s CCL Pharmceuticals had already applied same formulation for contract manufacturing from Ms Global Pharmcueticals, which had been deferred by Registration Board.

Decision of 330th meeting: The Board noted the information and decided to consider the application on its turn as per Que or as per the direction of DRAP Authority, whichever is earlier.

Firm's response: Firm has made following submission vide letter no. CCL/23/R-20 dated 18-07-2023: "We refer to our registration application vide no. CCL/21/R-127 dated 29.10.2021 for "Tablet Maxflow-S 0.4mg/0.6 mg" on Contract manufacturing from M/s. Global Pharmaceuticals Pvt. Ltd., Islamabad (copy enclosed for ready reference). The product was discussed/deferred in 323rd meeting of Registration Board. We would like to withdraw our above said registration application as we intend to shift contract manufacturer of said product."

Decision: Approved. Moreover, Registration Board declared the registration application for

	"Tablet Maxflow-S 0.4mg/0.6 mg" on Contract manufacturing from M/s. Global Pharmaceuticals Pvt. Ltd., Islamabad which was discussed/deferred in 323rd meeting of Registration Board as disposed off.	
62.	Name and address of manufacturer / Applicant	M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ketoride 30mg Ampoule
	Composition	Each Ampoule Contains: Ketorolac Tromethamine ……..…30mg
	Diary No. Date of R& I & fee	Dy. No.12453 dated 06.03.2019 Rs. 50,000/- dated 05.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 30mg/1mL (ketorolac trometamol 30mg without equivalency) injection ampoule. TGA approved.
	Me-too status	Syntor 30 mg Injection IV/IM. Reg. No. 83365
	GMP status	M/s Usawa Pharmaceuticals was inspected on 08.01.2019, wherein satisfactory level of GMP was reported M/s M/s Bio-lab was inspected on 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 wherein renewal of DML / regularization of layout plan, grant of additional section as well as change in section was recommended
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submitted complete manufacturing outlines. • Enclosure of Form 5 from point 16 onwards was missing. Submitted it. • For revision, submit the applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision of 321st meeting: Registration Board deferred the case for further deliberation regarding the sterilization method of the applied formulation whether by way of terminal sterilization or otherwise.	
	Firm's response: Firm has referred to the reference product wherein terminal sterilisation is not recommended for applied formulation.	
	Decision: Deferred for the product specific on-site inspection of applied product to be manufactured by M/s Bio-Labs including the determination of sterilisation method applied for the commercial batches of instant formulation.	
63.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Laxitol Syrup
	Composition	Each 5ml contain: Lactilol monohydrate...3.35gm
	Diary No. Date of R& I & fee	Dy. No.2612 ; 20-06-2016; Rs.20,000/- (20-06-2016)
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	120ml;As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved by Swissmedic of Switzerland
	Me-too status	Lacasil 10g/15ml syrup by M/s Sami Pharmaceuticals Pvt. Limited. (Reg#070552)
	GMP status	The firm is GMP compliant as per inspection conducted on 10-10-2016.
	Remarks of the Evaluator.	• Evidence of availability of RI detector shall be submitted. • Source of lactitol, along with stability studies data, GMP certificate of supplier and differential fee in case of import of shall be submitted.
	Decision of 274th meeting: Deferred for evidence of availability of HPLC with RI detector.	
	Fir's response: Firm has submitted following: • Capacity assessment inspection report of M/s Wimits pharmaceuticals wherein availability HPLC (with RI, UV, PDA detector) has been declared. • Documents of API bulk source i.e., M/s Shandong Lujian Biological Technology Co.s, Ltd., Yucheng high-tech development zone, Shandong, China, • Fee vouchers vide deposit slip no. 8360350481 & 9028977104 of Rs. 150,000/- each.	
	Decision: Approved.	
64.	Name and address of manufacturer / Applicant	M/s. Lisko Pakistan,L-10-D, Block No 21, Shaheed Rashid Minhas Road, FB Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Albezole Suspension (200mg/5ml)
	Composition	Each 5ml contains: Albendazole……200mg
	Diary No. Date of R& I & fee	657, 25-04-2016, Rs. 20,000/- (25-04-2016)
	Pharmacological Group	Benzimidazole antihelmintic
	Type of Form	Form 5
	Finished product Specification	BP(Veterinery)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Robiazole by Zinta
	GMP status	23-01-2017, Good
	Remarks of the Evaluator.	Is present in USFDA and daily med as animal drug.
	Decision of 274th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.	
	Remarks of the Evaluator: Firm has referred to the "ZENTEL 0.4 g/10 ml, oral suspension" approved by ANSM of France.	
	Decision: Approved.	
65.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan (Pvt) Ltd,L-10-D,Block-21, Shaheed Rashid Minhas Rd,F.B.Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ceflis Capsule 100mg
	Composition	Each capsule contains: Cefdinir ……100mg
	Diary No. Date of R& I & fee	Dy. No.621; 21-04-2016; Rs.20,000/- (18-04-2016)
	Pharmacological Group	cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	6's & 10's; Rs.55.5/-capsule
	Approval status of product in Reference Regulatory Authorities.	Not available in the applied strength (300mg available)
	Me-too status	Winsdinir capsule by M/s Wnsfeild Pharmaceuticals
	GMP status	Last inspection was conducted on 23-01-017 and the report concludes good GMP compliance.
	Remarks of the Evaluator.	Not available in the applied strength (300mg available)
	Decision of 274th meeting: Deferred for confirmation of approval status of product in reference regulatory authorities.	
	Remarks of the Evaluator: Firm has referred to Cefzone 100mg capsule approved by PMDA of Japan.	
	Decision: Approved.	

66.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Ivanic 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ivabradine (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No 38719 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	C01EB: Other cardiac preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Iva Tablet 5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Please clarify whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision of 295th meeting: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing does not contain step of coating.	
	Remarks of the Evaluator: Firm has submitted revised manufacturing procedure including details of coating step.	
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
67.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Ivanic 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ivabradine (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No 38719 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	C01EB: Other cardiac preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Iva Tablet 5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Please clarify whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision of 395th meetng: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing does not contain step of coating.	
	Remarks of the Evaluator: Remarks of the Evaluator: Firm has submitted revised manufacturing procedure including details of coating step.	
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

Case no.: 03 Applications of Finished Drug Import

a. New cases

68.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation.** **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 041 Address: **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan** Address of Godown: NA Validity: 19-11-2022. Status: Drug License By way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name, address of manufacturer(s)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 32616 dated 14-11-2022
	Details of fee submitted	Rs.150,000/- dated 23-09-2022
	The proposed proprietary name / brand name	**Metoclopramide 10mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Contains: Metoclopramide HCl …10mg
	Pharmacotherapeutic Group of (API)	Anti-emetic
	Reference to Finished product specifications	British Pharmacopoeia
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	--
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP issued by Hubei Medical Product Administration. The certificate confirms the free sale status of the product. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection after every 5 years. Firm has also submitted copy of GMP certificate no. HB2190553 issued by issued by Hubei Province Medical Product Administration , valid till 26-11-2024 for M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China

	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Agent and Distributor Agreement" between M/s Sohail Corporation & M/s Tianjin King for the applied product valid till 17-06-2026

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product since submitted COPP was valid till 08-02-2024.	Firm has submitted that the new COPP has been applied and will be submitted once received, while the previously submitted CoPP was valid at the time of submission of application.
1.3.4	• Submit valid DSL of the applicant.	Submitted
1.5.2	• The quantity of active ingredient shall be stated in terms of the equivalent amount of anhydrous metoclopramide hydrochloride.	Submitted
3.2.P.2.2.1	Details of the reference product i.e., Brand name, manufacturer , country of origin, against which Pharmaceutical equivalence has been performed, shall be submitted.	Firm has submitted Pharmaceutical equivalence against the PRIMPERAN Injection 10mg/2ml, manufactured by Sanofi.

Decision: Approved as per policy of Inspection of Manufacturer abroad. Registration letter will be issued upon submission of Original Valid, legalized CoPP.

69.	**Name, address of Applicant / Importer**	**M/s AGP Limited.** **B-23, S.I.T.E. Karachi**
	Details of Drug Sale License of importer	License No: 1-65/ Address: Plot no. **B-23, S.I.T.E. Karachi** Address of Godown: AGP Limited B-23 C, SITE Karachi Validity: 21-09-2023. Status: Drug License by way of Whole sale
	Name and address of marketing authorization holder (abroad)	M/s Besins Healthcare S.A., Rue Washington 80, 1050 lxelles, Belgium
	Name, address of manufacturer(s)	M/s Cyndea Pharma, S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110 (Soria) Spain.
	Name of exporting country	Belgium
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14705 dated 12-06-2023
	Details of fee submitted	Rs.75,000/- dated 04-04-2023
	The proposed proprietary name / brand name	**Utrogestan 300mg Soft Capsule (oral and vaginal)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Micronized Progesterone……300mg
	Pharmacotherapeutic Group of (API)	Genitourinary system hormones
	Reference to Finished product specifications	In-house
	The status in reference regulatory authorities	US FDA Approved (Discontinued)

	For generic drugs (me-too status)	--
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 00000118-07-22) issued by Federal Agency for Medicines and Health Products of Belgium dated 18-07-2022. The certificate declares that Product is not actually on market in the exporting country. **GMP:** Frim has submitted legalized copy of GMP certificate issued by competent authority of Spain, declaring GMP compliant status of Capsule (soft shell, Hormone) section.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized "Letter of Authorization" from M/s Besins Healthcare S.A., Rue Washington 80, 1050 lxelles, Belgium in name of M/s AGP Limited. B-23, S.I.T.E. Karachi for the applied product.

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Submitted COPP does not endorse the Free sale status of applied product in Exporting country i.e., "Belgium". Justification shall be submitted in this regard or else submit Free sale certificate or CoPP declaring free sale status of applied product in country of origin.	Firm has referred to the approval of applied product in Finland with same manufacturer and Market Authorisation holder. Vaginal route'·.
2.	Section 1.5.7 declares the route of administration of applied product as "oral and vaginal" while submitted CoPP declares "Vaginal route" only.	The route of administration for Utrogestan 300mg Capsule is only. There is a typographical error in the section 1.5. 7.
3.	Justification shall be submitted for not including "Quantitative rupture test" in drug product specifications.	The Quantitative Rupture Test requirement for soft gelatin capsules is guided by different pharmacopeias. This test is not mandatory in European Pharmacopoeia, However, as per USP, ifa soft gelatin capsule passes the disintegration test, it may not be necessary to perform the rupture test. Compliance with the disintegration test can allow for the omission of the rupture test. The Finished Product specification of Utrogestan contains Disintegration test as per European Pharmacopoca.
4.	Evidence of approval of applied formulation with claimed routes of administration form any of the reference regulatory authority, adopted by Registration Board in its 275th meeting, shall be submitted since provided reference product has been declared as "Discontinued" by US FDA.	The applied formulation with claimed route is also registered and available in Finland with the brand name of ·'Lugesteron'·.

Decision: Approved as per policy of Inspection of Manufacturer abroad.

70.	**Name, address of Applicant / Importer**	**M/s DKT Pakistan Private Limited.**

		RJ Building, 4th Floor, Plot # 37C. Satdium Lane, Stadium Commercial Area, Phase-V, D.H.A, Karachi
	Details of Drug Sale License of importer	License No: 716/- Address: RJ Building, 4th Floor, Plot # 37C. Satdium Lane, Stadium Comm: Area, Phase-V, D.H.A, Karachi Address of Godown: 1, TCS Loistic, Plot No. V-1 Survey No. 258 Sector-2karachi, Korangi Industrial Area, Karachi. Validity: 04-09-2023 Status: By way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Shanghai Dahua Pharmaceutical Co. Ltd., 3503 Changzheng Road, Changzheng Farm, Chongming County, Shanghai, China
	Name, address of manufacturer(s)	M/s Shanghai Dahua Pharmaceutical Co. Ltd., 3503 Changzheng Road, Changzheng Farm, Chongming County, Shanghai, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 12604 dated 22-07-2023
	Details of fee submitted	Rs.150,000/- dated 21-12-2022
	The proposed proprietary name / brand name	**Levoplant 75mg/rod**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rod Contains: Levonogestrel…….75mg
	Pharmacotherapeutic Group of (API)	Progestogens, Levonorgestrel
	Reference to Finished product specifications	In-House
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	Sterile plastic pouch containing a set of two Levonorgestrel containing implants. Ten sets of Levonorgestrel Siladstic Implants (II), 75mg are packaged in a cardboard secondary package.
	Container closure of drug product	Sterile plastic pouch containing a set of two Levonorgestrel containing implants
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 20220195) valid upto 21-09-2024 issued by Shanghai Muncipal Medical Products Administration. The certificate confirms the free sale status of the product in exporting country along with GMP status of the manufacturer ide inspection once a year. **GMP:** Firm has also submitted Legalized copy of GMP certificate no. SH20180058 issued by CFDA valid upto 15-11-2023 declaring scope of inspection as "Implant (Hormone class).
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of "Letter of Authorization" for applied product from M/s Shanghai Dahua Pharmaceutical Co. Ltd., 3503 Changzheng Road, Changzheng Farm, Chongming County, Shanghai, China

	Pharmaceutical Equivalence & CDP studies	Firm has submitted comparison against the innovator drug product Cetrotide injection
	Drug product stability studies	Firm has submitted Long term stability studies data (60 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.
Evaluation by PEC[II]: The applied product also holds WHO prequalification status as verified from following web link: RH028 | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control) WHO Product ID: RH 028		
Decision: Approved as per policy of Inspection of Manufacturer abroad.		
71.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt) Ltd.** BF1-01 First floor gate no. 1, Bahria Orchard Main Raiwind Road, District Lahore
	Details of Drug Sale License of importer	License No: 05-352-0066-059010D Address: BF1-01 First floor gate no. 1, Bahria Orchard Main Raiwind Road, District Lahore Address of Godown: NA Validity: 27-08-2027. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Livzon Group pharmaceutical Factory. No. 38 Chuangye Road North, Jinwan District, Zhuhai, PR China
	Name, address of manufacturer(s)	M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd. No. 16, Xuefu Road, Nanjing High and new technology Development zone, Nanjing, Jiangsu China.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7166 dated 13-03-2023
	Details of fee submitted	Rs.150,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Cetroject Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cetrorelix Acetate Powder (calculated as Cetrorelix)…0.25mg
	Pharmacotherapeutic Group of (API)	anti-gonadotropin-releasing hormones, ATC code: H01CC02
	Reference to Finished product specifications	As per Innovator
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	1's
	Container closure of drug product	Glass vial with rubber stopper
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of legalized CoPP (No. 20220128) valid upto 23-08-2024 issued by medical product Administration of Guangdong Province. The certificate confirms the free sale status of the product in

		exporting country along with GMP status of the manufacturer ide inspection once a year. **GMP:** Firm has also submitted GMP compliance declaration issued by Jiangsu Medical Product Administration in name of M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd. No. 16, Xuefu Road, Nanjing High and new technology Development zone, Nanjing, Jiangsu China on for "Lyophilized Powder for injection vial production line, on basis of inspection conducted on 04-08-2021. Firm has also submitted legalized copy of contract manufacturing agreement of Cetrorelix acetate injection between M/s Livzon Group pharmaceutical Factory & M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Cooperation & Distribution Agreement" between M/s RG Pharmaceutica (Pvt) Ltd. & M/s Livzon Group Pharmaceutical Factory for applied formulation.
	Pharmaceutical Equivalence & CDP studies	Firm has submitted comparison against the innovator drug product Cetrotide injection
	Drug product stability studies	Firm has submitted Long term stability studies data (36 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.

Evaluation by PEC[II]:

Section #	Observations	Firm's response
1.5.2	Submitted label claim shall be revised to declare the strength in terms of the Cetrorelix base along with submission of fee for revision of label claim.	
3.2.S.3	Characterisation studies of drug substance to establish the molecular structure and amino acid sequence against the innovator drug product.	
3.2.S.4	Drug substance specification, analytical procedure and analytical method verification studies shall be submitted form the drug product manufacturer.	
3.2.P.1	Details of the reconstitution diluent shall be submitted.	
3.2.P.2.6	Compatibility study with the reconstitution diluent shall be submitted.	
3.2.P.5.1	Justification shall be submitted for not including following tests in drug product specifications: • Filled weight per unit vial • Withdrawal volume form reconstituted injection.	

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

72.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises Pvt Ltd. 2nd Floor Plaza 60 Commercial, Block-K, Phase I, DHA, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D

		Address: 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore Address of Godown: NA Validity: 08-05-2028. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Reyoung Pharmaceutical Co. Ltd. Workshop 301, No.1, Ruiyang Road, Yiyuan County, Shandong Province, China
	Name, address of manufacturer(s)	M/s Reyoung Pharmaceutical Co. Ltd. Workshop 301, No.1, Ruiyang Road, Yiyuan County, Shandong Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 5902 dated 02-03-2023
	Details of fee submitted	Rs.150,000/- dated 04-01-2023
	The proposed proprietary name / brand name	**TAZBAC INJECTION**
	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)	Antibacterials for systemic use, Combinations of penicillins incl. beta-lactamase inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Tanzo Injection of M/s Bosch
	Proposed Pack size & Price	Packs of Piperacillin/Tazobactam 1 vial and WFI 1 ampoule
	Container closure of drug product	Glass vial with rubber stopper
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	--
	Details of letter of authorization / sole agency agreement	--
	Pharmaceutical Equivalence & CDP studies	Firm has submitted comparison against the innovator drug product Zosyn injection
	Drug product stability studies	Firm has submitted Long term stability studies data (36 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.

Evaluation by PEC[II]:

Section #	Observations	Firm's response
1.3	• Original valid legalized COPP shall be submitted.	• Firm has submitted original legalized COPP no. 20243018 issued by Shandong Province

		• Evidence of approval of dedicated manufacturing facility for the applied formulation shall e b submitted. • Notarized copy of letter of authorisation shall be submitted for applied product.	Medical Product Administration dated 06-02-2024. The CoPP confirms free slae status of te product in coutry of origin along with GMP status of the manufacturer. • Firm has submitted copy of GMP inspection report issued by Shandong Province Medical Product Administration, declaring availability of Penicillin powder for injection workshop. • Firm has also submitted legalized sole agency agreement for the applied product.
	3.2.P.2.2.1	Submitted reference product i.e., Zosyn Injection contains EDTA and citric acid as excipients, whereas no such excipient has been included in the applied formulation. Justification shall be submitted in this regard.	Firm has submitted declaration from drug product manufacturer as under: " We Reyong Pharmaceutical Co., declare that we are also using EDTA and Citric acid as excipients at API manufacturing level and we are using ready to fill powder at our finished product manufacturing site."
Decision: Approved as per policy of inspection of manufacturer abroad.			
73.	**Name, address of Applicant / Importer**	**M/s BF Biosciences Limited. 5-Km, Sunder Raiwind Road, Opposite Ijtima Chowk, Raiwind, Lahore, Pakistan**	
	Details of Drug Sale License of importer	License No: 05-352-0066-034461D Address: 5-Km, Sunder Raiwind Road, Raiwind, Lahore, Pakistan Address of Godown: NA Validity: 29-06-2022. Status: Drug License as a Distributor	
	Name and address of marketing authorization holder (abroad)	M/s Bioprofarma Bago S.A. Terrada 1270, Buenos Aires, Argentina	
	Name, address of manufacturer(s)	**Compression process, Dosing & Sealing:** M/s Laboratorio Eczane Pharma S.A, Laprida No 43, Avellaneda, Provincia de Buenos Aires, Republica Argentina **Secondary Packaging, QC of API and Finished product, Market release of Finished product, Stability program**: M/s Bioprofarma Bago S.A. Terrada 1270, Buenos Aires, Argentina	
	Name of exporting country	Argentina	
	Status of the applicant	☐ Manufacturer ☒ Importer	

		☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13376 dated 30-05-2023
	Details of fee submitted	Rs.75,000/- dated 07-12-2022
	The proposed proprietary name / brand name	**Kestava 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Abiraterone Acetate…250mg
	Pharmacotherapeutic Group of (API)	L02BX03, androgen biosynthesis inhibitors
	Reference to Finished product specifications	In-house
	The status in reference regulatory authorities	EMA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size & Price	120 tab per Bottle and unit price is Rs. 134,699/-
	Container closure of drug product	HDPE white bottles, 38 mm mouth diameter with white child-proof cap and security seal.
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of legalized CoPP valid upto 03-01-2024 issued by National Institute of Drugs, Argentina. The certificate confirms the free sale status of the product in exporting country along with GMP status of the manufacturer i.e., M/s Laboratorio Eczane Pharma S.A, Laprida No 43, Avellaneda, Provincia de Buenos Aires, Republica Argentina vide inspections every two years.
	Details of letter of authorization / sole agency agreement	Firm has submitted original notarized "Letter of Authorization" from M/s Bioprofarma Bago S.A. Terrada 1270, Buenos Aires, Argentina in name of M/s BF Biosciences Limited 5-Km, Sunder Raiwind Road, Lahore for applied formulation.
	Pharmaceutical Equivalence & CDP studies	Firm has submitted comparative analysis against the innovator drug product Zytiga
	Drug product stability studies	Firm has submitted Long term stability studies data (24 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.

Evaluation by PEC[II]:

Section #	Observations	Firm's response
1.3	Following shall be submitted: • Valid DSL of the applicant. • Original valid legalized COPP. • Legalized GMP certificate of M/s Bioprofarma Bago S.A. Terrada 1270, Buenos Aires, Argentina responsible for secondary packaging, batch release and stability programme of applied product. • Agreement between M/s Bioprofarma Bago S.A. & M/s Laboratorio Eczane Pharma S.A for third party manufacturing.	

	1.5.6	Justification shall be submitted for claiming In-House specifications, while the Pharmacopoeial monograph is available for the applied formulation.	
	3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted form the drug product manufacturer.	
	3.2.P.1	Submitted composition table refers the drug substance specifications as "In-House", while the section 3.2.S.4.5 claims specification so drug substance as per USP monograph. Clarification shall be submitted on this regard.	
	3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted. Comparative dissolution studies in three dissolution mediums across physiological pH range against the innovator/reference product shall be submitted.	
	3.2.P.3.1	As per section M/s Bioprofarma Bagó S.A., Terrada 1270 - City of Buenos Aires, Argentine Republic is responsible for the following operations: • Weighing of raw materials • Secondary Packaging • Quality Control of API and Finished Product • Market Release of Finished Product • Stability program While the submitted COPP does not declare the above cited roles of M/s Bioprofarma Bagó S.A	

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

74.	**Name, address of Applicant / Importer**	**M/s Bristol Mayer Biotech Pakistan.** **73-B, Guldasht Town Lahore Cantt Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0068-109282D Address: 73-B, Ground Floor Guldasht Town, Zarrar Shaheed Road , Lahore Cantt Address of Godown: NA Validity: 18-10-2028. Status: Drug License as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Olive Healthcare. Unit 2, Plot 163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, 396 210, India
	Name, address of manufacturer(s)	M/s Olive Healthcare. Unit 2, Plot 163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, 396 210, India
	Name of exporting country	China.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13178 dated 29-05-2023
	Details of fee submitted	Rs.150,000/- dated 30-03-2023 vide deposit slip#32687707325
	The proposed proprietary name / brand name	**Sugest 200mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gelatin Capsule Contains: Progesterone …… 200mg
	Pharmacotherapeutic Group of (API)	Progestens, Hormonal contraceptives
	Reference to Finished product specifications	In-house
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	U-Progest Capsule of M/s Aspin Pharma
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DD/689/12.1/2023(PAK-1) valid upto 05-07-2023 issued by UT Administration of Dadra & Nagar Haveli And Daman & Diu, Assistant Drugs Controller & Licensing Authority, Drugs Control Department, Primary Health Center, Moti Daman. The certificate confirms the free sale status of the product along with GMP status of the manufacturer vide yearly based inspections..
	Details of letter of authorization / sole agency agreement	Firm has submitted original legalized "Letter of Authorization" from M/s Olive Healthcare declaring as under: "M/s Olive HealthCare(Unit-II), having manufacturing unit at 163/2, M.G, Udyog Nagar, Village Dabhel, Nani Daman, Daman-396 210, India have an agreement with M/s Sanzyme (P) Ltd, having its registered office at Plot No.13, Sagar Society, Banjara Hills, Road No.2, Hyderabad - 500 034 to file our below said products in Pakistan. Hence, we hereby authorizes M/s Sanzyme P Ltd to file below said products through Bristol Mayer\ Biotech, Pakistan, a company duly registered in PAKISTAN, having its registered office at 73 B Guldasht Town, Zarrar Shaheed Road, Lahore Cantt, Pakistan and also to represent itself in all matters with regards to the registration, licensing, import, promote, store, distribute and participate tender for Sanzyme (P) Ltd's products in PAKISTAN.
Evaluation by PEC^{II}: • Firm has submitted CDP and Pharmaceutical equivalence against the reference product "Utrogestan capsules". Long term stability studies data (30 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.		
Decision: Approved as per policy of Inspection of Manufacturer abroad. Registration letter will be issued upon submission of Original Valid, legalized CoPP.		
75.	**Name, address of Applicant / Importer**	**M/s Bristol Mayer Biotech Pakistan. 73-B, Guldasht Town Lahore Cantt Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0068-109282D

		Address: 73-B, Ground Floor Guldasht Town, Zarrar Shaheed Road , Lahore Cantt Address of Godown: NA Validity: 18-10-2028. Status: Drug License as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Olive Healthcare. Unit 2, Plot 163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, 396 210, India
	Name, address of manufacturer(s)	M/s Olive Healthcare. Unit 2, Plot 163/2, Mahatma Gandhi Udyog Nagar, Dabhel Village, Nani Daman, 396 210, India
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13178 dated 29-05-2023
	Details of fee submitted	Rs.150,000/- dated 30-03-2023 vide deposit slip#4640101228
	The proposed proprietary name / brand name	**Sugest 100mg Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft Gelatin Capsule Contains: Progesterone ……. 100mg
	Pharmacotherapeutic Group of (API)	Progestens, Hormonal contraceptives
	Reference to Finished product specifications	In-house
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	U-Progest Capsule of M/s Aspin Pharma
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DD/689/11.1/2023(PAK-1) valid upto 05-07-2023 issued by UT Administration of Dadra & Nagar Haveli And Daman & Diu, Assistant Drugs Controller & Licensing Authority, Drugs Control Department, Primary Health Center, Moti Daman. The certificate confirms the free sale status of the product along with GMP status of the manufacturer vide yearly based inspections..
	Details of letter of authorization / sole agency agreement	Firm has submitted original legalized "Letter of Authorization" from M/s Olive Healthcare declaring as under: "M/s Olive HealthCare(Unit-II), having manufacturing unit at 163/2, M.G, Udyog Nagar, Village Dabhel, Nani Daman, Daman-396 210, India have an agreement with M/s Sanzyme (P) Ltd, having its registered office at Plot No.13, Sagar Society, Banjara Hills, Road No.2, Hyderabad - 500 034 to file our below said products in Pakistan. Hence, we hereby authorizes M/s Sanzyme P Ltd to file below said products through Bristol Mayer\ Biotech, Pakistan, a company duly registered in PAKISTAN, having its registered office at 73 B Guldasht Town, Zarrar Shaheed Road, Lahore Cantt, Pakistan and also to represent itself in all matters with regards to the

		registration, licensing, import, promote, store, distribute and participate tender for Sanzyme (P) Ltd's products in PAKISTAN.
Evaluation by PEC[II]: • Firm has submitted CDP and Pharmaceutical equivalence against the reference product "Utrogestan capsules". Long term stability studies data (30 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.		
Decision: Approved as per policy of Inspection of Manufacturer abroad. Registration letter will be issued upon submission of Original Valid, legalized CoPP.		

b. Deferred cases

76.	**Name, address of Applicant / Importer**	**M/s Innovegic Pharmaceuticals.** **Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad**
	Details of Drug Sale License of importer	License No: DSL-1605-ICT/2013 Address: Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad Address of Godown: NA Validity: 16-09-2023. Status: Whole sale distributor
	Name and address of marketing authorization holder (abroad)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name, address of manufacturer(s)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 32811 dated 15-11-2022
	Details of fee submitted	Rs.150,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Microgest-100 Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule Contains: Progesterone…….100mg
	Pharmacotherapeutic Group of (API)	Genito urinarysystem and sex hormones ATC: G03DA04
	Reference to Finished product specifications	Innovator specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DA/6-152/2011/16/6188) issued dated 25-08-2020 by DGDA of Bangladesh. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 2 years. **GMP:**Firm has also submitted copy of GMP certificate no. DAl6-15212011/4416 issued by DGDA of Bangladesh , valid till 22-02-2024 for M/s Renata Limited Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh

	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.
EVALUATION OF DATA		
Proposed Pack size		3 x 10's
Proposed unit price		As per SRO
The status in reference regulatory authorities		Approved by US FDA
For generic drugs (me-too status)		Uprogest capsule of M/s Aspin Pharma
Module-II (Quality Overall Summary)		Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer		**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.** Addresses of manufacturing site: Gedian Economic Development District,Ezhou, Hubei 436070, China
Module-III Drug Substance:		Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:		Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence		Firm has submitted Pharmaceutical equivalence and CDP report against reference product Utrogestan soft gelatin capsule
Analytical method validation/verification of product		Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product		Alu-PVC
Stability study data of drug product, shelf life and storage conditions		Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.
77.	**Name, address of Applicant / Importer**	**M/s Innovegic Pharmaceuticals.** **Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad**
	Details of Drug Sale License of importer	License No: DSL-1605-ICT/2013 Address: Plot No. C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad Address of Godown: NA Validity: 16-09-2023. Status: Whole sale distributor
	Name and address of marketing authorization holder (abroad)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name, address of manufacturer(s)	M/s Renata Limited. Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 31988 dated 07-11-2022
	Details of fee submitted	Rs.150,000/- dated 25-10-2022

	The proposed proprietary name / brand name	**Microgest-200 Soft Gelatin Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each soft gelatin Capsule Contains: Progesterone…….200mg
	Pharmacotherapeutic Group of (API)	Genito urinarysystem and sex hormones ATC: G03DA04
	Reference to Finished product specifications	Innovator specification
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. DA/6-152/2011/16/6189) issued dated 25-08-2020 by DGDA of Bangladesh. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 2 years. **GMP:**Firm has also submitted copy of GMP certificate no. DAl6-15212011/4416 issued by DGDA of Bangladesh , valid till 22-02-2024 for M/s Renata Limited Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur, Bangladesh
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Foreing Agency Agreement" between M/s Zhejiang CONBA Pharmaceutical Co., Ltd., No.1 Conba Road, Lanxi City, Zhejiang Province, China & M/s AMB HK Enterprises Pvt Ltd.

EVALUATION OF DATA

Proposed Pack size	3 x 10's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Uprogest capsule of M/s Aspin Pharma
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	**Hubei Gedian Humanwell Pharmaceutical Co., Ltd.** Addresses of manufacturing site: Gedian Economic Development District,Ezhou, Hubei 436070, China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalence and CDP report against reference product Utrogestan soft gelatin capsule
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Alu-PVC
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Decision of 336th meeting: Registration Board deferred the applications of Microgest-100 Soft Gelatin Capsule & Microgest-200 Soft Gelatin Capsule for submission of reply to below cited shortcomings, to hich firm has replied as detailed under:

Evaluation by PEC^{II}:

Section no.	Observations	Firm's response

1.3	• Submitted COPP declares the name of product as "Microgest-200 soft gelatin capsule", whereas the Active ingredient per unit dose has been declared as "Progesterone 100mng/capsule". • Submit evidence of dedicated manufacturing facility required for the manufacturing of applied formulation. • Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant firm shall be submitted.	• It was a typographical error and it was mistakenly written as 100mg/capsule instead of 200mg/capsule. • Firm has submitted a declaration and layout from M/s Renata Limited, submitting that firm has Soft gelatin capsule manufacturing area situated on second floor of five-storied dedicated manufacturing facility for producing hormonal products. • Notarized copy of sole agency agreement not submitted.
1.3.4	• Submit valid DSL of the applicant.	Submitted
3.2.P.2.1	• Drug excipient compatibility studies shall be provided since the qualitative composition of the formulation is not similar to innovator / reference product. • Justification shall be submitted for the use of preservative agents in the composition of soft gelatin capsule.	Not submitted
3.2.P.2.2.1	• Justify the comparative dissolution profile sampling time points i.e., 01hr, 02 hr,03hr,06hr,08hr,10hr,12hr,14hr & 16hr , considering the fact that applied product is an immediate release formulation.	As the release %age of product found less than 30% at 2 hrs for both strength and it was increasing with time, so upto 16 hrs has been tested as % release become plateau after 14 hours.
3.2.P.5.1	• Justification shall be submitted for not including "Quantitative rupture test" in the drug product specifications. • Justification shall be submitted for not including "Related substance/Impurity test" in the drug product specifications.	• Firm has submitted revised drug product specifications including Quantitative rupture test. • For Progesterone Capsules, no official monograph impurity test"" I like BP / Ph. Eur. / USP exists. That's why, we do not include the Related substance/ impurity test in the drug product specification & also in the stability data. • Note that, for Drug substance, Related substance/ Impurity test is routinely monitored for release test & controlled as per the BP monograph. All Related substance/

			impurity test results are found satisfactory & available in the certificate of analysis (COA) of the drug substance (Progesterone BP
	3.2.P.8.3	Justification shall be submitted for not performing following tests in stability studies: • Quantitative rupture test • Related substance/Impurity test • Microbial contamination test	Firm has submitted revised stability sheets for real time stability study, incorporating tests of Quantitative rupture test and Microbial enumeration test.

Decision: Registration Board deferred the applications of Microgest-100 Soft Gelatin Capsule & Microgest-200 Soft Gelatin Capsule for submission of following:

- **Revised Original, valid and legalized COPPs declaring the correct brand name as per the strength applied.**
- **Evidence of dedicated manufacturing facility required for the manufacturing of applied formulation issued by the relevant regulatory authority of country of origin.**
- **Notarized valid copy of Sole Agency agreement between the Market authorization holder in the country of origin and the applicant.**
- **Drug excipient compatibility studies since the qualitative composition of the formulation is not similar to innovator / reference product.**
- **Justification for the use of preservative agents in the composition of soft gelatin capsule**

78.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation.** **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 041 Address: **Plot No. 7, SR-5, Serai Quarter (Techno City), WH-42, Karachi, Pakistan** Address of Godown: NA Validity: 19-11-2022. Status: Drug License By way of Whole Sale
	Name and address of marketing authorization holder (abroad)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name, address of manufacturer(s)	M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 35670 dated 08-12-2022
	Details of fee submitted	Rs.150,000/- dated 23-09-2022
	The proposed proprietary name / brand name	**Sodium Lactate Riger's Injection 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 500ml Contains: Sodium Lactate…1.55gm Sodium Chloride…3gm Potassium Chloride…0.15gm Calcium Chloride…0.1gm

	Pharmacotherapeutic Group of (API)	Electrolyte
	Reference to Finished product specifications	British Pharmacopoeia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original & legalized CoPP (No. 20210144), valid till 09-08-2023 issued by Hubei Medical Product Administration. The certificate confirms the free sale status of the product. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection after every 5 years. Firm has also submitted copy of GMP certificate no. HB2190553 issued by issued by Hubei Province Medical Product Administration , valid till 26-11-2024 for M/s Tianjin King York Group Hubei Tian Yao Pharmaceutical Co., Ltd. No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Agent and Distributor Agreement" between M/s Sohail Corporation & M/s Tianjin King for the applied product valid till 17-06-2026

EVALUATION OF DATA	
Proposed Pack size	500ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	USFDA Approved. Lactated Ringer's in Plastic Container by Baxter healthcare
For generic drugs (me-too status)	Ringe Lac Lactated Ringer solution by Otsuka Pakistan
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Sodium Lactate: M/s Anhui Hongye Pharmaceutical Co., Ltd., China Sodium Chloride, Potassium Chloride, Calcium Chloride dihydrate: M/s Tianjin Haiguang Pharmaceutical Co. Ltd., China
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted Pharmaceutical equivalene report againstseveral brands of Sodium Lactate Ringer's injection solution including of the M/s Shandong Hualu Pharmaceutical Co., Ltd.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Polypropylene infusion bottle
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 36 months at 30±2°C, 35±5%RH and 6 months at 40°C±25%RH for three batches.
Decision of 336th meeting: Deferred for submission of reply to below cited shortcomings for which frim has replied as under:	

Evaluation by PEC[II]:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product since submitted COPP was valid till 09-08-2023.	Firm has submitted that the new COPP has been applied and will be submitted once received, while the previously submitted CoPP was valid at the time of submission of application.
1.3.4	• Submit valid DSL of the applicant.	Submitted
1.5.2	• The quantity of active ingredient shall be stated in terms of the equivalent amount of Calcium chloride dihydrate.	Submitted
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	Firm has submitted Pharmaceutical equivalence against the Lactated Ringer's solution of M.s Baxter.

Decision: Approved as per policy of Inspection of Manufacturer abroad. Registration letter will be issued upon submission of Original Valid, legalized CoPP.

Case no.: 04 Miscellaneous cases

Following case was presented in 336th meeting of Registration Board, while during subsequent processing and verifying the available record it was identified that the name of the applicant was inadvertently written as "M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad", while the application was submitted by M/s Werrick Pharmaceuticals 216-217, I-10/3, Industrial Area, Islamabad. The case is presented for correction.

79.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 36361 dated 14-12-2022
	Details of fee submitted	Rs.30,000/- dated 23-11-2022
	The proposed proprietary name / brand name	**Wardy Plus XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release film coated tablet contains; Empagliflozin …… 5mg Metformin Hydrochloride (extended release) ……. 1000mg
	Pharmacotherapeutic Group of (API)	**Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03 **Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02
	Reference to Finished product specifications	Innovator's Specs

Remarks of Evaluator:
Decision of 336th meeting: Approved with innovator's specifications. • Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application. • Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.
Decision: Registration Board noted the correction and approved the product in name of M/s Werrick Pharmaceuticals 216-217, I-10/3, Industrial Area, Islamabad.

Agenda of Dr. Muhammad Haseeb Tariq

Case No. 01 Registration applications of CTD cases

a. New cases

80.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 28542: 07-10-2022
	Details of fee submitted	PKR 30,000/- : 27-09-2022
	The proposed proprietary name / brand name	**AFERT 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine as HCl…250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Terbiderm Tablet by Atco
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
81.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 30583: 30-10-2022
	Details of fee submitted	PKR 30,000/- : 18-10-2022

	The proposed proprietary name / brand name	**AFERT 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Terbinafine HCl…1%
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Terbiderm Cream by Atco
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
82.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13937: 05-06-2023
	Details of fee submitted	PKR 75,000/- : 11-04-2023
	The proposed proprietary name / brand name	**BERELEX 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Eperisone HCl…100mg
	Pharmacotherapeutic Group of (API)	Antispasmodic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**AIFA Italy** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
83.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27279: 01-10-2021
	Details of fee submitted	PKR 30,000/- : 29-09-2021
	The proposed proprietary name / brand name	**DEXACURE 30mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole as dual delayed release pellets ...30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Source of pellets: M/s Vision Pharma		
Decision: Approved.		
84.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Cure Laboratories. Plot # 11,12,NS-2 RCCI, Industrial Estate, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27280: 01-10-2021
	Details of fee submitted	PKR 30,000/- : 29-09-2021
	The proposed proprietary name / brand name	**DEXACURE 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole as dual delayed release pellets ...60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Source of pellets: M/s Vision Pharma		
Decision: Approved.		
85.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13639: 01-06-2023
	Details of fee submitted	PKR 30,000/- : 24-02-2023
	The proposed proprietary name / brand name	**OPANAC FORTE 3mg/ml Ophthalmic Suspension**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Nepafenac…3mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Acukat Opthalmic Suspension 0.3% by Genix
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	Name of the firm mentioned in section 1.3.1 and 1.3.2. is M/s Polyfine Chempharma, while the name of the firm as per DML is M/s Polyfine Chempharma (Pvt) Ltd. Moreover, as per submitted fee challan the name of the firm is also M/s Polyfine Chempharma. Revision of the title of the firm is required along with submission of requisite fee.	
	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
2.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit COA of reference / working standard actually used in analysis of drug substance.	
4.	Submit microbiological attributes of the drug product in section 3.2.P.2.5 including preservative effectiveness studies.	
5.	Justify why test for assay of preservative i.e. benzalkonium chloride is not included in drug product specification.	
6.	Submit valid GMP certificate of API manufacturer	
7.	Submit documents for procurement of API including DRAP clearance certificate.	

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

86.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13638: 01-06-2023
	Details of fee submitted	PKR 30,000/- : 24-02-2023
	The proposed proprietary name / brand name	**Pedlote 0.5% Ophthalmic Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Loteprednol Etabonate…5mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Lotepred forte by Sante
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	Name of the firm mentioned in section 1.3.1 and 1.3.2. is M/s Polyfine Chempharma, while the name of the firm as per DML is M/s Polyfine Chempharma (Pvt) Ltd. Moreover, as per submitted fee challan the name of the firm is also M/s Polyfine Chempharma. Revision of the title of the firm is required along with submission of requisite fee.	
	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
2.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit COA of reference / working standard actually used in analysis of drug substance.	
4.	Submit microbiological attributes of the drug product in section 3.2.P.2.5 including preservative effectiveness studies.	
5.	Justify why test for assay of preservative i.e. benzalkonium chloride is not included in drug product specification.	
6.	Submit valid GMP certificate of API manufacturer	
7.	Submit documents for procurement of API including DRAP clearance certificate.	

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

87.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15396: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	**ONDANZ 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule (4ml) Contains: Ondansetron as HCl…8mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Onset Injection by Pharmedic
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Decision: Approved.

88.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15684: 21-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	**ONDANZ 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as Ondansetron HCl Dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Onset Syrup by Pharmedic
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
89.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15400: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	**CELEFOLD 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib…100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Firm has claimed innovator's specifications
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Celbexx capsule by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Sr. No	Shortcomings	Response by the firm
1.	The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	

5.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
6.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
7.	Submit valid GMP certificate of API manufacturer	
8.	Submit documents for procurement of API including DRAP clearance certificate.	

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

90.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15401: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	**CELEFOLD 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib…200mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Firm has claimed innovator's specifications
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Celbexx capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	
5.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
6.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
7.	Submit valid GMP certificate of API manufacturer	
8.	Submit documents for procurement of API including DRAP clearance certificate.	

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

91.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar**

	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69/2, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15402: 19-06-2023
	Details of fee submitted	PKR 30,000/- : 07-06-2023
	The proposed proprietary name / brand name	**CELEFOLD 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Celecoxib…400mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Firm has claimed innovator's specifications
	The status in reference regulatory authorities	Could not be confirmed
	For generic drugs (me-too status)	Could not be confirmed
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit evidence of me-too status	
3.	The drug product monograph is available in BP while the firm has developed the formulation as per innovator's specification.	
4.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
5.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
6.	Submit COA of reference / working standard actually used in analysis of drug substance.	
7.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
8.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
9.	Submit valid GMP certificate of API manufacturer	
10.	Submit documents for procurement of API including DRAP clearance certificate.	

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

92.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13944: 05-06-2023
	Details of fee submitted	PKR 30,000/- : 16-02-2023
	The proposed proprietary name / brand name	**NAPROXEN Plus 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…500mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
93.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13176: 29-05-2023
	Details of fee submitted	PKR 30,000/- : 08-05-2023
	The proposed proprietary name / brand name	**REVOC 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Risperidone…..…4mg
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Persch Tablets by Barret Hodgson
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
94.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt) Ltd. A-20, North Western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11785: 15-05-2023
	Details of fee submitted	PKR 30,000/- : 16-02-2023
	The proposed proprietary name / brand name	**REVOC 1mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Risperidone…1mg
	Pharmacotherapeutic Group of (API)	Atypical antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Persch solution by Barret Hodgson
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
95.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31- 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31- 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10975: 03-05-2023
	Details of fee submitted	PKR 30,000/- : 30-03-2023
	The proposed proprietary name / brand name	**VORTOX 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vorteoxetine as Hydrobromide…10mg
	Pharmacotherapeutic Group of (API)	Anti-Depressants
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorti Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
96.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31- 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31- 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10976: 03-05-2023
	Details of fee submitted	PKR 30,000/- : 30-03-2023
	The proposed proprietary name / brand name	**VORTOX 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vorteoxetine as Hydrobromide…20mg
	Pharmacotherapeutic Group of (API)	Anti-Depressants
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorti Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
97.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. Plot #122, Block B, Phase V, Industrial Estate Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122, Block B, Phase V, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9820: 12-04-2023
	Details of fee submitted	PKR 30,000/- : 17-03-2023
	The proposed proprietary name / brand name	**VORTEX 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vorteoxetine as Hydrobromide…10mg
	Pharmacotherapeutic Group of (API)	Anti-Depressants
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorti Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
98.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. Plot #122, Block B, Phase V, Industrial Estate Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122, Block B, Phase V, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9823: 12-04-2023

	Details of fee submitted	PKR 30,000/- : 17-03-2023
	The proposed proprietary name / brand name	**VORTEX 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vorteoxetine as Hydrobromide…20mg
	Pharmacotherapeutic Group of (API)	Anti-Depressants
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Vorti Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
99.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13527: 31-05-2023
	Details of fee submitted	PKR 30,000/- : 10-05-2023
	The proposed proprietary name / brand name	**RESTON 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron HCl eq. to Ondansetron…4mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Onset Tablet by Pharmedic
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
100.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13528: 31-05-2023
	Details of fee submitted	PKR 30,000/- : 10-05-2023
	The proposed proprietary name / brand name	**RESTON 8mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron HCl eq. to Ondansetron…8mg
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Onset Tablet by Pharmedic
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
101.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals (Pvt) Ltd. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals (Pvt) Ltd. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13636: 31-05-2023
	Details of fee submitted	PKR 30,000/- : 11-05-2023
	The proposed proprietary name / brand name	**SITALIP SR 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin (immediate release coat)… 50mg Metformin HCl (as extended release core)…. 500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Sita Met XR Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
• BP 2024 contains monograph of Metformin and Sitagliptin Prolonged-release Tablets.		
Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
102.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals (Pvt) Ltd. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals (Pvt) Ltd. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13637: 31-05-2023
	Details of fee submitted	PKR 30,000/- : 11-05-2023

	The proposed proprietary name / brand name	**SITALIP SR 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin (immediate release coat)… 50mg Metformin HCl (as extended release core)….1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Sita Met XR Tablet by CCL
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
• BP 2024 contains monograph of Metformin and Sitagliptin Prolonged-release Tablets.		
Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
103.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13513: 31-05-2023
	Details of fee submitted	PKR 75,000/- : 11-05-2023
	The proposed proprietary name / brand name	**LINAGLU-MET 2.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
104.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13947: 05-06-2023
	Details of fee submitted	PKR 75,000/- : 11-05-2023
	The proposed proprietary name / brand name	**LINAGLU-MET 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
105.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13773: 02-06-2023
	Details of fee submitted	PKR 30,000/- : 18-01-2023
	The proposed proprietary name / brand name	**MEGAMET 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glucophage Tablet by Martin Dow
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate / inspection report of drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance, since the submitted COA specifies that the standard can be used till June 2020 while API testing was performed in April 2021.	

5.	Source of API claimed in section 3.2.S.2.1 is Aarti Drugs Limited, Mumbai while the stability study data of API is provided for Aarti Tarapur Site	
6.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
7.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
8.	USP monograph has specified 3 different tests for dissolution, you are required to specify the type of dissolution test for your drug product.	
9.	The raw data sheets of stability studies show UV absorbance values of 800 and above. Clarification is required how such high UV absorbance values can be achieved and used in the studies.	
10.	Submit valid GMP certificate of API manufacturer	
11.	Submit documents for procurement of API including DRAP clearance certificate.	

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

106.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13774: 02-06-2023
	Details of fee submitted	PKR 30,000/- : 18-01-2023
	The proposed proprietary name / brand name	**MEGAMET 850mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glucophage Tablet by Martin Dow
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings**	**Response by the firm**
1.	Submit valid GMP certificate / inspection report of drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance, since the submitted COA specifies that the standard can be used till June 2020 while API testing was performed in April 2021.	

5.	Source of API claimed in section 3.2.S.2.1 is Aarti Drugs Limited, Mumbai while the stability study data of API is provided for Aarti Tarapur Site	
6.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
7.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
8.	USP monograph has specified 3 different tests for dissolution, you are required to specify the type of dissolution test for your drug product.	
9.	The raw data sheets of stability studies show UV absorbance values of 800 and above. Clarification is required how such high UV absorbance values can be achieved and used in the studies.	
10.	Submit valid GMP certificate of API manufacturer	
11.	Submit documents for procurement of API including DRAP clearance certificate.	

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

107.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14702: 12-06-2023
	Details of fee submitted	PKR 30,000/- : 18-01-2023
	The proposed proprietary name / brand name	**MEGAMET 1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glucophage Tablet by Martin Dow
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	Submit valid GMP certificate / inspection report of drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance, since the submitted COA specifies that the standard can be used till June 2020 while API testing was performed in April 2021.	

5.	Source of API claimed in section 3.2.S.2.1 is Aarti Drugs Limited, Mumbai while the stability study data of API is provided for Aarti Tarapur Site	
6.	Submit report of comparative dissolution profile studies as per FDA guidelines including result of individual unit at each time point for each dissolution medium along with %RSD values.	
7.	Justify why test for uniformity of dosage unit is not included in drug product specification.	
8.	USP monograph has specified 3 different tests for dissolution, you are required to specify the type of dissolution test for your drug product.	
9.	The raw data sheets of stability studies show UV absorbance values of 800 and above. Clarification is required how such high UV absorbance values can be achieved and used in the studies.	
10.	Submit valid GMP certificate of API manufacturer	
11.	Submit documents for procurement of API including DRAP clearance certificate.	

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

108.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9784: 11-04-2023
	Details of fee submitted	PKR 30,000/- : 28-11-2022
	The proposed proprietary name / brand name	**SILO-M XR 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin … 50mg Metformin HCl USP ……. 500mg (as extended release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Sita Met XR Tablet by CCL
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

- BP 2024 contains monograph of Metformin and Sitagliptin Prolonged-release Tablets.

Decision: Approved with BP specifications.

- **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

109.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Demont Research Laboratories (Pvt) Ltd. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
	Name, address of Manufacturing site.	M/s Demont Research Laboratories (Pvt) Ltd. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14712: 12-06-2023
	Details of fee submitted	PKR 30,000/- : 12-04-2023
	The proposed proprietary name / brand name	**NEXA PLUS 500/20 mg Modified Release Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen…500mg Esomeprazole as Magnesium Trihydrate…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 fir both drug substances.	
3.	Justify the performance of specificity test for naproxen API in the light of ICH Q2 guidelines.	
4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4 for both drug substances	
5.	Justify why particle size distribution test is not performed by drug product manufacturer for naproxen API since particle size is a critical quality attribute for the applied product.	
6.	Submit real time stability study data of esomeprazole API till claimed shelf life since the submitted data is till 6 months only.	
7.	Submit quantity of esomeprazole added in drug product per unit keeping in view salt factor and magnesium content etc.	
8.	Justify why pharmaceutical equivalence and CDP studies are not conducted against innovator's product.	
9.	Submit details of dissolution parameters used in comparative dissolution profile studies.	
10.	USFDA review documents reveals that for acid stage testing of naproxen tablet, 475ml dissolution medium is to be used with 75rpm paddle speed, while you have used 100rpm paddle speed. Clarification is required in this regard.	
11.	USFDA review documents reveals that for buffer stage testing of naproxen tablet, 900ml of 0.05 M phosphate buffer pH 7.4 dissolution medium is to be used with 75rpm paddle speed, while you have used 100rpm paddle speed. Clarification is required in this regard.	
12.	Submit valid GMP certificate of both API manufacturer	
13.	Submit documents for procurement of both API including DRAP clearance certificate.	
14.	Submit complete analytical record of stability testing of all batches including chromatograms for assay and dissolution test for each time point with proper separators.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
110.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14078: 06-06-2023
	Details of fee submitted	PKR 75,000/- : 30-05-2023
	The proposed proprietary name / brand name	**ASEFO 2.5mg Sublingual Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sublingual Tablet Contains: Asenapine Maleate Eq. to Asenapine…2.5mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of drug substance	Form H
2.	Specify whether the drug substance is available as racemic mixture or otherwise.	API has two chiral centresbut is developed as a racemate.
3.	Justify why the qualitative composition of your product is different from the innovator's product.	Submitted.

Decision: Approved.		
111.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14079: 06-06-2023
	Details of fee submitted	PKR 75,000/- : 30-05-2023
	The proposed proprietary name / brand name	**ASEFO 5mg Sublingual Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sublingual Tablet Contains: Asenapine Maleate Eq. to Asenapine…5mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of drug substance	Form H
2.	Specify whether the drug substance is available as racemic mixture or otherwise.	API has two chiral centresbut is developed as a racemate.
3.	Justify why the qualitative composition of your product is different from the innovator's product.	Submitted.

Decision: Approved.

112.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14080: 06-06-2023
	Details of fee submitted	PKR 75,000/- : 30-05-2023
	The proposed proprietary name / brand name	**ASEFO 10mg Sublingual Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sublingual Tablet Contains: Asenapine Maleate Eq. to Asenapine…10mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of drug substance	Form H
2.	Specify whether the drug substance is available as racemic mixture or otherwise.	API has two chiral centresbut is developed as a racemate.
3.	Justify why the qualitative composition of your product is different from the innovator's product.	Submitted.

Decision: Approved.

113.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6028: 03-03-2023
	Details of fee submitted	PKR 75,000/- : 22-02-2023
	The proposed proprietary name / brand name	**ZOBLIN 120mg/4.8ml Oral Solution**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Celecoxib……25mg
	Pharmacotherapeutic Group of (API)	COX 2 Inhibitor
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	10ml bottle (containing 4.8ml liquid), 6's pack size / Price As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	The innovator's product is a stable non-aquous microemulsion and available as viscous solution, while your formulation is a oral solution available as clear and colorless solution.	
2.	Justify why the test for viscosity, droplet size, and microbiological testing is not included in drug product specifications.	

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

114.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10768: 28-04-2023
	Details of fee submitted	PKR 30,000/- : 28-03-2023
	The proposed proprietary name / brand name	**NAPESO 375/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Coated Modified Release Tablet Contains: Naproxen…375mg Esomeprazole as Magnesium…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…375mg Esomeprazole as Magnesium trihydrate (immediate release coat)…20mg
2.	Justify the performance of specificity test for naproxen API in the light of ICH Q2 guidelines.	Firm has submitted detailed protocols and test results for

		specificity test as per USP method.
3.	Justify why particle size distribution test is not performed by drug product manufacturer for naproxen API since particle size is a critical quality attribute for the applied product and the same is also included in the COA from drug substance manufacturer.	Particle size distribution test has been performed by API manufacturer and is evident from the COA.
4.	Justify how naproxen API complies both BP/USP while complete testing of API has not been performed.	API complies USP specs completely, however some tests are also added from BP and complies BP monograph.
5.	Submit drug substance testing method of both API from respective API manufacturer.	Submitted.
6.	Justify why test for magnesium content is not performed for esomeprazole API by drug product manufacturer.	Test protocols and results are submitted by the firm.
7.	Justify the use of omeprazole working standard from Surge Laboratories while the API manufacturer is Metrochem India.	Firm has submitted complete trail of the standardization of working standard against USP RS.
8.	USFDA review documents reveals that for acid stage testing of naproxen tablet, 475ml dissolution medium is to be used with 75rpm paddle speed, while you have used 1000ml dissolution medium with 50rpm paddle speed. Clarification is required in this regard.	We have followed FDA dissolution database parameters which are updated as compared to the review report
9.	USFDA review documents reveals that for buffer stage testing of naproxen tablet, 900ml of 0.05 M phosphate buffer pH 7.4 dissolution medium is to be used with 75rpm paddle speed, while you have used 1000ml of 0.05M phosphate buffer pH 6.8 dissolution medium with 50rpm paddle speed. Clarification is required in this regard.	We have followed FDA dissolution database parameters which are updated as compared to the review report
10.	Module 3.2.S for naproxen API specifies that the manufacturer is Dr. Reddy Laboratories, Mexico and the API COA also specify the same source. While the commercial invoice as well as GMP certificate of Dr. Reddy Laboratories Andhra Pradesh India is submitted. Clarification is required in this regard.	We have mistakenly attached GMP of Andhra Pradesh while our API manufacturing site is of Mexico.
11.	Submit documents for loan of API along with evidence of R&I submission in DRAP.	Submitted.

Decision: Approved.

- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

115.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9199: 05-04-2023
	Details of fee submitted	PKR 30,000/- : 28-03-2023
	The proposed proprietary name / brand name	**NAPESO 500/20 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Coated Modified Release Tablet Contains: Naproxen…500mg Esomeprazole as Magnesium…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…500mg Esomeprazole as Magnesium trihydrate (immediate release coat)…20mg
2.	Justify the performance of specificity test for naproxen API in the light of ICH Q2 guidelines.	Firm has submitted detailed protocols and test results for specificity test as per USP method.
3.	Justify why particle size distribution test is not performed by drug product manufacturer for naproxen API since particle size is a critical quality attribute for the applied product and the same is also included in the COA from drug substance manufacturer.	Particle size distribution test has been performed by API manufacturer and is evident from the COA.
4.	Justify how naproxen API complies both BP/USP while complete testing of API has not been performed.	API complies USP specs completely, however some tests are also added from BP and complies BP monograph.
5.	Submit drug substance testing method of both API from respective API manufacturer.	Submitted.
6.	Justify why test for magnesium content is not performed for esomeprazole API by drug product manufacturer.	Test protocols and results are submitted by the firm.
7.	Justify the use of omeprazole working standard from Surge Laboratories while the API manufacturer is Metrochem India.	Firm has submitted complete trail of the standardization of working standard against USP RS.
8.	USFDA review documents reveals that for acid stage testing of naproxen tablet, 475ml dissolution medium is to be used with 75rpm paddle speed, while you have used 1000ml dissolution medium with 50rpm paddle speed. Clarification is required in this regard.	We have followed FDA dissolution database parameters which are updated as compared to the review report
9.	USFDA review documents reveals that for buffer stage testing of naproxen tablet, 900ml of 0.05 M phosphate buffer pH 7.4 dissolution medium is to be used with 75rpm paddle speed, while you have used 1000ml of 0.05M phosphate buffer pH 6.8 dissolution medium with 50rpm paddle speed. Clarification is required in this regard.	We have followed FDA dissolution database parameters which are updated as compared to the review report
10.	Module 3.2.S for naproxen API specifies that the manufacturer is Dr. Reddy Laboratories, Mexico and the API COA also specify the same source. While the commercial invoice as well as GMP certificate of Dr. Reddy Laboratories Andhra Pradesh India is submitted. Clarification is required in this regard.	We have mistakenly attached GMP of Andhra Pradesh while our API manufacturing site is of Mexico.

11.	Submit documents for loan of API along with evidence of R&I submission in DRAP.	Submitted.

Decision: Approved.

- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

116.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2389: 25-01-2023
	Details of fee submitted	PKR 75,000/- : 22-11-2022
	The proposed proprietary name / brand name	**HYDROCORTISONE 100mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Hydrocortisone as Sodium Succinate…100mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Cortizone injection of M/s Vision pharmaceuticals
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

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 Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad
Manufacturer firm	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	Nagson 100mg IV Injection
Registration Board meeting	336

Decision: Approved.

a. Deferred cases

117.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Medasia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate Risalpur.
	Name, address of Manufacturing site.	M/s Medasia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate Risalpur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the drug product manufacturer	Firm has submitted copy of DML No. 000690 (Formulation) issued on 10-11-2021 along with covering letter on which the approved sections are mentioned including section namely Tablet (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000690 (Formulation) issued on 10-11-2021 along with covering letter on which the approved sections are mentioned including section namely Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32617 dated 14-11-2022
	Details of fee submitted	PKR 30000 dated: 26.10.2022 bearing Deposit Slip No. 76509063897
	The proposed proprietary name / brand name	**MOXASIA TABLET (400mg)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCL ….. 400mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's in ALU-ALU Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Molox 400 mg tablet by M/s CCL Pharma, Lahore. Registration No. 042716
	Name and address of API manufacturer.	Moxifloxacin HCL (USP): Sheer Jee Laboratory Private Limited, (Subsidery of Mankind Pharma Limited, C-24 & 25, Riico Industrial Area, Sontanala, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance. **(Batch no. MXYSQ005, MXYSQ006, MXYSQ007)**
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Moxiget 400 mg Tablet of M/s Getz Pharma (Pvt) Ltd, Krachi Batch No. 224C31 by performing quality tests including Identification, uniformity of dosage form, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Moxiget 400 mg Tablet of M/s Getz Pharma (Pvt) Ltd, Krachi Batch No. 224C31 in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Moxifloxacin HCL (USP): Sheer Jee Laboratory Private Limited, (Subsidery of Mankind Pharma Limited, C-24 & 25, Riico Industrial Area, Sontanala, India		
API Lot No.	**Not Provided**		
Description of Pack (Container closure system)	The proposed pack size of Pixiz Tablet 100/10mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3,6 (Months)		
Batch No.	001	002	003
Batch Size	1000 TABLETS	1000 TABLETS	1000 TABLETS
Manufacturing Date	10- 2021	10- 2021	10- 2021
Date of Initiation	15-10-2021	15-10-2021	15-10-2021

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Medasia Pharma is a new license facility hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	. GMP certificate No. DC-I/A-I/WHO-GMP/2019/203 dated 07/2-19 valid till three years
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• **Not Provided**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted**

Evaluation by PEC:

Following Documents are found deficient:

1. Provide valid GMP certificate of API manufacturer.
2. In the standard testing method for assay testing of API Moxifloxacin HCL (USP) the preparation of diluent and Mobile Phase is not done as specified in the USP monograph.
3. USP Specified test namely Microbial Enumeration test and enantiomeric impurity are performed by DS manufacturer in COA but not in stability test reports of API batches.
4. Specifications of excipients are not mentioned. The excipients used are different from the innovator Product (MHRA), therefore, submit compatibility studies .
5. The CDP and test reports are un-signed.
6. Uniformity of content test is USP specified test but is not performed during stability of Drug Product.
7. The HPLC conditions (Injection volume and flow rate) are different from the ones specified in USP in assay testing of Drug Product.
8. Chromatograms supporting the stability studies are not submitted for every point of stability testing.
9. Compliance Record of HPLC software 21CFR & audit trail reports on product testing & Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.
10. BMR of trial batches is not submitted.
11. Specify the API Lot No being used in trial batches along with Documents for the procurement of API with approval from DRAP (in case of import).

Decision of 323rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Submission by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Provide valid GMP certificate of API manufacturer.	Submitted.
2.	In the standard testing method for assay testing of API Moxifloxacin HCL (USP) the preparation of diluent and Mobile Phase is not done as specified in the USP monograph.	Submitted.

3.	USP Specified test namely Microbial Enumeration test and enantiomeric impurity are performed by DS manufacturer in COA but not in stability test reports of API batches.	The enantiomeric test and microbial enumeration test is not included in stability specifications as its values are constant and do not change with temperature.
4.	Specifications of excipients are not mentioned. The excipients used are different from the innovator Product (MHRA), therefore, submit compatibility studies.	Firm has submitted that all excipients are pharmacopoeial. Moreover, results of stability studies evident that the formulation is compatible.
5.	The CDP and test reports are un-signed.	Submitted.
6.	Uniformity of content test is USP specified test but is not performed during stability of Drug Product.	This test is included in shelf life and release specifications however it is not part of stability specification.
7.	The HPLC conditions (Injection volume and flow rate) are different from the ones specified in USP in assay testing of Drug Product.	**Not submitted.**
8.	Chromatograms supporting the stability studies are not submitted for every point of stability testing	Submitted.
9.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing & Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.	HPLC system is not 21 CFR compliant. Record of data logger is submitted.
10.	BMR of trial batches is not submitted.	Submitted.
11.	Specify the API Lot No being used in trial batches along with Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted **non** attested commercial invoice.

Decision: Deferred for following:

- **Clarification since the HPLC conditions (Injection volume and flow rate) are different that specified in USP in assay testing of Drug Product.**
- **Documents for the procurement of API with approval from DRAP.**

118.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3146: 02-02-2023
	Details of fee submitted	PKR 75,000/- : 09-01-2023
	The proposed proprietary name / brand name	**Ampica 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Ampicillin (as trihydrate)……..500mg
	Pharmaceutical form of applied drug	Gray opaque cap and light blue opaque body hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Penbritin Capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK. Firm has submitted results of pharmaceutical

		equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00002/012/2022		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-01	A-02	A-03
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.

- Specify whether the drug substance used is in compacted form or micronized.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.
- Submit evidence of automatic analyzer equipped with spectrophotometer having analysis capability at 480 nm.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide description of container closure system whether Alu-Alu blister or otherwise.
- USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard.
- Justify how the dissolution testing performed in stability studies is according to the method specified in USP monograph.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer..	**Not Submitted.** Firm has submitted analytical method of drug product.
2.	Provide verification studies of drug substance from drug product manufacturer.	**Not Submitted.** Firm has not submitted report of verification studies, instead a tabulated summary, raw data and chromatograms are submitted.
3.	Specify whether the drug substance used is in compacted form or micronized.	Compacted
4.	Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.	**Not Submitted.** Again the same table is submitted.
5.	Submit evidence of automatic analyzer equipped with spectrophotometer having analysis capability at 480 nm.	**Not Submitted.**
6.	Provide COA of reference standard / working standard actually used in the analysis of drug product.	Submitted.
7.	Provide description of container closure system whether Alu-Alu blister or otherwise.	Alu-Alu blister in unit carton
8.	USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard.	**Not Submitted.**

9.	Justify how the dissolution testing performed in stability studies is according to the method specified in USP monograph.	**Not Submitted.**
10.	Submit copy of invoice for procurement of drug substance from Pharmagen.	**Not Submitted.**
11.	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
12.	Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	Submitted

Decision: Deferred for following:

- **Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.**
- **Provide verification studies of drug substance from drug product manufacturer.**
- **Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.**
- **Submit evidence of automatic analyzer equipped with spectrophotometer having analysis capability at 480 nm.**
- **USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard.**
- **Justify how the dissolution testing performed in stability studies is according to the method specified in USP monograph.**
- **Submit copy of invoice for procurement of drug substance from Pharmagen.**

119.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5489,: 27-02-2023
	Details of fee submitted	PKR 30,000/- : 20-01-2023
	The proposed proprietary name / brand name	**APRIN 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Apremilast…30mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	

2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision of 336th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted
3.	Submit details against which CDP and PE studies are conducted	Submitted
4.	Submit GMP certificate of the API manuafcturer.	Submitted
5.	Submit evidence of purchase of API.	Firm has submitted copy of drug import License, commercial invoice, Form 3, Form 7 and Fedex slip

Decision: Approved.

120.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt) Ltd Plot No. 241, Sector-24, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt) Ltd Plot No. 241, Sector-24, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 27-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 07-06-2022 specifying Liquid Injection Vial/Ampoule (Steroid) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 30260: dated 05-11-2021
	Details of fee submitted	PKR 30,000/- Dated 28-05-2021
	The proposed proprietary name / brand name	**DEXACORT Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml injection contains: Dexamethasone (as sodium phosphate).....3.3mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Systemic corticosteroid
	Reference to Finished product specifications	USP

	Proposed Pack size	25's:
	Proposed unit price	Rs. 1250
	The status in reference regulatory authorities	Dexamethasone Sodium Phosphate Injection (MHRA Approved)
	For generic drugs (me-too status)	Decadron Injection by OBS
	Name and address of API manufacturer.	Zhejiang Xianju Pharmaceutical Co Ltd. No 1, Xianyao Road, Xianju Taizhou Zhejiang China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Dexamethasone Injection from Hospira UK Limited
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA	
Manufacturer of API	Zhejiang Xianju Pharmaceutical Co Ltd. No 1, Xianyao Road, Xianju Taizhou Zhejiang China
API Lot No.	150815
Description of Pack (Container closure system)	Glass ampoule
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TB-101	TB-102	TB-103
Batch Size	1 L	1 L	1 L
Manufacturing Date	01-2017	01-2017	01-2017
Date of Initiation	01-2017	01-2017	01-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by CFDA China valid till 28-10-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice clared dated 28-11-2017 specifying dexamethasone base raw material
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit IR spectra for characterization of drug substance in section 3.2.S.3	Submitted
2.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	Submitted
3.	Specify details including the expiry date and manufacturer of the product against which pharmaceutical studies are conducted	Dexamthasone Injection 3.3mg/ml by Hospira UK Limited. Batch No FDT258
4.	Submit valid GMP certificate of API manufacturer	Not submitted
5.	The submitted API clearance specify dexamethasone base while the product contains dexamtheasone sodium phosphate. Clarify	No justification is submitted
6.	The submitted API clearance is dated 28-11-2017 while your batches have been manufactured in January 2017	No justification is submitted
8.	Submit copy of BMR of all batches	Submitted.

Decision of 336th RB meeting: Deferred for following:

- Valid GMP certificate of API manufacturer.
- Clarification since the submitted API clearance specify dexamethasone base while the product contains dexamtheasone sodium phosphate.

- Clarification since the submitted API clearance is dated 28-11-2017 while the batches have been manufactured in January 2017.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Valid GMP certificate of API manufacturer.	GMP certificate of API manufacturer has issue date October 2015 and was valid till October 2020. The new certificate shall be collected on commercial order of API.
2.	Clarification since the submitted API clearance specify dexamethasone base while the product contains dexamtheasone sodium phosphate.	Firm has submitted that they are using dexamethasone in two already registered products, Tobra-D and Ophth Dex. The assistant mistakenly attach COA of Dexamethasone instead of dexamethasone sodium phosphate.
3.	Clarification since the submitted API clearance is dated 28-11-2017 while the batches have been manufactured in January 2017.	Firm has submitted that they are using dexamethasone in two already registered products, Tobra-D and Ophth Dex. The assistant mistakenly attach clearance certificate of 24-11-2016 instead of required certificate. Firm has now submitted another copy of commercial invoice cleared dated 01-12-2016. The new submitted invoice has the same invoice number as that of previously submitted invoice as well as Bank contract number.

Decision: Registration Board decided to defer the case for following:

- **Verification of the submitted clarance certificate / cleared invoice from DRAP Karachi office.**
- **Valid GMP certificate of API manufacturer.**
- **Clarification since the submitted API clearance is dated 28-11-2017 while the batches have been manufactured in January 2017.**

121.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 35495: 07-12-2022
	Details of fee submitted	PKR 30,000/- : 04-10-2022
	The proposed proprietary name / brand name	**PHYTONADIONE 10mg/1ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Vitamin K1…10mg
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted
3.	Submit details against which PE studies are conducted	Submitted
4.	Submit GMP certificate of the API manuafcturer.	Submitted.
5.	Submit evidence of purchase of API.	Submitted.

Decision: Approved.

122.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.**
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33635: 22-11-2022
	Details of fee submitted	PKR 75,000/- : 08-11-2022
	The proposed proprietary name / brand name	**DELA 450mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Delafloxacin Meglumine Eq. to Delafloxacin…450mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of your drug substance.	
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
3.	Submit signed and stamped stability study data of API from API manufacturer.	

4.	The review of innovator's product specify that the drug product release more than 85% in 10 minutes in 0.1 N HCl while your results show less than 70% results. Clarification is required in this regard.	
5.	Submit pictorial evidence of the reference pack used for PE and CDP studies.	
6.	Submit 6 month's stability study data.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Specify the polymorphic form of your drug substance.	Crystal Form I A
2.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
3.	Submit signed and stamped stability study data of API from API manufacturer.	Submitted.
4.	The review of innovator's product specify that the drug product release more than 85% in 10 minutes in 0.1 N HCl while your results show less than 70% results. Clarification is required in this regard.	CDP carried out against innovator's show similar release pattern of dissolution in acidic media. Furthermore FDA review also depicts that the product is insoluble in acidic medium.
5.	Submit pictorial evidence of the reference pack used for PE and CDP studies.	Submitted.
6.	Submit 6 month's stability study data.	Submitted.

Decision: Approved.

123.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1180: 13-01-2023
	Details of fee submitted	PKR 30,000/- : 15-11-2022
	The proposed proprietary name / brand name	**METFORMIN HCl 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hcl…500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	

2.	Submit verification studies of the analytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted
3.	Submit details against which CDP and PE studies are conducted	Submitted
4.	Submit GMP certificate of the API manuafcturer.	Submitted
5.	Submit evidence of purchase of API.	Submitted

Decision:

124.	Name, address of Applicant / Marketing Authorization Holder	M/s Gray's Pharmaceuticals., 7 km, Pasrur Road, Sialkot.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot # 145 Industrial Triangles, kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) The firm has submitted copy of agreement between M/s Islam Pharmaceuticals and M/s Bio-Labs (Pvt.) Ltd, Islamabad made on 21-01-2020.
	GMP status of the firm	**M/s Gray's Pharmaceuticals:** The firm has submitted copy of GMP certificate based on inspection conducted on 14-09-2021. **M/s Bio-Labs Pvt Ltd:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	The manufacturer has provided Lyophilized vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3564: 01-02-2021
	Details of fee submitted	PKR 50,000/-: 17-11-2020
	The proposed proprietary name / brand name	Epra 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole…….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor

	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole powder for solution for infusion of M/s Sandoza Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Rajasthan Antibiotics Ltd., Plot no A-619 & 630, Rico Industrial Area Bhiwadi-301019 Rajasthan, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted stability study data of 6 months accelerated and 36 months real time data of 3 batches of API as per Zone-IV A.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of their developed formulation Delka 40mg IV Injection (B # L 289) with comparator product Risek 40mg Injection IV (B # 788P06) of M/s GETZ Pharma, Karachi. Quality tests of both products including description, identification, pH, assay, Sterility and bacterial endotoxins were performed and compared.

	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Rajasthan Antibiotics Ltd., Plot no A-619 & 630, Rico Industrial Area Bhiwadi-301019 Rajesthan, India		
API Lot No.	AOSS19032		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Delka 40mg IV Injection			
Batch No.	L-140	L-163	L-197
Batch Size	25000 vials	20,000 vials	15,000 vials
Manufacturing Date	03-2018	06-2018	11-2018
Date of Initiation	10-03-2018	15-06-2018	13-12-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of Omeprazole sodium.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

S.#	**Observations communicated**	**Response by the firm**
1.	Provide results of analysis of relevant batch(es) of Drug Substance used during product development and stability studies, along with Certificate of Analysis (CoA) of the	The firm has submitted that API lot used in stability studies procured from Rajasthan Antibiotics while provided DMF was from Metrochem. We are

	same batch from Drug Substance manufacturer.	submitting DMF from Rajasthan antibiotics and COAs accordingly.
2.	Details of applicant batch number and comparator product batch number used for pharmaceutical equivalence studies are required.	Revised pharmaceutical equivalence report has been submitted.
3.	Data of commercial batches with different batch numbers was given in process validation reports, batch analysis of finished product and stability studies.	We do not perform process validation on all manufactured batches. We performed stability study and process validation on different batches however we are submitting revised batch analysis of stability batches.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator product should be submitted and discussed as per requirements of section 3.2.P.2.	The firm has submitted we used market leader product (Risek 40mg Injection) of GETZ pharma which was approved by DRAP.
5.	Justification is required for using UV spectrophotometric method in place of HPLC method for assay testing of Delka 40mg Injection IV.	The firm has submitted that since product is of in-house specifications and in-house validated method is applied for testing which is UV-visible spectrophotometer. Validation of analytical method is provided in module 3.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Response not submitted against this point.
7.	Evidence of procurement of drug substance with approval from DRAP is required.	Response not submitted against this point.

Decision of 316th meeting of RB:

Deferred for submission of following:

- Scientific justification of manufacturing of applied formulation by way of lyophilization using pre-lyophilized omeprazole sodium from M/s Rajasthan Antibiotics, India.
- Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.
- Approval of API/ DML/GMP certificate of API manufacturer (Rajasthan antibiotics) issued by concerned regulatory authority of country of origin.
- Evidence of procurement of drug substance with approval from DRAP.
- Submission of Pharmaceutical equivalence studies against innovator/reference product, manufactured by way of lyophilization.

Response by the firm:

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.

125.	Name, address of Applicant / Marketing Authorization Holder	M/s Gray's Pharmaceuticals Plot # 2, St. N-3, National Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd, Plot No. 145industrial Triangle Kahuta road Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Gray's Pharma:** **M/s Bio-Labs (Pvt) Ltd:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Bio-Labs (Pvt) Ltd:** The manufacturer has provided Lyophilized vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13163; Dated: 06-05-2021
	Details of fee submitted	PKR 50,000/-: Dated: 25-02-2021
	The proposed proprietary name / brand name	Panazole 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Pantoprazole sodium eq. to Pantoprazole (lyophilized powder)..…….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Protonix IV 40mg Injection of M/s Wyeth Pharms (USFDA Approved)
	For generic drugs (me-too status)	Toprazole 40mg Injection by M/s Morgan Technologies Services (Reg # 045728).
	Name and address of API manufacturer.	M/s Rajasthan Antibiotics Ltd. A-619 & 630 RIICO Industrial Area, Bhiwadi – India.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C±2°C / 65% ± 5%RH for 36 months Accelerated: 40°C±2°C/ 75% ± 5%RH for 6 months Batches: (PSS-032/10, PSS-033/10, PSS-034/10)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has submitted pharmaceutical equivalence data against the comparator product Zopent 40mg Injection (Batch No:) by NabiQasim Industries by performing quality tests (Physical appearance, water content, pH, BET, Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Rajasthan Antibiotics Ltd. A-619 & 630 RIICO Industrial Area, Bhiwadi Dist. Alwar (Rajasthan) – India.		
API Lot No.	17-12902, APSS18001,		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Real Time: 0, 3, 6, 9, 12, 18, 24 (Months) Accelerated: 0, 3, 6 (Months)		
Pan Cap 40mg IV Injection			
Batch No.	L-181	L-105	L-134
Batch Size	7000 vials	7100 vials	8000 vials
Manufacturing Date	09-2018	04-2017	12-2017
Date of Initiation	15-11-2018	03-06-2017	26-02-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No. DC/A-I/WHO-GMP/2020/1961) issued by Government of Rajasthan dated 09-12-2020. The certificate is valid till 26-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Pantoprazole sodium sterile (Batch no. UIPSS20037) attested by AD (I & E) dated 24-02-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has not submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
The firm has submitted new data which need to be evaluated		
Decision of 322nd RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
Evaluation by PEC: The submitted data by the firm has been evaluated.		
Decision: Approved.		

126.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories, Plot # 121 Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.

		Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16114: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 30-04-2021
	The proposed proprietary name / brand name	**NALPHIN Injection 10mg/mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and

		process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Kinz injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.	~~1909000314~~		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit contract manufacturing agreement between contract giver and contract acceptor.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.

- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

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

Response by the firm:
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 Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	NALCIN 10mg Injection
Registration Board meeting	336

Decision: Approved.

127.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Alliance Pharmaceuticals (Pvt) Ltd. 112-A Industrial Estate Hayatabad Peshawar.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 01-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16111: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 07-04-2021
	The proposed proprietary name / brand name	**ALLOPHINE Injection 10mg/mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical

		procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Kinz injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.			
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.

- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

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

Response by the firm:
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 Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	NALCIN 10mg Injection
Registration Board meeting	336

Decision: Approved.

128.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 29331: 17-10-2022
	Details of fee submitted	PKR 75,000/-: 26-08-2022
	The proposed proprietary name / brand name	**Nextphen 10mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product

		against the comparator i.e. Kinz injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.			
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The product development and stability study data of the contract manufacturer was considered by Registration Board in its 323rd meeting and deferred for submission of following documents:

- Submit contract manufacturing agreement between contract giver and contract acceptor.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures

used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."

- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.

- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

Decision of 333rd RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:
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 Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	NALCIN 10mg Injection
Registration Board meeting	336

Decision: Approved.

129.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31989: 07-11-2022
	Details of fee submitted	PKR 75,000/-: 01-11-2022
	The proposed proprietary name / brand name	**NALB 10mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Nalbuphine HCl……10mg

	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Kinz injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.			
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The product development and stability study data of the contract manufacturer was considered by Registration Board in its 323rd meeting and deferred for submission of following documents:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit contract manufacturing agreement between contract giver and contract acceptor.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed*

by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".

- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

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

Response by the firm:
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 Focus & Rulz Pharmaceuticals (Pvt) Ltd44 - Industrial Triangle, Kahuta RoaD, Islamabad
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Brand Name	NALCIN 10mg Injection
Registration Board meeting	336

Decision: Approved.

130.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31570: 03-11-2022
	Details of fee submitted	PKR 30,000/- : 11-10-2022
	The proposed proprietary name / brand name	**JENSOLOR 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Prucalopride as Succinate…1mg
	Pharmacotherapeutic Group of (API)	Drugs for constipation
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	
3.	Submit details against which CDP and PE studies are conducted	
4.	Submit GMP certificate of the API manuafcturer.	
5.	Submit evidence of purchase of API.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specificaions and analytical procedure of drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit verification studies of the nalaytical method of API from drug product manufacturer	Submitted
3.	Submit details against which CDP and PE studies are conducted	Submitted
4.	Submit GMP certificate of the API manuafcturer.	Submitted

5.	Submit evidence of purchase of API.	Submitted
Decision: Approved.		

131.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 12-01-2022 specifying Tablet (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22084: 03-08-2022
	Details of fee submitted	PKR 30,000/-: 27-07-2022
	The proposed proprietary name / brand name	**BRICIP 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……250mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against novidat tablet of Sami Firm has submitted results of CDP for their product against novidat tablet of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/055/2020		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B1	T-B2	T-B3
Batch Size	1666 Tablet	1666 Tablet	1666 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	08-05-2021	08-05-2021	08-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note for 5Kg Ciprofloxacin hydrochloride dated 11-06-2020 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit GMP certificate / inspection report of the drug product manufacturer.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Submit API stability data till complete shelf life since the real time stability data is only for 12 months.
- Justify why the qualitative composition of your product is different from that of innovator's product.
- Provide description of pharmaceutical development as per the CTD guidance document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".
- Submit information in section 3.2.P.2.1.1 as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."
- Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.
- Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.
- Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.
- Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.
- Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.
- Provide information in section 3.2.P.8.2 as per the CTD guidance document.

- Justify why dissolution test is not performed in stability studies.
- USP monograph specifies that the retention time for ciprofloxacin is 6.4 - 10.8min, while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes.
- USP monograph specifies the use of Ciprofloxacin Ethylenediamine Analog in standard solution as system suitability solution and that The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively, while your analysis does not show any other peak within the relative retention time of 0.7 and 1.0.
- Submit evidencd of column oven having capacity to maintain column temperature at 30°.
- Submit Reference of previous approval of applications with stability study data of the firm (if any).
- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Provide proper raw data sheets showing calculation of results of assay instead of just submitting results without any calculation.
- Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

Response by the firm:

Deficiencies	Response by the firm
Submit GMP certificate / inspection report of the drug product manufacturer	Submitted
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration board which specifies that Copies of the drug substance specification and analytical procedures used for routine testing of the drug substance /active pharmaceutical ingredient by both drug substance & drug product manufacturer is required .you have only submitted the specifications of API from the drug product manufacturer .	Submitted
Provide verification studies of drug substance from drug product manufacturer.	Submitted
Submit COA of reference standard / working standard actually used in the analysis of drug substance.	Submitted
Submit API stability data till complete shelf life since the real time stability data is only for 12 month.	Submitted
Justify why the qualitative composition of your product is different from that of innovator's product.	Submitted
Provide description of pharmaceutical development as per the CTD guidance document which specifies that A brief information on the pharmaceutical development shall be included this information specifies the justification of formulation and method of manufacturing it is also important that critical quality attributes (CQAs) and critical process parameters (CCP) shall be discussed	Submitted
Submit information in section 3.2.P.1.1 as per the CTD guidance document which specifies that discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, and particle size distribution, polymorphic or solid state form) of the drug substance (s) that can influence performance of the drug product.	Submitted
Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	As Product specifications are of USP specification so the Pharmaceutical equivalence studies were performed against the same USP specification comparator product.

Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients	Section 3.2.P.4 is revised.
Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.	Complete analytical method of the drug product is submitted
Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.	Submitted
Provide COA of working standard /reference standard actually used in the analysis of drug product in section 3.2.P.6.	Submitted
Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section	Submitted
Provide information in section 3.2.P.8.2 as per CTD guidance document	Submitted
Justify why dissolution test is not performed in stability studies	Dissolution data was performed in stability studies but the test was skipped unintentionally in the documentation of stability data.
USP monograph specifies that the retention time for ciprofloxacin is 6.4-10.8 min , while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes	Testing was performed as per specified method of Ciprofloxacin tablet USP monograph and RT of peak obtained was about 6.2minutes. No change was done to adjust the retention time.
USP monograph specifies the use of ciprofloxacin ethylenediamine analog in standard solution as system suitability solution and that the relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0 respectively, while your analysis does not show any other peak within the relative retention times of 0.7 and 1.0.	For stability testing, system suitability solution was not used. After registration, we will use system suitability solution and will follow the method as per the USP monograph.
Submit evidenced of column oven having capacity to maintain column temperature at 30◦	Evidence of Column oven is Submitted
Submit reference of previous approval of applications with stability study data of the film (if any)	Submitted
Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.	Submitted
Provide proper raw data sheets showing calculation of results of assay Instead of just submitting results without any calculation.	Submitted
Submit compliance record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

Decision: Approved.

132.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 12-01-2022 specifying Tablet (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22085: 03-08-2022
	Details of fee submitted	PKR 30,000/-: 27-07-2022
	The proposed proprietary name / brand name	**BRICIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……500mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.

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

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/055/2020		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B1	T-B2	T-B3
Batch Size	834 Tablet	834 Tablet	834 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	08-05-2021	08-05-2021	08-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note for 5Kg Ciprofloxacin hydrochloride dated 11-06-2020 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets,

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

Evaluation by PEC:

- Submit GMP certificate / inspection report of the drug product manufacturer.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Submit API stability data till complete shelf life since the real time stability data is only for 12 months.
- Justify why the qualitative composition of your product is different from that of innovator's product.
- Provide description of pharmaceutical development as per the CTD guidance document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".
- Submit information in section 3.2.P.2.1.1 as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."
- Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.
- Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.
- Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.
- Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.
- Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.
- Provide information in section 3.2.P.8.2 as per the CTD guidance document.
- Justify why dissolution test is not performed in stability studies.
- USP monograph specifies that the retention time for ciprofloxacin is 6.4 - 10.8min, while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes.
- USP monograph specifies the use of Ciprofloxacin Ethylenediamine Analog in standard solution as system suitability solution and that The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively, while your analysis does not show any other peak within the relative retention time of 0.7 and 1.0.
- Submit evidencd of column oven having capacity to maintain column temperature at 30°.
- Submit Reference of previous approval of applications with stability study data of the firm (if any).

- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Provide proper raw data sheets showing calculation of results of assay instead of just submitting results without any calculation.
- Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

Response by the firm:

Deficiencies	**Response by the firm**
Submit GMP certificate / inspection report of the drug product manufacturer	Submitted
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration board which specifies that Copies of the drug substance specification and analytical procedures used for routine testing of the drug substance /active pharmaceutical ingredient by both drug substance & drug product manufacturer is required .you have only submitted the specifications of API from the drug product manufacturer .	Submitted
Provide verification studies of drug substance from drug product manufacturer.	Submitted
Submit COA of reference standard / working standard actually used in the analysis of drug substance.	Submitted
Submit API stability data till complete shelf life since the real time stability data is only for 12 month.	Submitted
Justify why the qualitative composition of your product is different from that of innovator's product.	Submitted
Provide description of pharmaceutical development as per the CTD guidance document which specifies that A brief information on the pharmaceutical development shall be included this information specifies the justification of formulation and method of manufacturing it is also important that critical quality attributes (CQAs) and critical process parameters (CCP) shall be discussed	Submitted
Submit information in section 3.2.P.1.1 as per the CTD guidance document which specifies that discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, and particle size distribution, polymorphic or solid state form) of the drug substance (s) that can influence performance of the drug product.	Submitted
Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	As Product specifications are of USP specification so the Pharmaceutical equivalence studies were performed against the same USP specification comparator product.
Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients	Section 3.2.P.4 is revised.
Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.	Complete analytical method of the drug product is submitted
Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.	Submitted
Provide COA of working standard /reference standard actually used in the analysis of drug product in section 3.2.P.6.	Submitted

Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section	Submitted
Provide information in section 3.2.P.8.2 as per CTD guidance document	Submitted
Justify why dissolution test is not performed in stability studies	Dissolution data was performed in stability studies but the test was skipped unintentionally in the documentation of stability data.
USP monograph specifies that the retention time for ciprofloxacin is 6.4-10.8 min , while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes	Testing was performed as per specified method of Ciprofloxacin tablet USP monograph and RT of peak obtained was about 6.2minutes. No change was done to adjust the retention time.
USP monograph specifies the use of ciprofloxacin ethylenediamine analog in standard solution as system suitability solution and that the relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0 respectively, while your analysis does not show any other peak within the relative retention times of 0.7 and 1.0.	For stability testing, system suitability solution was not used. After registration, we will use system suitability solution and will follow the method as per the USP monograph.
Submit evidenced of column oven having capacity to maintain column temperature at 30◦	Evidence of Column oven is Submitted
Submit reference of previous approval of applications with stability study data of the film (if any)	Submitted
Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.	Submitted
Provide proper raw data sheets showing calculation of results of assay Instead of just submitting results without any calculation.	Submitted
Submit compliance record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

Decision: Approved.

133.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan**
	Name, address of Manufacturing site.	M/s Lucky Core Industries Limited. 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2734: 31-01-2023
	Details of fee submitted	PKR 30,000/- : 25-01-2023
	The proposed proprietary name / brand name	**LUMONT 4mg Sachet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast as Sodium…4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Myteka sachet by Hilton
	Proposed Pack size	As per SRO

Evaluation by PEC[3] :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
2.	Submit COA of relevant batch of API from both API manufacturer as well as drug product manufacturer.	
	Submit COA of reference standard / working standard actually used in the analysis of API.	
3.	Provide details about the particle size of API as well as mannitol used for the product development.	
4.	CDP studies show negligible drug release in 15 minutes while innovator's product literature reveals that the drug product release more than 85% within 10-15 inutes. Clarification is required in this regard.	
5.	Submit evidence of import of API including clearance certificate.	
6.	Submit BMR of three stability batches.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
2.	Submit COA of relevant batch of API from both API manufacturer as well as drug product manufacturer.	Submitted
	Submit COA of reference standard / working standard actually used in the analysis of API.	Submitted
3.	Provide details about the particle size of API as well as mannitol used for the product development.	Submitted
4.	CDP studies show negligible drug release in 15 minutes while innovator's product literature reveals that the drug product release more than 85% within 10-	The dissolution recovery (or drug release) of Montelukast oral granules (Lumont sachet) has been found to be negligible within 15 minutes. This is because the innovator of Singulair Oral Granules employed the surfactant Sodium Dodecyl Sulfate (SDS) as a dissolution medium, which is recommended by the US Phanuacopoeia for routine

	15 inutes. Clarification is required in this regard.	dissolution testing of Montelukast Oral Granules, but not as CDP medium. The comparative dissolution media recommended by the FDA BCS are 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5), and Phosplate Buffer (pH 6.8). Therefore, during the CDP study in these media, according to the DRAP Minutes of the 293rd Meeting of the Registration Board (6th -8th January, 2020 the use of any surfactant is not acceptable. Conseouentlv, the firm did not use any surfactant, which explains why our drug release is negligible within 15 minutes.
5.	Submit evidence of import of API including clearance certificate.	Submitted.
6.	Submit BMR of three stability batches.	Submitted.
Decision: Approved.		

Case No. 02 Cases of Import applications

a. Deferred cases

134.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories. B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 002 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 15-08-2022 **Status:** by way of wholesaler **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	TÜM EKİP İLAÇ A.Ş; Address: İstanbul Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.55 34956 Tuzla-İSTANBUL/TURKEY
	Name, address of manufacturer(s)	TÜM EKİP İLAÇ A.Ş; Address: Tuzla Kimya Organize Sanayi Bölgesi, Aromatik Cad. No.63 34956 Tuzla-Istanbul/Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Firm has submitted original, legalized copy of CoPP certificate (No. 2020/2988) dated 13-10-2020 issued by Republic of Turkey Ministry of health and medical education. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 13-10-2022. • Firm has submitted GMP certificate no. 06244 issued by Turkish Medicine & Medical Devices Agency.	
	Details of letter of authorization / sole agency agreement • Firm has submitted copy of letter of authorization from TÜM EKİP İLAÇ A.Ş; Company. The letter shows that the manufacturer appoints M/s Gene-Tech Laboratories to register and market their products in Pakistan.	

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported product s, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 21170 dated 03-08-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021 & Rs.50,000/- dated 05-07-2021
	The proposed proprietary name / brand name	**Agrabloc 12.5mg/50ml Concentrate Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml Vial Contains: Tirofiban as hydrochloride monohydrate…12.5mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	B01AC17 Platelet aggregation inhibitors, except heparin
	Reference to Finished product specifications	In house
	Proposed Pack size	12.5mg/50ml, 1 vial per box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Aggrastat 250mcg/ml injection approved by MHRA of UK
	For generic drugs (me-too status)	Agraban 12.5mg/50ml of M/s Pharmasol (Reg.106293)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability	The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months.

	studies)	The real time stability data is conducted at 25°C ± 2°C and 60% ± 5% for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of Caelyx injection has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	AGRABLOC 12.5 mg/50 ml IV Concentrate Solution For Infusion is packed with the following primary packaging materials: - 50 ml colorless Type I glass vial - 20 mm bromobutyl red rubber stopper - 20 mm flip-off cover AGRABLOC is supplied as 1 vial with a PIL in box containing approved text, batch number and expiration date.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40 ± 2°C, 75 % ± 5 % R.H for 6 months. The real time stability study data is conducted at 30 ± 2°C, 75 % ± 5 % R.H for 24 months.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.3.3	Submit original valid legalized GMP certificate of drug product manufacturer and COPP of applied product issued by relevant regulatory authority of country of origin.	• Firm has submitted copy of GMP certificate no. IT-API/249/H/2022 issue din name of M/s Farmabios S.p.A on basis of inspection conducted on 01-10-2021 by competent authority of Italy, wherein API manufacturing activity of Tirofiban has been endorsed. • Firm has submitted original, legalized CoPP certificate (No. 2023/3145) dated 25-07-2023 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 24-07-2025. • Firm has submitted original legalized GMP certificate no. TR/GMP/2023/150 issued by Turkish Medicine & Medical Devices Agency covering manufacturing operations of Sterile products.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL as per following details: **License No:** 0311 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan

		Validity: 30-01-2028 **Status:** by way of wholesaler **Address of Godown:** N/A
3.2.P.2.1	Submit drug-excipient compatibility studies since qualitative composition of applied formulation is different from that of the innovator drug product. Moreover Clarification shall be submitted regarding inclusion of mannitol in master formulation since innovator drug product does not contain it.	Agrabloc formulaton differs from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is differen the pH range of the solution has not changed. Likewise the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that th prdouct retains the same properties as at time of manufacture.
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	Agrabloc and original product's pH is same.
3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization.	Terminal sterilization cannot be applied to solution-type products that are not resistant to autoclave temperature in the final primary packaging the drug solution is sterilized by passing through a suitable bacteria retaining filter after preparation. When the filter integrity test records made before and after this filtration process confirm the performance of the filtration process it is proven that the solution has been fully sterilised at this point. The portion of the manufcaturing process from thi s point until the fully closed finished product will be viewed as an aseptic processin. In other words, aseptic filling and closure will ensure sterility for all vials of the series produced depending on the adequacy of the measures taken at the facility. "In accordance with the general section titled "Methods for the Preparation of Sterile Products", validation studies accordance (including with sterility assurance level study) of the aseptic processes cesses (filling and closing steps) of this product after Sterile filtration are carried out at regular intervals (separately for each dosage form and volume) according to the relevant procedure.
3.2.P.8.3	• Long term stability studies on Zone-IV conditions till claimed shelf life shall be submitted for three batches	Firm has submitted long term stability studies data of three batches of applied product at Zone-IVb conditions for 24 months.

Decision of 330th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response:

Section#	Observations	Firm's response
1.3.3	Submit original valid legalized GMP certificate of drug product manufacturer and COPP of applied product issued by relevant regulatory authority of country of origin.	• Firm has submitted copy of GMP certificate no. IT-API/249/H/2022 issue din name of M/s Farmabios S.p.A on basis of inspection conducted on 01-10-2021 by competent authority of Italy, wherein API manufacturing activity of Tirofiban has been

		endorsed. • Firm has submitted original, legalized CoPP certificate (No. 2023/3145) dated 25-07-2023 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. • The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP was valid till 24-07-2025. • Firm has submitted original legalized GMP certificate no. TR/GMP/2023/150 issued by Turkish Medicine & Medical Devices Agency covering manufacturing operations of Sterile products.
1.3.5	Copy of valid DSL of the applicant shall be submitted.	Firm has submitted copy of DSL as per following details: **License No:** 0311 **Address:** 246-B, Block 6, P.E.C.H.S, Karachi, Pakistan **Validity:** 30-01-2028 **Status:** by way of wholesaler **Address of Godown:** N/A
3.2.P.2.1	Submit drug-excipient compatibility studies since qualitative composition of applied formulation is different from that of the innovator drug product. Moreover Clarification shall be submitted regarding inclusion of mannitol in master formulation since innovator drug product does not contain it.	Agrabloc formulaton differs from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is differen the pH range of the solution has not changed. Likewise the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that the prdouct retains the same properties as at time of manufacture.
3.2.P.2.2.1	Justification shall be submitted for the limit & results of pH test applied in Pharmaceutical equivalence studies with reference to pharmacopoeial monograph.	Agrabloc and original product's pH is same.
3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization.	Terminal sterilization cannot be applied to solution-type products that are not resistant to autoclave temperature in the final primary packaging the drug solution is sterilized by passing through a suitable bacteria retaining filter after preparation. When the filter integrity test records made before and after this filtration process confirm the performance of the filtration process it is proven that the solution has been fully sterilised at this point. The portion of the manufcaturing process from thi s point until the fully closed finished product will be viewed as an aseptic processin. In other words, aseptic filling and closure will ensure sterility for all vials of the series produced depending on the adequacy of the measures taken at the facility. "In accordance with the general section titled "Methods for the Preparation of Sterile Products", validation studies accordance (including with sterility assurance level

		study) of the aseptic processes cesses (filling and closing steps) of this product after Sterile filtration are carried out at regular intervals (separately for each dosage form and volume) according to the relevant procedure.
3.2.P.8.3	• Long term stability studies on Zone-IV conditions till claimed shelf life shall be submitted for three batches	Firm has submitted long term stability studies data of three batches of applied product at Zone-IVb conditions for 24 months.

Decision of 331st meeting: Deferred for clarification of applied dosage form and formulation with reference to the innovator drug product

Firm's response: Firm has submitted that applied dosage form is "Liquid Concentrate solution for injection" and further stated that Agrabloc formulaton differs from the original prioduct formulation by two excipients, the buffer system and the substance used for isotonic adjustment. However, although the buffer is different, the pH range of the solution has not changed. Likewise, the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride. Another confirmation is that the 24 month stability test results show that the prdouct retains the same properties as at time of manufacture.

Decision of 336th RB meeting: Deferred for submission of clarification on scientific grounds for variation in excipients from the innovatr drug product and rationale for use of Mannitol for the intended role in the formulation.

Response by the firm:

With reference to your letter of the 336th DRB meeting regarding deficiency documents for our product "Agrabloc" (Tirofiban 12.5mg/50ml) Concentrate solution for infusion. We have submitted this query already and still asked the same for further clarification. Submission of clarification on scientific grounds for variation in excipients from the innovator drug product and rationale for use of Mannitol for the intended role in the formulation.

During the period of patent protection for the original product, a group of generic equivalents were uthorized in various countries with a different buffer system from the original product and these products continued to be on the market with the same formula after the patent protection of the original product ended. Among these generic products, one of them (TIROFIBAN JUNO), for which explicit formula information is given in the short product information, has the same concentrated formula as AGRABLOC

The AGRABLOC formulation differs from the original product formulation by two excipients: the buffer system and the substance used to adjust isotonicity. However, although the buffer is different, the pH range of the solution has not changed. In other words, the use of different substances did not change the effect (performance) of the buffer effect on product stability in the 24th month stability test results. / Likewise, the osmolality of the solution did not show a significant difference with the use of mannitol instead of sodium chloride.

In conclusion, both the original formulation and the generic alternative formulation of tirofiban have been in use for a long time. This is an important confirmation that AGRABLOC components are compatible. Another confirmation is that the 24-month stability test results show that the product retains its properties at the date of manufacture.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

135.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No.: 0002** **Address:** 246-B, Block-6, PECHS, Karachi **Validity:** 15-08-2022 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	South Korea

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020-D1-3552) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **The name of importing country on CoPP is mentioned as Pakistan.** **GMP:** Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
	Details of letter of authorization / sole agency agreement	Firm has submitted Legalized NOC from M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea which authorises **M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan** to register their products in Pakistan. The authorization letter is valid till 09-11-2022.
	Status of the applicant	☐ Manufacturer ☒Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐ Buk import and local repackaging Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 10553 dated 06-04-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021
	The proposed proprietary name / brand name	**Hyal Forte Pre Filled Syringe**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe (2ml) Contains 20mg of Sodium Hyaluronate
	Pharmaceutical form of applied drug	Pre-filled syringe
	Pharmacotherapeutic Group of (API)	Hyaluronic acid
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	1's;AS per SRO
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	Hyalgan PFS 20mg/2ml approved by ANSM of France
	For generic drugs (me-too status)	Hyalgan PFS of M.s Matrix Pharma Reg.# 031340

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence Euflexxa
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Pre-filled syringe
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at
		25ºC ±2ºC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at5ºC ±3ºC / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

- The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg
- Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.
- Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
- Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Submission by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg	Firm has submitted copy of CoPP certificate (No. 2024-D1-0199) dated 08-02- 2024 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection (pre-filled syringe). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years.
2.	Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.	Firm has submitted copy of NOC from M/s Shin Poong Pharmaceutical Co., Ltd. which authorises M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi,Pakistan to register their products in Pakistan. The authorization letter is issued on 29-01-2024.
3.	Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministryof Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.	Firm has submitted copy of GMP certificate (No. 2024-D1-0201) dated 08-02-2024 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro,Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has been mentioned in injections.
4.	Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.	Firm has **not** submitted any written justification instead a chart is submitted which does not specify any product.

Decision of 336th RB meeting: Deferred for following:

- **Justification for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.**

Response by the firm:

We, Shin Poon Pharm. Co., Ltd., would like to justify the reason of performing stability studies as per refrigerating conditions since the reference product recommends storage condition of store below 25°C.

While developing the product, our R&D team found a potential risk of viscosity reduction due to an increase in temperature. Therefore, we conducted stability studies as per refrigerating conditions and set the storage condition as 2~8°C.

Decision: Registration Board deferred for clarification as the product is not stable at/below 25^0 C, since the reference product recommends the storage condition below 25^0 C

136.	**Name and address of Applicant**	**M/s Scilife Pharma (Pvt) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi**
	Detail of Drug Sale License	**Address:** **Validity:** **Status:**
	Name and address of manufacturer	Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
	Name and address of marketing authorization holder	
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16163: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	PAZONIB 200mg Tablet
	Composition	Each film coated tablet contains: Pazopanib (as pazopanib hydrochloride)…….200mg
	Finished Product Specification	
	Pharmacological Group	Antineoplastic agent
	Shelf life	24 months, Firm has submitted stability study data of 3 batches as per zone IV-A conditions for 24 months.
	Demanded Price	53,000
	Pack size	30's
	International availability	Not provided
	Me-too status	Not provided
	Detail of certificates attached	• Firm has submitted copy of letter from Laboratorio Eczane Pharma to DRAP, authorizing Scilife Pharma (Pvt) Ltd to register, import, distribute and commercialize their products in Pakistan

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	
2.	Submit valid drug sale license	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
4.	Submit evidence of me-too status	
5.	Submit evidence of finished product specifications.	
6.	Submit valid, original, legalized certificate of pharmaceutical product.	
7.	Submit notarized / legalized sole agency agreement.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	Scuilife pharma has valid DML as well as DSL. The warehouse where the product will be stored is within DML facility.

	2.	Submit valid drug sale license	**Address:** Plot No F-D 57/58-A2 Korangi Creek Industrial Park (KCIP) Karachi. **Validity: 20-02-2029** **Status:** Drug Sale License by way of wholesale
	3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	**Not submitted**
	4.	Submit evidence of me-too status	**Not submitted**
	5.	Submit evidence of finished product specifications.	**Not submitted**
	6.	Submit valid, original, legalized certificate of pharmaceutical product.	Firm has submitted copy of CoPP which confirms free sale status of product in country of origin as well as GMP certificate. The Product License holder and manufacturer as per CoPP is Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
	7.	Submit notarized / legalized sole agency agreement.	Firm has submitted copy of agency agreement dated 16-03-2018.
	Decision: Deferred for following: • **Clarification since the fee is submitted against DML number while the applicant for imported product is a DSL facility.** • **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.** • **Evidence of me-too status** • **Reference of finished product specification.** • **Valid, original, legalized certificate of pharmaceutical product.** • **Valid notarized / legalized sole agency agreement.**		

137.	**Name and address of Applicant**	**M/s Scilife Pharma (Pvt) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP) Karachi**
	Detail of Drug Sale License	**Address:** **Validity:** **Status:**
	Name and address of manufacturer	Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
	Name and address of marketing authorization holder	
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16164: 07-03-2019
	Fee including differential fee	PKR 100,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	PAZONIB 400mg Tablet
	Composition	Each film coated tablet contains: Pazopanib (as pazopanib hydrochloride)…….400mg
	Finished Product Specification	
	Pharmacological Group	Antineoplastic agent
	Shelf life	24 months, Firm has submitted stability study data of 3 batches as per zone IV-A conditions for 24 months.

Demanded Price	53,000
Pack size	30's
International availability	Not provided
Me-too status	Not provided
Detail of certificates attached	• Firm has submitted copy of letter from Laboratorio Eczane Pharma to DRAP, authorizing Scilife Pharma (Pvt) Ltd to register, import, distribute and commercialize their products in Pakistan

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	
2.	Submit valid drug sale license	
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
4.	Submit evidence of me-too status	
5.	Submit evidence of finished product specifications.	
6.	Submit valid, original, legalized certificate of pharmaceutical product.	
7.	Submit notarized / legalized sole agency agreement.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	The fee is submitted against DML number while the applicant for imported product is a DSL facility. Clarification is required in this regard along with submission of fee by DSL facility.	Scuilife pharma has valid DML as well as DSL. The warehouse where the product will be stored is within DML facility.
2.	Submit valid drug sale license	**Address:** Plot No F-D 57/58-A2 Korangi Creek Industrial Park (KCIP) Karachi. **Validity: 20-02-2029** **Status:** Drug Sale License by way of wholesale
3.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	**Not submitted**
4.	Submit evidence of me-too status	**Not submitted**
5.	Submit evidence of finished product specifications.	**Not submitted**
6.	Submit valid, original, legalized certificate of pharmaceutical product.	Firm has submitted copy of CoPP which confirms free sale status of product in country of origin as well as GMP certificate. The Product License holder and manufacturer as per CoPP is Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda, Buenos Aires Argentina
7.	Submit notarized / legalized sole agency agreement.	Firm has submitted copy of agency agreement dated 16-03-2018.

Decision: Deferred for following:

	• **Clarification since the fee is submitted against DML number while the applicant for imported product is a DSL facility.** • **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.** • **Evidence of me-too status** • **Reference of finished product specification.** • **Valid, original, legalized certificate of pharmaceutical product.** • **Valid notarized / legalized sole agency agreement.**

Case No. 03 Deferred Cases of Form 5

138.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd.** **A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Dolium C 20/15 mg Tablet
	Composition	Each Tablet Contains: Cinnarizine…20mg Domperidone Maleate Eq. To Domperidone…15mg
	Diary No. Date of R& I & fee	Dy No. 16844: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-emetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Dozin Tablet by Hilton Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 327th meeting of RB: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Response by the firm: Firm has submitted multiple applications stating the following references: • Reference of Touristil Tablet from www.ndrugs.com which is not a reference regulatory authority. • A label of Touristil tablet in a language other than English which does not specify the name of any regulatory authority where this product is approved. As per the 1st reference name of two countries have been mentioned i.e. Belgium and Luxembourg. The database of Belgium has been thoroughly reviewd and no product with either this brand name or this composition is available. Moreover, Luxembourg is not a reference regulatory authority. The database of Luxembourg was also reviewed and no such product is available in that database as well.	
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. **1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.**	

	3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. **4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**

Case No. 04 Miscellaneous case

Case Referred back by Drugs Appellate Board

Additional Director, Legal Affairs has forwarded the decision of 166th sitting of Drugs Appellate Board held on 5th June 2024. The case details are as under:

Appeal No	23/2024
Appellant	M/s Pharma Health Pakistan (Pvt.) Limited, Lahore
Appeal preferred against the decision of:	Registration Board
Decision Appealed Against:	Against the decision rendered by Drug Registration Board in its 329th held on 6th to 8th June, 2023 regarding product "E Dol 2mg Tablet"
Date of the issuance of the decision:	11/01/2024
Date of the Appeal received:	09/03/2024
Appellant represented by:	Ms. Samra Ahsan, Manager Regulatory, Affairs

1. The Drug Registration Board in its 329th Meeting held on 06th to 08th of June, 2023 ('Impugned Decision') rejected the Appellant's application for registration of 'E Dol 2mg Tablet' on the ground that "it is neither approved by any reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th Meeting nor approved previously by the Registration Board."

2. Ms. Samra Ahsan appearing on behalf of the Appellant contended that the Subject Drug is an international registered brand of Bayer PLC with the brand name Progynova 2mg, further that a generic of the said drug has already been registered by the Registration Board by the name and style of 'Progens Tablet 2mg in favor of Dson Research Laboratories Pvt. Limited, having Registration No. 071383. The Appellant further contended that the subject drug is approved by the MHRA and submitted documentary evidence in this regard.

3. The Board prima facie finds credence in Appellant's claim and is of the opinion that the matter should be reviewed afresh by the Registration Board in light of the Appellant's contentions which do not seem to have been taken into consideration by the Registration Board.

4. For the reasons as provided above, the instant Appeal is allowed and the matter is remanded back to the Registration Board. The Appellant is directed to file a detailed representation with the Registration Board, placing all details of Subject Drug's approval by Reference Regulatory Authorities and previous registration (if any) by the Registration Board. The Registration Board shall decide the application through a well-reasoned and speaking order and shall be free to seek all necessary information from the Appellant as it deems fit in accordance with the laws.

History of the case

The case was presented in 329th meeting of Registration Board wherein the following decision was made

Name and address of manufacturer / Applicant	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
Brand Name +Dosage Form + Strength	E Dol 2mg Tablet
Composition	Each Gram Contains: Estradiol Valerate…2mg
Diary No. Date of R& I & fee	Dy No. 17253: 07-03-2019

	PKR 20,000/-: 06-03-2019
Pharmacological Group	Estrogens
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Could not be confirmed
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarification is required since on some pages of Form 5, tablet dosage form is written while the label claim specifies that it is a topical dosage form. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	

Evaluation:

As per the submissions of the firm, the reference of RRA approval has been verified from MHRA with following details:

- Name: Progynova® 2 mg Tablets
- Label claim: Each sugar coated tablet contains: Estradiol valerate… 2mg
- RRA: MHRA, UK

Moreover, following me-too status is also verified:

- Name: Progens Tablets 2mg
- Registration No: 71303
- Company: Dyson Research Laboratories (Pvt.) Ltd

Decision of 339th meeting of Registration Board: Registration decided to convey the decision of Appellate Board to the applicant for complianmce.

Agenda of Mst. Farzana Raja

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

a. New cases

139.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10002: 13-04-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 85181116723 PKR 120,000/- : Deposit slip # 87244847388
	The proposed proprietary name / brand name	**Moderate XR 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Venlafaxine HCl ER Pellets Eq. to Venlafaxine…150mg
	Pharmacotherapeutic Group of (API)	Antidepressant (Selective serotonin and norepinephrine reuptake inhibitors)
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Effexor XR of , USFDA Approved
	For generic drugs (me-too status)	Effexor XR by M/s Wyeth Pakistan Reg# 031368
	Proposed Pack size	10's , 14's, 20's and 28's

Evaluation by PEC (No[4]):

Source of pellets: M/s Alphamed Formulations (Pvt) Ltd.
Survey # 225, Sampanbole Village, Shamirpet Mandal, Medchal- Malkajgiri Dist., Telangana, India.

S.No	Section	Shortcomings	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for relevant site.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for relevant site submitted.
2.	3.2.S.4.4	Dissolution limits should be mentioned instead of comply in COA of drug substance by drug product manufacturer	Revised COA od drug substance with dissolution limits submitted.

Decision: Approved.

140.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6372: 06-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 294753404600
	The proposed proprietary name / brand name	**Ozyrus 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Obeticholic Acid.....5 mg
	Pharmacotherapeutic Group of (API)	Bile and liver therapy
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	OCALIVA 5mg film coated tablets

		USFDA
	For generic drugs (me-too status)	Abeticolic Tablet 5mg Tablet of M/s Dyson Laboratories
	Proposed Pack size	7's, 10's ,14's, 20's, 28's and 30's

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.1	Please justify that why, particle size distribution, are not included in Drug substance testing specification while same are part of Innovator specifications.	Revised/Updated drug substance specifications by considering particle size distribution is attached
3.	3.2.S.7	Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance.	Stability of drug substance have been conducted as per Zone-IV-A conditions & found stable that's why manufacturer has not recommended storage condition i. e. 5°C ±3°C
4.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document. • Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	• Revised Pharmaceutical equivalence by considering all quality tests is attached. • CDP studies were carried out with addition of surfactant in the dissolution mediums and the detail was included in protocol
5.	3.2.P.3.4	Particle size distribution is not conducted by bot drug substance manufacturer and drug product manufacturer and Particle size distribution plays a critical role in the content uniformity and dissolution of the tablets, so what steps has been taken by Drug product manufacturer to confirm the **"**Particle size control**"** of active substance in formulation.	At the time of drug product development particle size distribution was conducted but was not included in specifications, Revised/Updated drug substance specifications by considering particle size distribution is attached
6.	3.2.P.5.1	Please justify that why test for water content have not been included in stability studies while it is included in innovator product specification.	Revised/Updated drug product specifications and testing method by considering water content is attached
7.	3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15	Revised/Updated drug product specifications and testing method by considering dissolution limit as NLT 75%

		minutes" whereas submitted specifications declare the dissolution limits as "NLT 75% in 30 minutes". Clarification is required.	in 15 minutes is attached. Moreover the results of already conducted CDP are already in revised limit i.e. NLT 75% in 15 minutes .
8.	3.2.P.5.3	• How sample is prepared for different concentrations in analytical method validation parameter Accuracy.(In method 10 tablet eq to 50mg dissolved in 100ml and final concentration is 0.5mg while in accuracy 100% concentration 100mf taken) • In analytical method validation parameter, Precision (Repeatability) in 5mg tablet amount found is in the range of 10. Clarification is required.	• Analytical Method Validation Protocol including all such detail is attached. • Revised analytical method validation report is attached
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API with approval from DRAP.

Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

141.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5810: 01-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 294753404600
	The proposed proprietary name / brand name	**Ozyrus 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Obeticholic Acid.....10 mg
	Pharmacotherapeutic Group of (API)	Bile and liver therapy
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	OCALIVA 10mg film coated tablets USFDA
	For generic drugs (me-too status)	Abeticolic Tablet 10mg Tablet of M/s Dyson Laboratories
	Proposed Pack size	7's, 10's ,14's, 20's, 28's and 30's

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
10.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.

11.	3.2.S.4.1	Please justify that why, particle size distribution, are not included in Drug substance testing specification while same are part of Innovator specifications.	Revised/Updated drug substance specifications by considering particle size distribution is attached
12.	3.2.S.7	Justification shall be submitted for declaring stability conditions of room temperature as per zone IV-A for drug substance, while innovator product literature has recommended storage conditions of 5°C ± 3°C for drug substance.	Stability of drug substance have been conducted as per Zone-IV-A conditions & found stable that's why manufacturer has not recommended storage condition i. e. 5°C ±3°C
13.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by innovator product review document. • Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	• Revised Pharmaceutical equivalence by considering all quality tests is attached. • CDP studies were carried out with addition of surfactant in the dissolution mediums and the detail was included in protocol
14.	3.2.P.3.4	Particle size distribution is not conducted by bot drug substance manufacturer and drug product manufacturer and Particle size distribution plays a critical role in the content uniformity and dissolution of the tablets, so what steps has been taken by Drug product manufacturer to confirm the **"**Particle size control**"** of active substance in formulation.	At the time of drug product development particle size distribution was conducted but was not included in specifications, Revised/Updated drug substance specifications by considering particle size distribution is attached
15.	3.2.P.5.1	Please justify that why test for water content have not been included in stability studies while it is included in innovator product specification.	Revised/Updated drug product specifications and testing method by considering water content is attached
16.	3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 75% in 30 minutes". Clarification is required.	Revised/Updated drug product specifications and testing method by considering dissolution limit as NLT 75% in 15 minutes is attached. Moreover the results of already conducted CDP are already in revised limit i.e. NLT 75% in 15 minutes .
17.	3.2.P.5.3	• How sample is prepared for different concentrations in analytical method validation parameter Accuracy.(In method 10 tablet eq to 50mg dissolved in 100ml and final concentration is 0.5mg while in accuracy 100% concentration 100mf taken)	• Analytical Method Validation Protocol including all such detail is attached. • Revised analytical method validation report is attached

		• In analytical method validation parameter, Precision (Repeatability) in 5mg tablet amount found is in the range of 10. Clarification is required.	
18.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API with approval from DRAP.

Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

142.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6380: 06-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 1632383645
	The proposed proprietary name / brand name	Q-Pine 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Quetiapine as Quetiapine Fumarate…200mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	SEROQUEL 200mg Tablet of By ASTRAZENECA of USFDA Approved
	For generic drugs (me-too status)	Qutyl Tablet 200mg of M/s CCL Pharmaceuticals
	Proposed Pack size	1 x 10's & 3 x 10's

Evaluation by PEC (No[4]):

S.No	Section	Shortcoming	Reply
1.	3.2.P.1	Justify quantity of each tablet Quetiapine with theoretical factor of fumarate.	Calculations of dispensing are as follows. 883.1 is molecular weight of Quetiapine Fumarate. 767 is molecular weight of Quetiapine. 883.1/767 = 1.151 So Factor will be 1.151. For a tablet of 200 mg of Quetiapine Fumarate, following quantity 200 x 1.151 = 230.2 mg 230.2 mg of Quetiapine Fumarate is equivalent to 200mg of Quetiapine.

Decision: Approved.

143.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6379: 06-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 05136816
	The proposed proprietary name / brand name	Q-Pine 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Quetiapine as Quetiapine Fumarate…100mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	SEROQUEL 100mg Tablet of By ASTRAZENECA of USFDA Approved
	For generic drugs (me-too status)	Qusel Tablet 200mg of M/s Hilton Pharma.
	Proposed Pack size	1 x 10's & 3 x 10's

Evaluation by PEC (No[4]):

S.No	Section	Shortcoming	Reply
1.	3.2.P.1	Justify quantity of each tablet Quetiapine with theoretical factor of fumarate.	Calculations of dispensing are as follows. 883.1 is molecular weight of Quetiapine Fumarate. 767 is molecular weight of Quetiapine. 883.1/767 = 1.151 So Factor will be 1.151. For a tablet of 100 mg of Quetiapine Fumarate, following quantity 100 x 1.151 = 115.1 mg 115.1.2 mg of Quetiapine Fumarate is equivalent to 100mg of Quetiapine.

Decision: Approved.

144.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Pvt Ltd 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6378: 06-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 68299855531
	The proposed proprietary name / brand name	Q-Pine 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Quetiapine as Quetiapine Fumarate…25mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	SEROQUEL 25mg Tablet of By ASTRAZENECA of USFDA Approved
	For generic drugs (me-too status)	Pequit Tablet 25mg of M/s Genetics Pharmaceuticals
	Proposed Pack size	1 x 10's & 3 x 10's

Evaluation by PEC (No[4]):

S.No	Section	Shortcoming	Reply
1.	3.2.P.1	Justify quantity of each tablet Quetiapine with theoretical factor of fumarate.	Calculations of dispensing are as follows. 883.1 is molecular weight of Quetiapine Fumarate. 767 is molecular weight of Quetiapine. 883.1/767 = 1.151 So Factor will be 1.151. For a tablet of 25 mg of Quetiapine Fumarate, following quantity 25 x 1.151 = 28.78 mg 28.78 mg of Quetiapine Fumarate is equivalent to 25mg of Quetiapine.

Decision: Approved.

145.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 16133: 26-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 3731218266
	The proposed proprietary name / brand name	**Nepco CR 82.5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Pregabalin……82.5mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP certificate of the manufacturing unit issued within the last three years submitted.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for relevant site.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for relevant site submitted.
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 submitted.
4.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) are submitted
5.	3.2.P.4.4	Specification and analytical testing method of drug substance are as per BP monograph while Certificate of analysis claimed USP specification. Clarification is required.	Due to drafting mistake, Please Note that the USP test method and specifications for the drug substance which were intended to be included are attached.
6.	3.2.S.4.5	justification of specification states that " Pregabalin is not official in any pharmacopeia. Specification for Pregabalin are established on in house requirements" While on drug substance COA USP specifications are claimed. Clarification is required.	It was a typo error , To clarify, Pregabalin USP grade was used in the development of pregabalin CR tablet
7.	3.2.S.6	On COA of drug substance USP specifications are claimed than how BP reference standard used.	Working standard COA with USP grade submitted

Decision: Approved with innovator's specification.

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

146.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12731: 23-05-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 50695713
	The proposed proprietary name / brand name	**Gabal 20mg/ml Oral Solution**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Pregabalin…….20mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	Lyrica oral solution 20mg/ml(Pregabalin) Manufactured by: Pfizer USA (FDA Approved)
	For generic drugs (me-too status)	
	Proposed Pack size	1x60ml, 1x90ml, 1x120ml

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.5.6 & 3.2.P.5.1	Product is available in BP than how Innovator specifications are applied. Clarification is required	The Limits are within BP monograph and we submitted the revised analytical method as per BP
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	The Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is Provided in Module 3 section 3.2.P.8.3 is Attached
3.	3.2.P.2.2.1	Details of product against which Pharmaceutical Equivalence conducted.	Pharmaceutical Equivalence are against the product which are as follows Lyrica(Pregabalin) 20mg/ml Oral Solution Distribuited by Parke-Davis Division of Pfizer Inc NY, NY 10017 Lot # EY4069 | Exp Date 04/2023
4.	3.2.P.5.3	As per ICH guidelines on VALIDATION OF ANALYTICAL PROCEDURES: TEXT AND METHODOLOGY Q2(R1) Repeatability should be assessed using: a) a minimum of 9 determinations covering the specified range for the procedure (e.g., 3 concentrations/3 replicates each); or b) a minimum of 6 determinations at 100% of the test concentration. While you are using single determinant.	As per ICH guideline on Validation of Analytical Procedures: Text & Methodology Q2(R1) Repeatability should be assessed using: a) A minimum of 9 determination is covering the specified range for the procedure (e.g., 3 concentration/3replicates each); or b) a minimum of 6 determination at 100% of the test concentration was performed and attached.
5.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance record of HPLC software 21CFR & audit trial reports on Product testing is Attached

Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

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

147.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14710: 12-06-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 499041469308
	The proposed proprietary name / brand name	**Invital-D 25,000 IU/2.5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Contains: Cholecalciferol…25,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	THORENS 25 000 I.U. /2.5 ml oral solution by Galen Limited of MHRA approved.
	For generic drugs (me-too status)	.
	Proposed Pack size	2.5ml/bottle

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Latest GMP inspection report is submitted.
2.	2.3.A.1	Provide Packaging facility for 2.5ml bottle.	Filling facility of minimum 1ml-25ml is available in production department. List of production equipment is attached mentioning the filling machine with capacity of filling.
3.	3.2.P.5.3	• In Analytical method validation parameter Accuracy, How different concentrations are prepared. • In accuracy report in 100% concentration and 120% concentration why volume of sample is mentioned in mg. Clarification is required.	• In Analytical method validation parameter sample of accuracy were prepared as below: **For 100%:** Dissolve 5mL of the oral solution in 100ml volumetric flask. Add 70ml of 1st diluent and dissolve by sonicating on ultrasonic water bath for 5 minutes. Cool to room temperature and makeup the volume with 1st diluent and mix. Transfer 20mL of stock sample solution in 50mL volumetric flask and makeup the volume with 2nd diluent. **For 80%:** Dissolve 5mL of the oral solution in 100ml volumetric flask. Add 70ml of 1st diluent and dissolve by sonicating on ultrasonic water bath for 5 minutes. Cool to room temperature and makeup the volume with 1st diluent and mix.

			Transfer 18mL of stock sample solution in 50mL volumetric flask and makeup the volume with 2nd diluent. **For 120%:** Dissolve 5mL of the oral solution in 100ml volumetric flask. Add 70ml of 1st diluent and dissolve by sonicating on ultrasonic water bath for 5 minutes. Cool to room temperature and makeup the volume with 1st diluent and mix. Transfer 22mL of stock sample solution in 50mL volumetric flask and makeup the volume with 2nd diluent. • Volume of sample in mg in accuracy report is mentioned by mistake by the analyst. The actual amount of sample taken for 80%, 100% and 120% concentration is 18ml, 20ml and 22ml respectively.

Decision: Approved with innovator's specification.

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

148.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15823: 22-06-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 239538788039
	The proposed proprietary name / brand name	**Invital-D 2740 IU/ml Oral Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Cholecalciferol…2740 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Fultium-D3 Drops by Internis Pharmaceuticals Ltd. of MHRA approved.
	For generic drugs (me-too status)	
	Proposed Pack size	25ml/bottle

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Latest GMP inspection report is submitted.

2.	3.2.P.1	Which oil is used in formulation of solution	Medium chain triglyceride (from coconut oil and palm oil) is used in formulation of solution.
3.	3.2.P.3.2	Justify your dispensed quantity with reference to reference product.	We have used cholecalciferol concentration of 40MIU/g (million IU). 1 mg contains 40,000 IU. Therefore, for 2740 IU we require 0.0685mg of cholecalciferol. 5% of overage is recommended.
4.	3.2.P.5.3	• In Analytical method validation parameter Accuracy, How different concentrations are prepared. • In accuracy report in 100% concentration and 120% concentration why volume of sample is mentioned in mg. Clarification is required.	• In the accuracy parameter of the analytical method validation, a typographic error occurred by the analyst. For the 100% concentration, 5 ml of the sample was taken for the preparation of 100% sample solution. 4 ml and 6 ml of the sample were taken for the 80% and 120% sample preparation, respectively. Corrected calculation data sheet is also attached for reference. • The volume of the sample mentioned in mg in the accuracy report for 100% and 120% concentrations is a typographic error. The correct volumes are 5 ml for 100% and 6 ml for 120%. Corrected calculation data sheet is also attached for reference
5.	3.2.P.7	Details of container closure system for drops.	Amber glass bottles are used in reference product available in reference regulatory authority. We have also used amber glass bottles in our stability studies.

Decision: Approved with innovator's specification.

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

149.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14704: 12-06-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 4240476168
	The proposed proprietary name / brand name	**Invital-D 50,000 IU/2.5ml Oral Solution**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Contains: Cholecalciferol…50,000 IU
	Pharmacotherapeutic Group of (API)	Vitamin D3 and analogue, Cholecalciferol
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	**Deltius 50,000 IU /2.5 ml oral solution** by Abiogen Pharma SpA of Spain approved
	For generic drugs (me-too status)	
	Proposed Pack size	2.5ml/bottle

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Latest GMP inspection report is submitted.
2.	2.3.A.1	Provide Packaging facility for 2.5ml bottle.	Filling facility of minimum 1ml-25ml is available in production department. List of production equipment is attached mentioning the filling machine with capacity of filling.
3.	3.2.P.2.2.1	Details of product against which pharmaceutical equivalence conducted.	We have used product of Spain i.e. Deltius as innovator.
4.	3.2.P.3.2	Justify your dispensed quantity with respect to reference product available in reference regulatory authority specified by Registration Board	We have used cholecalciferol concentration of 40MIU/g (million IU). 1 mg contains 40,000 IU. Therefore, for 50,000 IU we require 1.25mg of cholecalciferol. The same quantity i.e. 1.25mg of cholecalciferol per 2.5ml
5.	3.2.P.5.3	• Sample preparation in analytical method validation and accuracy is different from analytical testing method. • In Analytical method validation parameter Accuracy, How different concentrations are prepared. • In accuracy report in 100% concentration and 120% concentration why volume of sample is mentioned in mg. Clarification is required.	• In the accuracy parameter of the analytical method validation, a typographic error occurred by the analyst. For the 100% concentration, 5 ml of the sample was taken for the preparation of the sample solution. Meanwhile, 4 ml and 6 ml of the sample were taken for the 80% and 120% sample solutions, respectively. Corrected calculation data sheet is also attached for reference. • Similarly, the volume of the sample mentioned in mg in the accuracy report for 100% and 120% concentrations is also a typographic error. The correct volumes are 5 ml for 100% and 6 ml for 120%. Corrected calculation data sheet is also attached for reference.
6.	3.2.P.7	Submit details of container closure system .	Amber glass bottles are used in reference product available in reference regulatory authority. We have also used amber glass bottles in our stability studies.

Decision: Approved with innovator's specification.

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

150.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7167: 13-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 35302995019
	The proposed proprietary name / brand name	**Metvar 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metronidazole…400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Metronidazole 400 mg film-coated tablets of , MHRA Approved
	For generic drugs (me-too status)	Flagyl 400mg Tablet by M/s Sanofi Aventis
	Proposed Pack size	100's

Evaluation by PEC (No^{4}):

S.No	Section	Shortcomings	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years submitted
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 submitted.
3.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted.
4.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted.
5.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) are submitted. However accuracy parameter not submitted.
6.	3.2.P.2.2.1	In comparative dissolution profile F2 is not calculated.	Comparative dissolution with F2 calculation submitted.

Decision: Approved.

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

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

151.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7695: 17-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 0385279769
	The proposed proprietary name / brand name	**Amfold 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amlodipine as Besylate…….5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	NORVASC 5mg Tablet of Pfizer Inc., USA (USFDA Approved).
	For generic drugs (me-too status)	Dispan 5mg Tablet of M/s Sante Pharma Reg# 081458
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5 (a)	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
3.	3.2.S.4.1 3.2.S.4.2 3.2.S.5 3.2.S.7	Copies of the Drug substance specifications , Detailed analytical procedures used for routine testing , COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.
4.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
5.	3.2.P.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.
6.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm

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

152.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7696: 17-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 00276911474
	The proposed proprietary name / brand name	**Amfold 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amlodipine as Besylate…….10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	NORVASC 10mg Tablet of Pfizer Inc., USA (USFDA Approved).
	For generic drugs (me-too status)	Dispan 10mg Tablet of M/s Sante Pharma Reg# 081459
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
7.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
8.	1.6.5 (a)	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.
	1.6.5(b)	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
9.	3.2.S.4.1 3.2.S.4.2 3.2.S.5 3.2.S.7	Copies of the Drug substance specifications , Detailed analytical procedures used for routine testing , COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.
10.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
11.	3.2.P.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.
12.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm

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

153.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14081: 06-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 75118010943
	The proposed proprietary name / brand name	**AD 100mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Racecadotril…100mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Hidrasec® Capsules 100mg by Bioprojet Europe Ltd. of MHRA approved.
	For generic drugs (me-too status)	"Hidrasec® Capsules 100mg" by M/s Abbott Laboratories Reg# 087518
	Proposed Pack size	10's, 20's, 2 x 7', 4 x 7's, 30's

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid DML and GMP certificate of M/s Symed Labs limited issued by relevant regulatory authority of country of origin submitted.
2.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Detailed Analytical Method Verification studies for Racecadotril performed by Scotmann are submitted.
3.	3.2.P.5.1	Please justify that why test for water content and microbial limits form have not been included in stability studies while it is included in innovator product specification	We have performed the microbial test and moisture content of said batches placed on stability study and the results were found satisfactory.

Decision: Approved with innovator's specification.

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

154.	Name, address of Applicant / Marketing Authorization Holder	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11237: 05-05-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 9483401411
	The proposed proprietary name / brand name	**Toficit 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib as Citrate…….5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant (Janus kinase (JAK) inhibitor)

	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	XELJANZ Tablets of , USFDA Approved
	For generic drugs (me-too status)	Tofajak Tablet by M/s Hiranis Pharmaceuticals Reg# 110057
	Proposed Pack size	10's

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin for relevant site.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.	Crystalline Form A
3.	3.2.S.4.1	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copies of the Drug substance specifications Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
4.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
5.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance are submitted.
6.	3.2.P.1 & 3.2.P.3.2	• Innovator product contains Tofacitinib Citrate while you are using Tofacitinib. Clarification is required. • Justify your dispensed quantity with respect to reference product.	• We have used Tofacitinib citrate. There is typographical error in the BMR. Revised BMR are attached. All the calculations are according to Tofacitinib citrate.
7.	3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed	Complete Pharmaceutical Equivalence report submitted.
8.	3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 80% in 30 minutes". Clarification is required.	In our submitted CDP results of our product (toficit 5mg tablet) with innovator tofajak 5mg tablet clearly shows that drug is completely released in 15 minutes in all the three medium. We have performed the dissolution test for 15 mint but in reports mistakenly written as 30 mint. We assure you in future we

			will use same parameters as given by innovators.
9.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.	We have performed all the tests except testing of related substances. We assure you after approval of drug in our commercial batches we will perform related substances too.
10.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import).	Documents for the procurement of API with approval from DRAP submitted.

Decision: Approved with innovator's specification..

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

155.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6420: 07-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 89820391
	The proposed proprietary name / brand name	**Medopa 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Methyldopa……250mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	METHYLDOPA TABLETS 250mg by Aspen Pharma Trading Limited of , MHRA Approved
	For generic drugs (me-too status)	Cara Dopa 250mg by M/s Caraway Pharma.
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
3.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
4.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
5.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
6.	3.2.P.2.2.1	In pharmaceutical Equivalence Manufacturer of Aldomet mentioned is Hilton while in CDP OBS pharma mentioned.
7.	3.2.P.5.3	• Submit complete analytical method validation parameter.

		• In precision concentration of sample is change from submitted analytical testing method • Assay method according to monograph is UV than how analytical method validation is performed by HPLC

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

156.	Name, address of Applicant / Marketing Authorization Holder	M/s Hansel Pharmaceutical Pvt Ltd. Plot No. 2, Pharma City, 30 Km Multan Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Hansel Pharmaceutical Pvt Ltd. Plot No. 2, Pharma City, 30 Km Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9817: 12-04-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 48598359717
	The proposed proprietary name / brand name	**Ketlac 30mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule Contains: Ketorolac Tromethamine…30mg
	Pharmacotherapeutic Group of (API)	Nonsteriodal Antiinflammatory Drugs (NSAID)
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Toradol 30mg/ml Solution for Injection (1ml ampoule) MHRA Approved
	For generic drugs (me-too status)	Toradol Injection 30mg/ml by M/s Martin Dow Marker Limited (Reg# 108584)
	Proposed Pack size	1ml x 5 Ampoule

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin. • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate
3.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4.	3.2.S.4.1	Copies of the Drug substance specifications Drug Product manufacturer is required.
5.	3.2.S.4.2	Detailed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
6.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
7.	3.2.S.4.4	In Submitted COA of drug substance by drug substance manufacturer USP specifications are claimed while specification in section 3.2.S.4.1 and analytical testing method in section 3.2.S.4.2 As per BP monograph. Clarification is required.
8.	3.2.S.7	Submit Real time stability data of 3 batches as per zone IV A/B till claimed shelf life.

9.	3.2.P.5.1	Specifications mentioned in this section are In-house while in section 1.5.6 USP specifications are claimed. Clarification is required. Injection volume use is 20µL while USP monograph 100µL is mentioned.
10.	3.2.P.5.2 &3.2	Analytical testing method of assay Concentrations of standard and sample preparation are different from USP monograph.
11.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.

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

157.	Name, address of Applicant / Marketing Authorization Holder	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15012: 14-06-2023
	Details of fee submitted	PKR 75,000/- : Deposit slip # 36167063
	The proposed proprietary name / brand name	**Tramal-D Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tramadol Hcl……75mg Dexketoprofen (As Dexketoprofen trometamol) …….25mg
	Pharmacotherapeutic Group of (API)	Nonsteriodal Anti-inflammatory Drugs (NSAID) and Opioid Analgesic
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	Skudexa 75 mg/25 mg film-coated tablets of MHRA Approved
	For generic drugs (me-too status)	
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
1.	1.6.5	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer of relevant manufacturing site issued by relevant regulatory authority of country of origin for both Dexketoprofen trometamol and Tramadol HCl
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted for both Dexketoprofen trometamol and Tramadol HCl.
4.	3.2.S.4.4	Certificate of analysis of Dexketoprofen trometamol by drug product manufacture used during product development and stability studies.
5.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided for Dexketoprofen trometamol.

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

b. Deferred cases

158.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 366: 04-01-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 25226483
	The proposed proprietary name / brand name	**Rheumatib 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib as Citrate…….5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	XELJANZ Tablets of , USFDA Approved.
	For generic drugs (me-too status)	Tofajak Tablets 5mg of M/s Hiranis Pharmaceuticals
	Proposed Pack size and Proposed unit price	7's, 10's, 14's, 20's, 28's and 30's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.
4.	3.2.S.4.3	Accuracy parameter in Analytical method verification of drug substance by drug product manufacturer is not performed
5.	3.2.S.4.5	Justification is required for Performance of LOD instead of Water content as Drug substance specification includes water content.
6.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product as mentioned in section 3.2.P.5.1 of this application . • Submit detail results of comparative dissolution profile.
7.	3.2.P.5.2	Justify the variation of dissolution parameters from that recommended by Innovator product
8.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

S.No	Section	Shortcoming	Reply
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	cGMP certificate on the basis of evaluation conducted on 15-06-2022 submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug	Batch Manufacturing Record (BMR) for all the batches of drug product for which

		product for which stability studies data is provided in Module 3 section 3.2.P.8.3	stability studies data is provided in Module 3 section 3.2.P.8.3 submitted
3.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.	Crystalline Citrate Salt Form A
4.	3.2.S.4.3	Accuracy parameter in Analytical method verification of drug substance by drug product manufacturer is not performed	Complete Analytical method verification of drug substance submitted.
5.	3.2.S.4.5	Justification is required for Performance of LOD instead of Water content as Drug substance specification includes water content.	As per DS specification provided by DS manufacturer LOD was performed Specifications attached
6.	3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product as mentioned in section 3.2.P.5.1 of this application . • Submit detail results of comparative dissolution profile.	• Revised pharmaceutical equivalence by considering all quality test is/are attached. • Detail results of comparative dissolution profile are submitted.
7.	3.2.P.5.2	Justify the variation of dissolution parameters from that recommended by Innovator product	As per FDA Drug Database for Dissolution Method of Tofacitinib Citrate Immediate release tablets, Dissolution Guidance 2018 is recommended and the same parameters were adopted Reference attached
8.	3.2.P.5.6	Justification of not performing all the test as performed by Innovator product.	As per Innovator product all quality tests were performed, however Water Content was not mentioned in Specifications so revised Specifications is/are attached.
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Documents for the procurement of API with approval from DRAP submitted.

Decision: Approved with innovator's specification..

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

159.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36818: 19-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit slip # 3181685383
	The proposed proprietary name / brand name	**Dotril 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Racecadotril (BP)…….100mg
	Pharmacotherapeutic Group of (API)	Antidiarrheal
	Reference to Finished product specifications	Innovator specification.

	The status in reference regulatory authorities	Racecadotril Capsules 100mg by Biogran of France Approved.
	For generic drugs (me-too status)	"Hidrasec® Capsules 100mg" by M/s Abbott Laboratories Reg# 087518
	Proposed Pack size and Proposed unit price	10's As per SRO

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
2.	3.2.S.4.2	Ph.Eur Specfications are applied on drug substance than how limits of assay are 90- 110% by drug product manufacturer
3.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
4.	3.2.S.7	Submit Real time stability studies for 3 batches till shelf life as submitted stability studies are of 12 months.
5.	3.2.P.5.1	• Justification is required for Performance of LOD instead of Water content as Innovator includes water content test. • You have mentioned dissolution specification NLT 80% (Q) in section 3.2.P.5.1 while in rest of documents mentioned as NLT 75% (Q). Clarification is required.
6.	3.2.P.5.2	• Reference shall be submitted for the dissolution parameters adopted. • You have applied Paddle speed = 100 rpm in dissolution parameters. You are advised to justify the speed of paddle apparatus with reference to USP general chapter <1092> (The Dissolution Procedure; Development and Validation).
7.	3.2.P.5.3	• Your sample preparation in Analytical method verification parameter are different than submitted in analytical testing method of assay . Clarification is required.
8.	3.2.P.5.4	In COA's of stability batches BP specifications are mentioned while product is not available in BP pharmacopeia. Clarification is required.
9.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • Initiation date of stability studies not mentioned. • In Stability studies summary sheets batch No mentioned and Batch No BMR's rest of documents Batch No are different. Clarification is required. • In stability studies raw data sample preparation is different from applied analytical testing method of assay • In submitted raw data of dissolution Type I Apparatus is used while in analytical testing method of dissolution Type 2 Apparatus is mentioned. Clarification is required.

Previous Decision (M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Evaluation by PEC (No. IV):

S.No	Section	Shortcoming	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin

2.	3.2.S.4.2	Ph.Eur Specfications are applied on drug substance than how limits of assay are 90- 110% by drug product manufacturer	The submitted documents has also assay limits as per European Pharmacopoeia i.e 98.00 - 102.0%. Reference documents attached.
3.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) are submitted.
4.	3.2.S.7	Submit Real time stability studies for 3 batches till shelf life as submitted stability studies are of 12 months.	Real time stability studies for 3 batches till 36 months submitted.
5.	3.2.P.5.1	• Justification is required for Performance of LOD instead of Water content as Innovator includes water content test. • You have mentioned dissolution specification NLT 80% (Q) in section 3.2.P.5.1 while in rest of documents mentioned as NLT 75% (Q). Clarification is required.	• As LOD was specified in the Eurpean Pharmacopoeia of raw material i.e Racecadotril and recommended by the API manufacturer. And we have tested raw material as per EP. Consequently, the same LOD test was performed for drug product testing.Additionally, the LOD test for finished product serves as an in-house measure to assess the impact of high humidity over the stability testing period • NLT 75% (Q) dissolution specification was mentioned in section 3.2.P.5.1. reference documents are attached.
6.	3.2.P.5.2	• Reference shall be submitted for the dissolution parameters adopted. • You have applied Paddle speed = 100 rpm in dissolution parameters. You are advised to justify the speed of paddle apparatus with reference to USP general chapter <1092> (The Dissolution Procedure; Development and Validation).	As we have used Type I Basket apparatus for dissolution of Racecadotril Capsule. According to USP general chapter <1092> (for immediate-release capsule or tablet formulations, Apparatus 1 (basket) at 50-100 rpm or Apparatus 2 (paddle) at 50 or 75 rpm are commonly used.
7.	3.2.P.5.3	Your sample preparation in Analytical method verification parameter are different than submitted in analytical testing method of assay . Clarification is required.	Mistakenly wrong document of Racecadotril 100mg Capsule Trail testing method was attached at the time of dossier submission. Actual testing method was attached.
8.	3.2.P.5.4	In COA's of stability batches BP specifications are mentioned while product is not available in BP pharmacopeia. Clarification is required.	Stability batches are tested as per in-house specification and COA are attached.
9.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm. • Documents for the procurement of API with approval from DRAP. • Initiation date of stability studies not mentioned. • In Stability studies summary sheets batch No mentioned and Batch No BMR's rest of documents Batch No	• Submitted. • Documents for the procurement of API with approval from DRAP submitted. • Mistakenly wrong document of Racecadotril 100mg Capsule Trial testing method was attached at the time of dossier submission (paddle apparatus Type-2 was written in place of Basket apparatus type-1) Please find the actual testing method.

		are different. Clarification is required. • In stability studies raw data sample preparation is different from applied analytical testing method of assay • In submitted raw data of dissolution Type I Apparatus is used while in analytical testing method of dissolution Type 2 Apparatus is mentioned. Clarification is required.	

Decision: Approved with innovator's specification.

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

160.	Name, address of Applicant / Marketing Authorization Holder	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate on the basis of evaluation conducted on 15-06-2020 and valid for 3 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of renewal of DML dated:07-07-2021 in which tablet (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28771 dated 11-10-2022
	Details of fee submitted	Rs.75,000/- Deposit slip # 42090440956
	The proposed proprietary name / brand name	P-Cab 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…20mg
	Pharmaceutical form of applied drug	Potassium-Competitive Acid Blocker (P-CAB). WHO ATC CODE**:** A02BC08
	Pharmacotherapeutic Group of (API)	White to almost white, round, scored, biconvex, film coated Tablet.
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg Tablets (PMDA Japan Approved)
	For generic drugs (me-too status)	

	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceuticals Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, P.r. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Takecab 20mg Tablets of Takeda Pharmaceuticals by performing quality tests Identification, Weight of tablets, Thickness, Disintegration test, Dissolution, Assay. CDP has been performed against the Takecab 20mg manufactured by Takeda Pharmaceuticals in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Jiangxi Synergy Pharmaceuticals Co., Ltd Address: Jiangxi Fengxin Industrial Park, Fengxin 330700, Jiangxi Province, P.r. China.
API Lot No.	20190802BD
Description of Pack	Alu-Alu blister

(Container closure system)			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PC20-T001	PC20-T002	PC20-T003
Batch Size	3000 Tablet	3000 Tablet	3000 Tablet
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	08-02-2021	09-02-2021	09-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate #2020002 in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Jiangxi Province, P.R. China issued by ***Jiangxi API Engineering Technology Research Center*** valid upto 11-03-2025 Firm has submitted Copy of DML (No. 20160125) in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China valid upto 26-11-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # jxsg200352, dated; 26-03-2020 cleared by DRAP (Peshawar) dated: 08-04-2020 specifying Vonoprazan fumarate batch # 20190802BD
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	2.3.R.1.1	In BMR during dispensing of vonoprazan fumarate potency is not adjusted as potency mentioned in COA is 98.58%.	Molecular weight of Vonoprazan Fumarate is 461.5 g/mol. The correlation factor is 1.336. Hence we have used 26.72mg of Vonoprazan Fumarate per tablet, which will give 20mg of Vonoprazan per tablet
2.	3.2.S.4.2	Injection volume in the assay test of the drug substance provided by the finished product manufacturer is 20µl while that of the drug substance manufacturer is 10 µl. clarify?	The Injection volumes is 20 ul is selected for analysis due to fixed loop of 20 ul is installed in manual rheodyne of HPLC. The same procedure with 20ul is validated and the validation data is submitted

3.	3.2.S.4.3	Submitted analytical method verification report by drug product manufacturer of drug substance shows different concentration for standard and sample preparation than submitted analytical testing method of assay of drug substance. Clarification is required.	The concentration of Standard and Sample used in analytical method & validation report is same as per submitted Stability Studies calculation sheets . Therefore it is requested to consider the typographical error in Analytical Method and validation report. Revised analytical method and validation report is enclosed for your kind consideration
4.	3.2.S.5	Submitted COA of working standard Complies with USP specification while drug substance specification Claimed Ph.EU	COA of working standard submitted.
5.	3.2.S.7.3	Submit drug substance stability studies of 3 batches till shelf life.	Drug substance stability studies of 3 batches till shelf life submitted.
6.	3.2.P.2.2.1	Details of product against which pharmaceutical equivalence and Comparative dissolution conducted.	Details of product against which pharmaceutical equivalence and Comparative dissolution conducted submitted.
7.	3.2.P.5.2	Justification to be provided for the selection of dissolution parameters including dissolution media buffer (6.8) volume of dissolution medium, rpm and type of USP apparatus.	Vonoprazan is a highly soluble drug substance based on ICH Q6A, which states that the drug substance should be considered highly soluble if it meets following two conditions: 1. The dissolution profile of all strengths of the dosage form should be rapid i.e. Dissolution >80 % in 15 minutes at pH 1.2, 4.5 & 6.8. 2. The highest drug product's strength is soluble in 250mL or less of aqueous media over the pH range of 1.2 to 6.8 at 37°C ± 1°C. As per ICH Q6A, for dosage forms having drug substances falls in above conditions will be considered as highly soluble drugs and do not require development of discriminatory dissolution method / parameters. Generally, a single time point with one medium is acceptable. Comparative Dissolution Study by Genome the 'P-CAB Tablets' against the Innovator Product 'Takecab Tablets' Vonoprazan release more than 85% in all three mediums within 15minutes at 50 RPM. Also, the solubility of Vonoprazan is very high throughout the physiological pH range (1.2 to 6.8). The lowest solubility of Vonoprazan is found to be in pH 6.8 as compared to solubility in pH 1.2 (about 16.5mg/ml) & pH 4.5 (8.1mg/ml) i.e. is about 4.7 mg/ml which is greater than the highest

			strength divided by 250 (20mg/250=0.08mg/ml), so we selected dissolution medium having pH 6.8 as a worst-case scenario. In light of above discussion and high solubility of drug substance, discriminatory dissolution parameters are not required for Vonoprazan Tablets 10mg and 20mg. Therefore, generalized lowest 50 RMP with 900ml medium (Most common volume as per USP <1092>) was selected for release and stability studies of the drug product. As per Comparative Dissolution Study by Genome the 'P-CAB Tablets' against the Innovator Product 'Takecab Tablets' Vonoprazan release more than 85% in all three mediums within 15minutes. Therefore, we selected the time point i.e. 15 minutes for dissolution ***However as per USFDA review report Medium used for dissolution medium is Acetate buffer pH 4.5 while firm used phosphate buffer pH 6.8***
8.	3.2.P.8	Initiation date of stability studies not mentioned.	Submitted.

Previous Decision (M-336): Deferred for clarification of use of phosphate buffer i.e pH 6.8 as dissolution medium while from Innovator product review documents it is evident that Acetate buffer pH 4.5 is used as dissolution medium

Reply: Vonoprazan is a highly soluble drug substance based on ICH Q6A, which states that the drug substance should be considered highly soluble if it meets following two conditions:

1. The dissolution profile of all strengths of the dosage form should be rapid i.e. Dissolution >80 % in 15 minutes at pH 1.2, 4.0 & 6.8.
2. The highest drug product's strength is soluble in 250mL or less of aqueous media over the pH range of 1.2 to 6.8 at 37°C ± 1°C.

As per ICH Q6A, for dosage forms having drug substances falls in above conditions will be considered as highly soluble drugs and do not require development of discriminatory dissolution method / parameters. Generally, a single time point with one medium is acceptable.

During *Comparative Dissolution Study* of 'P-CAB 20mg Tablets' manufactured by Genome Pharmaceuticals versus the Innovator Product 'Takecab 20mg Tablets', Vonoprazan release was observed to be more than 85% in all three mediums within 15minutes at 50 RPM. Also, the solubility of Vonoprazan is very high throughout the physiological pH range (1.2 to 6.8). The lowest solubility of Vonoprazan is found to be in pH 6.8 as compared to solubility in pH 1.2 (about 16.5mg/ml) & pH 4.5 (about 8.1mg/ml) i.e. is about 4.7 mg/ml which is greater than the highest strength divided by 250ml (20mg/250ml=0.08mg/ml), so we selected dissolution medium having pH 6.8 as a worst-case scenario.

Moreover, we developed our product early in 2021 and after successful development the batches were charged on stability in March, 2021 and 6 months stability was completed on August, 2021. Till that there was no dissolution method available in USFDA website. While the innovator report NDA 215152 for Voquenza Triple Pack was published on 05-03-2022.
After Publication we tested our product, P-CAB 20mg Tablets, during 18th month Stability Studies on August 2022

as per FDA Dissolution Medium and results are in limit.

Further, we have revised the Specification and Method of Analysis. Documents are attached for your kind consideration.

- The Result of dissolution testing on stability studies batches are submitted along with chromatograms.
- Revised Method.

Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

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

161.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	G-Mol 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: paracetamol…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	20×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated

1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Film coated Tablet) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of application.

Previous Decision (M-326): Registration Board deferred the application for submission of Product development, Pharmaceutical Equivalence ,CDP, Batch manufacturing record and complete stability studies for revised formulation of "uncoated tablet".

Evaluation by PEC: A fee of Rs: 7500/- deposit slip # 7593549277 for pre Registration Variation

S.No	Shortcomings Communicated	Reply
1.	Product Development	We, M/s AGM Pharma, during the product development of **G-Mol 500mg** Tablet (Paracetamol), followed the British Pharmacopeia monograph/method for an uncoated tablet. However, unintentional mistakes were made during the preparation of the CTD Dossier documentation from our side. Further we have submitted the fee for the preregistration variation as per the SRO.
2.	Pharmaceutical Equivalence with CDP	Fresh Pharmaceutical Equivalence with comparative Dissolution Profile is Attached.
3.	Batch Manufacturing Record	Revised Batch Manufacturing Record is attached
4.	Complete stability studies for revised formulation of uncoated tablet	Stability studies of G-Mol 500mg Tablet (Paracetamol) were also conducted for the uncoated tablet formulation. Complete stability study Record is Attached

Evaluation of application

Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 374 dated 04-01-20223
Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
The proposed proprietary name / brand name	G-Mol 500mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: paracetamol…500mg
Pharmaceutical form of applied drug	Tablet
Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
Reference to Finished product specifications	BP
Proposed Pack size	20×10's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Paracetamol 500MG tablet of USFDA Approved.
For generic drugs (me-too status)	Panadol 500mg Tablet of M/s GSK
GMP status of the Finished product manufacturer	New DML issued on 10/11/2021

	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TRT016, TRT017, TRT018)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Panadol 500mg capsules BY GSK Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is PARACETAMOL TABLET 500MG capsule by GSK in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
API Lot No.	PGP21-401
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRT016	TRT017	TRT018
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	01-12-21	02-12-21	03-12-21
Date of Initiation	04-12-2021	04-12-2021	04-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Previous Decision (M-330): Deferred for submission of complete new pharmaceutical development data including the stability data of newly formulated trial batches along with full fee of registration.

Full fee of registration is paid challan is attached Rs:30000/- Deposit slip # 2532443628
Module III is Attached with complete new pharmaceutical development data including CDP, Pharmaceutical equivalence, Product AMV Report, Product analytical Method, Product Process validation Protocol, BMRs, Finished Product COAS, API Manufacturer GMP Certificate, Commercial Invoice, the stability data of newly formulated trial batches and Record of Digital data logger for temperature and humidity monitoring of stability chambers. (real time and accelerated) data is as follows

	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	The proposed proprietary name / brand name	G-Mol 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Paracetamol……500mg
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Paracetamol 500MG tablet of USFDA Approved.
	For generic drugs (me-too status)	Panadol 500mg Tablet of M/s GSK
	Proposed Pack size	20×10's

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

Evaluation by PEC (No[4]): Firm submitted stability data of 3 new batches.

Batch No.	TRT-016	TRT-017	TRT-018
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	09-2023	09-2023	09-2023
Date of Initiation	21-09-2023	21-09-2023	21-09-2023

Decision: Approved.

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

162.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Oral Liquid (General) section mentioned. mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28940 dated 12-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 98276743408
	The proposed proprietary name / brand name	Ondonix 4mg/5ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron Hcl Dihydrate Eq. to Ondansetron…….4mg
	Pharmaceutical form of applied drug	Light orange colour oval shape, biconvex, film coated Tablet.
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP
	Proposed Pack size	30ml, 60ml, 50ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOFRAN Oral solution of (USFDA Approved)
	For generic drugs (me-too status)	Ondanles 4mg/5ml Oral solution of M/s Neomedix Reg# 066472

	Name and address of API manufacturer.	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 72 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Onseron Solution 4mg/5ml of by M/s Indus Pharma. performing quality tests Identification, Appearance, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s CTX Lifesciences PVT, LTD Address: Block no. 251-252 Sachin- Magdalla Road GIDC, Sachin Surat, Gujrat, India
API Lot No.	21ON000044
Description of Pack (Container closure system)	Amber glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-019-01	22SB-020-02	22SB-021-03
Batch Size	2400ml(40bottles)	2400ml(40bottles)	2400ml(40bottles)
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	23-02-2022	23-02-2022	23-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 issued by Food & Drugs Control Administration, Gujrat valid till 29/05/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # EI/3012100703, dated; 22-12-2021 cleared by DRAP (Karachi) dated: 05-01-2022 specifying Ondansetron Hydrochloride batch # 21ON000044
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	2.3.R.1.1	• As mixing is a critical step and batch is prepared in beaker by hand mixer than how it is ensured that uniform mixing is done. • Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.
2.	3.2.S.4.3	Submitted analytical method verification report by drug product manufacturer of drug substance shows different concentration than submitted analytical testing method of assay of drug substance.
3.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with Sucralose shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
4.	3.2.P.5.1 & 3.2.P.5.4	Deliverable volume is not part of specification as specified in USP monograph.. Clarification is required.
5.	3.2.P.5.2	Concentration of sample preparation is not as per USP monograph. Clarification is required.
6.	3.2.P.4.4	Composition of the Drug Product includes Sorbitol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit CoA's by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.

Previous Decision (M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division**.**

Evaluation by PEC:

<table>
<tr><th>S.No</th><th>Section</th><th>Shortcoming</th><th>Reply</th></tr>
<tr><td>1.</td><td>2.3.R.1.1</td><td>• As mixing is a critical step and batch is prepared in beaker by hand mixer than how it is ensured that uniform mixing is done.
• Scientific rationale for selecting the batch size of 40 bottles for manufacturing of trial batches, along with the submission of complete record of no. of bottles used in analytical testing of trial batches of finished product at different time points of stability studies.</td><td>• Ondensetron HCl is BCS class II drug. Therefore, in ondonix solution, mixing is the critical process parameter which have an impact on critical quality attributes and was monitored closely to obtain the desire quality. For mixing, stirrer was used and mentioned in product development data. During development, subsequent sampling was performed and after analytical testing mixing time was optimized. Stability studies of the Applied product are evident that the product complies with all its Quality targets.
• The Criteria for fixation of Batch size is based on the minimum requirements of samples being used for the stability analysis of products. Selected batch size was sufficient enough for stability time points and to allow the process capability to establish and obtain homogenous solution.
<table>
<tr><td colspan="4">Batch Size: 40 Bottles</td></tr>
<tr><td>Initial Testing</td><td>Realtime</td><td>Accelerated</td><td>Total</td></tr>
<tr><td>13 Bottles</td><td>12 Bottles</td><td>4 Bottles</td><td>29 Bottles</td></tr>
</table></td></tr>
<tr><td>2.</td><td>3.2.S.4.3</td><td>Submitted analytical method verification report by drug product manufacturer of drug substance shows different concentration than submitted analytical testing method of assay of drug substance.</td><td>Analytical method verification report by drug product manufacturer is attached</td></tr>
<tr><td>3.</td><td>3.2.P.2.1.1</td><td>Compatibility studies of the Drug Substance(s) with Sucralose shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.</td><td>Formulation of Ondonix oral solution 4mg/5ml is qualitatively similar with reference except sodium saccharine/ Sucralose. Innovator is using Sodium Saccharine while we used sucralose to meet our quality target product profile. Therefore, drug Compatibility study protocol & Report are attached</td></tr>
<tr><td>4.</td><td>3.2.P.5.1 & 3.2.P.5.4</td><td>Deliverable volume is not part of specification as specified in USP monograph..
Clarification is required.</td><td>Deliverable volume test has been included in specification, and the test is conducted at initial time point Report attached</td></tr>
<tr><td>5.</td><td>3.2.P.5.2</td><td>Concentration of sample preparation is not as per USP monograph.</td><td>As per USP monograph, preparation of sample solution is volume of sample eq. to 9mg of ondansetron in 100ml flask. As per our product label claim i.e. 4mg ondansetron/5ml, if we take sample volume eq. to 9mg of ondansetron so</td></tr>
</table>

		Clarification is required.	required sample volume will be 11.25ml, practically it is not possible to take 11.25ml quantitatively with accuracy. That's why we take 10ml sample which is eq.to 8mg of ondansetron and 9mg of ondansetron hydrochloride.
6.	3.2.P.4.4	Composition of the Drug Product includes Sorbitol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit CoA's by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	Analytical report of Sorbitol M./s 'Genix Pharma along with Vendors COA are attached

Decision: Approved.

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

163.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Dry Powder Injection (General) section mentioned.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28939 dated 12-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 5040866617
	The proposed proprietary name / brand name	Colmixin 2 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…2MIU
	Pharmaceutical form of applied drug	Powder for Solution for Injection

	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial, polymyxins.
	Reference to Finished product specifications	USP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Powder for Solution for Injection by Teva UK Limited of (MHRA Approved)
	For generic drugs (me-too status)	Nogotex injection 3MIU of M/s Nabiqasim Industries Reg# 110206
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40˚C ± 2˚C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Colomycin Injection 2 MIU of Teva UK limited performing quality tests Identification, Appearance, pH, Loss on drying , Free colistin, Assay.

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

STABILITY STUDY DATA			
Manufacturer of API	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.		
API Lot No.	CMS2106004		
Description of Pack (Container closure system)	10ml clear tubular glass vial Type-1		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-252-01	21SB(B)-253-02	21SB(B)-254-03
Batch Size	500 Vial	500 Vial	500 Vial
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	24-11-2021	24-11-2021	24-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Written confirmation for active substance to EU #FJ00006 to M/s Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309 Valid upto 21-09-2022.The certificate confirms that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.2	Label claim of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications i.e mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams with requisit fee.

2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
3.	3.2.S.4.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81>
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
5.	3.2.S.5.4	As per USP monograph Test for free colistin not performed, Clarification is required
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
7.	3.2.P.5.4	Copies of complete analysis of three batches shall be provided.
8.	3.2.P.5.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81> MICROBIAL ASSAYS Justify your sample preparation for assay in Analytical testing method with reference to USP monograph
9.	3.2.P.5.3	Analytical Method Verification studies performance is not in accordance to USP General Chapter <81> —MICROBIAL ASSAYS
10.	3.2.P.8	• Submit legible form of import documents • In submitted stability studies performance of microbial Assay is different than USP General Chapter <81> of MICROBIAL ASSAYS • Concentration of S_1-S_5 and U_3 are different than their own method

Previous Decision (M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.5.2	Label claim of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications i.e mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams with requisit fee.	Revise label claim along with the requisite fees of Rs 30,000/- Having Deposit Slip # 22355197 attached as Annex-I Each Vial Contains: Colistin as colistimethate Sodium equivalent 2MIU.
2.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Copy of DML attached valid till 21-09-2025
3.	3.2.S.4.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81>	➢ Our method of bioassay is according to USP Chapter 81 we can justify as: ➢ We have made dilutions of Standard and Sample According to USP 81, Stock solution concentration(1mg/ml) is same as USP monograph 81 ,plz see point number 6.3 and 6.4 in our Bioassay Method and table 2 in USP monograph 81. The successive solutions increase stepwise in Concentration in the ratio of 1:1.25 which is required by USP see dilution flow chart given in our bioassay method in point number 6.3 and 6.4. ➢ The median Concentration shows in USP chapter 81 for Colistimethate Sodium is 1 µg/Mlbut we make the 57.6 µg/mL because of Zone size which cannot

			readable on 1 µg/mL median concentration which we cannot estimate or read properly (*that It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range).* Please see USP chapter 81 cylinder-Plate Method says (in Table 2 attached as Annex-III) ➢ We have made the dilution in the ratio of 1:1.25 and the data remain in the linear range. ➢ According to the USP 81 we have made sample and standard dilution according to USP and both concentrations are same. ➢ The size of zones diameter that was produce in Bioassay method, analytical method verification & Stability studies is according to USP Chapter 81which were between 11-19mm see attached USP 81 Heading Inocula *They are using medium 10 while USP Bioassay specifies Medium 9*
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer drug substance(s) are attached.
5.	3.2.S.5.4	As per USP monograph Test for free colistin not performed, Clarification is required	We are using Colistimethate sodium sterile ready to fill material, according to USP monograph of **Colistimethate for Injection,** all tests including free colistin will be performed as per colistimethate sodium USP monograph. So, we performed free colistin test in finished product after filling of material. Revised COA having with free colistin test is attached
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Compatibility study attached
7.	3.2.P.5.4	Copies of complete analysis of three batches shall be provided.	Complete analysis of three batches are attached
8.	3.2.P.5.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81> MICROBIAL ASSAYS Justify your sample preparation for assay in Analytical testing method with reference to USP monograph	Please see the justification as mentioned in Section 3.2.S.4.2
9.	3.2.P.5.3	Analytical Method Verification studies performance is not in accordance to USP General Chapter <81> —MICROBIAL ASSAYS	Please see the justification as mentioned in Section 3.2.S.4.2
10.	3.2.P.8	• Submit legible form of import documents	• Import documents submitted.

		• In submitted stability studies performance of microbial Assay is different than USP General Chapter <81> of MICROBIAL ASSAYS • Concentration of S_1-S_5 and U_3 are different than their own method	• Please see the justification as mentioned in Section 3.2.S.4. ***In their method different concentrations are prepared for standard S_1-S_5 and sample U_3 while in performance different concentration are used.***
Decision: Deferred for clarification of using different concentration of standard *S_1-S_5 and sample U_3* in analytical testing method and stability stability data.			

Agenda of Mst. Iqra Aftab

Agenda Item No. 01:

Form 5 F

Deferred Cases

164.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: WJU-9LL-A9D9: 12-03-2024
	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	CellCar Tablets 400mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Carbamazepine….400mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AF01
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	USFDA Approved (Extended Release)
	For generic drugs (me-too status)	Product Name: **Tegral Tablets** Registration No: **021529** (Me too is of 200mg)
	Proposed Pack size	50’s.

Evaluation by PEC-V:

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluator Remarks
1.	1.5.9	Clarification regarding its formulation/composition whether its immediate release or extended release. The	Our product CellCar 400mg Tablet is an Immediate Release.	Submission of the evidence of approval of the applied formulation in 400mg strength as "**immediate**

		application shall be further evaluated on the provision of aforesaid clarification.		**release "** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. The application will be further evaluated on the provision of evidence as immediate release tablet in applied strength.

Previous Decision(M-336) : The Registration Board deferred for submission of evidence of approval of the applied formulation in 400mg strength as "immediate release " in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluator Remarks	Firms Response	Evaluator Remarks
1.	1.5.9	Clarification regarding its formulation/composition whether its immediate release or extended release. The application shall be further evaluated on the provision of aforesaid clarification.	Our product CellCar 400mg Tablet is an Immediate Release.	Submission of the evidence of approval of the applied formulation in 400mg strength as **"immediate release "** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. The application will be further evaluated on the provision of evidence as immediate release tablet in applied strength.	Our product CellCar 400mg Tablet is an Immediate Release and its reference is attached here. » Tegretol-400mg-Plain-tablet-SPC-MHRA-Approved.pdf	The SMPC provided by the firm is of MHRA approved product but it is of uncoated tablet whereas, the applied product is film coated.

Decision: Deferred for clarification since the reference product is uncoated tablet while you have applied for film coated tablet.

165.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Q3U-6A3-5NJN: 12-03-2024

	Details of fee submitted	PKR 30,000/- : 29-12-2023
	The proposed proprietary name / brand name	EpiCell 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Divalproex sodium equivalent to valproic acid…500mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic:N03AG01
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	FDA Approved(as enteric coated)
	For generic drugs (me-too status)	o Product Name: Epival 250mg Tablet o Registration No: 007160 Me too submitted by firm is of 250mg.
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.5.9	Submit clarification regarding formulation/composition whether its immediate release or delayed release. If "**immediate release " submit evidence** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. Moreover, the provided fee challan is of sustain release. The me too and RRA are of delayed release .The application shall be further evaluated on the provision of aforesaid clarification.	Reply Awaited.

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings.

Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.5.9	Submit clarification regarding formulation/composition whether its immediate release or delayed release. If "**immediate release " submit evidence** in one of the reference regulatory authorities specified by Registration Board in its 275th Meeting. Moreover, the provided fee challan is of sustain release. The me too and RRA are of delayed release .The application shall be further evaluated on the provision of aforesaid clarification.	Our product EpiCell SR 500mg is Sustained Release. In Section 1.5.2 there is a typographical mistake as has been written enteric coat.

Sr. No.	Section No.	Shortcomings
1)	1.1	The provided fee challan is of Epicell Tablet SR 500mg tablet.
2)	1.3.5.	Submit evidence of approval of relevant section from Licensing Authority.
3)	1.5.2	The applied formulation mentions "Each film coated tablet " whereas, the formulation is enteric coated tablet. Submit requisite fee for correction in label claim.
4)	1.5.8	Submit reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number.
5)	1.5.9	Submit the registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention.
6)	2.3.R.1.1	Submit Executed Production Documents.

7)	Drug Substance part	The data should be provided in relevant sections of drug substance part instead of referring to DMF.
8)	3.S.4.4	The drug substance manufacturer mentions reference of specs. USP whereas, drug product manufacturer mentions BP.Justify.
9)	3.2.P.1	The applied strength is 500mg whereas, composition is of 250mg tablet.
10)	3.2.P.2	• Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product. • Provide the details of product against which pharmaceutical studies have been performed. • The pharmaceutical equivalence studies dissolution is not as per USP.Moreover, the identification test mentions amisulpride. • Submit complete CDP protocol, CDP report and supporting documents.
11)	3.2.P.3.2	The batch formula is of 250mg tablet.
12)	3.2.P.3.5	Submit process validation protocol of commercial batches.
13)	3.2.P.5.1	The specifications are not as per USP like test of identification, dissolution specs. and uniformity of dosage units.
14)	3.2.P.5.2	• Submit which detector has been used in assay determination. • The assay is not as per USP which mentions NLT 80% of the labeled amount of valproic acid and you have mentioned labeled amount of Divalproex sodium is dissolved. • The sample stock solution preparation not provided.
15)	3.2.P.5.3	The sample stock solution preparation not provided.
16)	3.2.P.5.4	The copies of complete analysis of at least two batches shall be provided.
17)	3.2.P.8.3	a) The section 3.2.P.5.1 mentions tablet weight 420 mg ,whereas, stability summary data sheets mention 800mg. b) Align all the chromatograms in proper sequence month wise. c) Submit stability data of six months. d) Submit system suitability. e) Submit audit trail. f) The chromatographic conditions mentioned on chromatograms is different than analytical test method. The injection volume in test method is 15ul whereas, in chromatograms is 1ul.The detector wavelength in test method is 210nm whereas, in chromatograms is 215nm.Justify. g) Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. h) Submit documents for the procurement of API with approval from DRAP (in case of import).

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

166.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4535: 16-02-2023
	Details of fee submitted	Slip No:7324123640

		PKR 30,000/-
	The proposed proprietary name / brand name	Leomide Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Leflunomide…10mg**
	Pharmacotherapeutic Group of (API)	Immunosupressant;L04AK01 Dihydroorotate dehydrogenase (DHODH) inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Product Name: **Lefona Tab 10mg** Registration No: **048313**
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	3.2.P.2.1	a) Clarification is required for the use of surfactant in the formulation. b) Justify the use of fumed silicon dioxide instead of colloidal form.
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 5.97 mg. Justification is required.
4.	3.2.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.
5.	3.2.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	GMP certificated submitted dated:3rd August 2022.	Submitted
2.	3.2.P.2.1	a) The USFDA inactive database provides the maximum potency per unit of amaranth as 0.01mg whereas , you have used 0.073mg. Justification/clarification is required .	a) At the time of dossier submission i.e Faburary-2023, no safe limit for amaranth color was available on the USFDA inactive ingredient database	The limit of amaranth in oral film coated tablet as per USFDA inactive database is 0.01mg whereas, the limit provided by firm is

		b) Clarification is required for the use of surfactant in the formulation. c) Justify the use of fumed silicon dioxide instead of colloidal form.	and as per reference Annexure I it can be seen that the inactive data base was updated on 24-April-2024.Also, according to the newly updated database the allowable FDA safe limit for amaranth color in oral tablets is 0.48mg/MDE and the quantity of Amaranth color used in our formulation is 0.073mg per tablet, which falls well within the allowable limit b) Sodium lauryl sulfate is added as a surfactant. It is an anionic surfactant that act as a wetting or solubilizing agent. Hence, it enhances the dissolution. As far as the safety and efficacy of the product is concerned, the maximum allowed FDA safe limit of sodium lauryl sulfate in oral tablet film coated is 40mg/MDE. Whereas, the quantity of sodium lauryl sulfate used in our formulation is 5.00mg/tablet i.e. 3.03% which is well within the safe limit defined by FDA. Also, Leflunomide 10mg tablet Manufactured by Medac Gesellschaft für klinische Spezialpräparate mbH Fehlandstr.3, 20354 Hamburg Germany, also contains sodium lauryl sulphate in its formulation.	of uncoated tablet i.e 0.48mg.

			a) Both fumed silicon dioxide and colloidal silicon dioxide are same material.	
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 5.97 mg. Justification is required.	The weight of core tablet is 160mg The weight of coated tablet is 160mg + 5.97mg = 165.97mg The Average weight of coated tablet specified in BMR is 165mg ± 5%. Therefore, the average weight of coated tablet i.e 165.97mg is well within the specified limit. Also 0.97mg is the amount of extra film coating material taken in order to compensate the process loss faced during the coating operation.	
4.	3.2.P.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.	Submitted.	
5.	3.2.P.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).	Submitted.	The GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin validity is 28-02-2021.

Decision: Approved.

167.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt. Ltd. F-95 Hub River Road S.I.T.E Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3928: 10-02-2023
	Details of fee submitted	Slip No:4420698935 PKR 30,000/-
	The proposed proprietary name / brand name	Leomide Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Leflunomide…20mg
	Pharmacotherapeutic Group of (API)	Immunosupressant;L04AK01 Dihydroorotate dehydrogenase (DHODH) inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	o Product Name: **Leflu Tablet 20mg** o Registration No: **094328**
	Proposed Pack size	As per SRO

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	3.2.P.2.1	a) Clarification is required for the use of surfactant in the formulation. b) Justify the use of fumed silicon dioxide instead of colloidal form.
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 6.401 mg. Justification is required.
4.	3.2.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.
5.	3.2.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	GMP certificated submitted dated:3rd August 2022.
2.	3.2.P.2.1	a) Clarification is required for the use of surfactant in the formulation. b) Justify the use of fumed silicon dioxide instead of colloidal form.	Sodium lauryl sulfate is added as a surfactant. It is an anionic surfactant that act as a wetting or solubilizing agent. Hence, it enhances the dissolution. As far as the safety and efficacy of the product is concerned, the maximum allowed FDA safe limit of sodium lauryl sulfate in oral tablet film coated is 40mg/MDE. Whereas, the quantity of sodium lauryl sulfate used in our formulation is 5.00mg/tablet i.e. 3.03% which is well within the safe limit defined by FDA. Also, Leflunomide 20mg tablet Manufactured by Medac Gesellschaft für klinische Spezialpräparate mbH Fehlandstr.3, 20354 Hamburg Germany also contains sodium lauryl sulphate in its formulation (Reference attached in Annexure I) Moreover, for the maximum assurance, we have also performed compatibility of all ingredients with the API during developmental studies, and the result shows that all ingredients are compatible with the API and this have also been ensured by satisfactory stability results b) Both fumed silicon dioxide and colloidal silicon dioxide are same material.
3.	3.2.P.5.1	The weight of coated tablet is 165mg whereas, total quantity of film coating material in section 3.2.P.1 is 6.401 mg. Justification is required.	Justification submitted.
4.	3.2.8.3	a) Provide the results/calculation sheets for system suitability as per USP. b) Provide relative retention time for leflunomide related compound B, leflunomide related compound A, leflunomide related compound C, and leflunomide. c) Provide resolution results for leflunomide related compound C and leflunomide.	Submitted.

5.	3.2.8.3	a) Reference of previous approval of applications with stability study data of the firm (if any). b) Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. c) Documents for the procurement of API with approval from DRAP (in case of import).	The GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin validity is 28-02-2021.

Decision: Approved.

168.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore**
	Name, address of Manufacturing site.	M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32620: 14-11-2022
	Details of fee submitted	Slip No:861661442 PKR 30,000/-
	The proposed proprietary name / brand name	Lipikan Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Atorvastatin as atorvastatin calcium trihydrate…….10mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Registration Number:023620 Brand Name:Lipitor Tablet 10mg
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.

5.	3.2.S.4.1	a) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. b) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. c) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. d) Submit specification of drug substance by drug product manufacturer.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021). b) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. c) Justification is required for performance of LOD instead of water content.
9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Clarification is required for addition of three diluents in the formulation. c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.
11.	3.2.P.2.2.1	a) Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
13.	3.2.P.5.1	a) Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.6	Submit COA of primary reference standard.
16.	3.2.P.8.3	a) Submit date of initiation of stability on stability summary data sheets. b) Submit stability summary data sheets as per DRAP CTD guidance document. c) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	a) Provide supporting documents of stability for initial testing. b) Submit justification for not performing system suitability before assay at each time point.

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluation Remarks
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	Applied for issuance of GMP.	
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Submitted.	
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.	It is Atorvastatin Calcium Trihydrate , copy of structural formula and chemical name Attached.	
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.	The firm has submitted field of the invention of polymorphic forms.	The submitted document doesnot mention the polymorphic form used in drug product.
5.	3.2.S.4.1	a) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. b) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. c) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. d) Submit specification of drug substance by drug product manufacturer.	We wrote to Drug substance manufacturer and new **CoA has been submitted** for your kind consideration. **b)** Propylene glycol has not been used as solvate in manufacturing of API. **c)** We wrote to Drug substance manufacturer and new **CoA has been submitted** for your kind consideration.	Firm has submitted COAs instead of specifications. The specification of drug substance by drug product manufacturer provided.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.	Submitted.	
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.	Submitted.	
8.	3.2.S.4.4	a) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021).	It was a typographical mistake corrected CoA is submitted	

		b) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. c) Justification is required for performance of LOD instead of water content.	for your kind consideration. It was a typographical mistake corrected CoA is submitted for your kind consideration.	
9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.	Stability data of 48 months submitted by the firm.	
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Clarification is required for addition of three diluents in the formulation. c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.	a) The end quantity is same either calculated by atorvastatin calcium or Atorvastatin calcium trihydrate factor basis as the differences of molecular weights of atorvastatin calcium or Atorvastatin calcium trihydrate. b) Calcium Carbonate is used as diluent. Avicel is diluent and for disintegration Lactose monohydrate is used as diluent and for compaction of tablet c) The excipients are compatible with the drug substance . the excipients are same as of innovator.	
11.	3.2.P.2.2.1	Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.		CDP not submitted by the firm.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.	Submitted.	

13.	3.2.P.5.1	Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.	Submitted.	
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.	Submitted.	
15.	3.2.P.6	Submit COA of primary reference standard.		COA of working standard has been submitted.
16.	3.2.P.8.3	a) Submit date of initiation of stability on stability summary data sheets. b) Submit stability summary data sheets as per DRAP CTD guidance document. c) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.	
17.	3.2.P.8.3	a) Provide supporting documents of stability for initial testing. b) Submit justification for not performing system suitability before assay at each time point.	Submitted.	

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

169.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore**
	Name, address of Manufacturing site.	M/s Jaskan pharmaceuticals Pvt Ltd Company Address: Plot No 50 Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 32621: 14-11-2022
	Details of fee submitted	Slip No:9136459420 PKR 30,000/-
	The proposed proprietary name / brand name	Lipikan Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Atorvastatin as atorvastatin calcium trihydrate…….20mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Product Name: Lipitor Tablet 20mg Registration No: 023621
	Proposed Pack size	As per SRO.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. b) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. c) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. d) Submit specification of drug substance by drug product manufacturer.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021). b) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. c) Justification is required for performance of LOD instead of water content.

9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Clarification is required for addition of three diluents in the formulation. c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.
11.	3.2.P.2.2.1	b) Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
13.	3.2.P.5.1	a) Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.6	Submit COA of primary reference standard.
16.	3.2.P.8.3	a) Submit date of initiation of stability on stability summary data sheets. b) Submit stability summary data sheets as per DRAP CTD guidance document. c) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
17.	3.2.P.8.3	c) Provide supporting documents of stability for initial testing. d) Submit justification for not performing system suitability before assay at each time point.

Previous Decision(M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response	Evaluation Remarks
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	Applied for issuance of GMP.	
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	Submitted.	
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate as the chemical name and structural formula does not mention trihydrate.	It is Atorvastatin Calcium Trihydrate , copy of structural formula and chemical name Attached.	

4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.	The firm has submitted field of the invention of polymorphic forms.	The submitted document doesnot mention the polymorphic form used in drug product.
5.	3.2.S.4.1	e) The reference for drug substance manufacturer mentions both USP and in house. Clarification is required. f) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. g) The acceptance criteria for assay as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**" whereas, your specifications do not mention solvent free. Clarification is required. h) Submit specification of drug substance by drug product manufacturer.	We wrote to Drug substance manufacturer and new **CoA has been submitted** for your kind consideration. **b)** Propylene glycol has not been used as solvate in manufacturing of API. **c)** We wrote to Drug substance manufacturer and new **CoA has been submitted** for your kind consideration.	Firm has submitted COAs instead of specifications. The specification of drug substance by drug product manufacturer provided.
6.	3.2.S.4.2	Submit analytical method of drug substance by drug product manufacturer.	Submitted.	
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.	Submitted.	
8.	3.2.S.4.4	d) The manufacturing date of drug substance is different on COA of drug substance (24-06-2021) and COA of drug product manufacturer (March 2021). e) Justification is required for not performing test of calcium (by AAS) and enantiomeric purity by drug product manufacturer. f) Justification is required for performance of LOD instead of water content.	It was a typographical mistake corrected CoA is submitted for your kind consideration. It was a typographical mistake corrected CoA is submitted for your kind consideration.	
9.	3.2.S.7.3	The stability data of drug substance is of 36 months whereas, retest date is of 4 years. Submit stability data of 48 months at long term condition as per Zone IVa/IVb.	Stability data of 48 months submitted by the firm.	
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance whereas, you have applied factor which is on trihydrate form. Justification is required.	a) The end quantity is same either calculated by atorvastatin calcium or Atorvastatin	

		b) Clarification is required for addition of three diluents in the formulation. c) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. d) Provide the average weight of core and coated tablet.	calcium trihydrate factor basis as the differences of molecular weights of atorvastatin calcium or Atorvastatin calcium trihydrate. b) Calcium Carbonate is used as diluent. Avicel is diluent and for disintegration Lactose monohydrate is used as diluent and for compaction of tablet c) The excipients are compatible with the drug substance . the excipients are same as of innovator.	
11.	3.2.P.2.2.1	Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.		CDP not submitted by the firm.
12.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.	Submitted.	
13.	3.2.P.5.1	Submit copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure as per USP, instead of providing analytical test method with it.	Submitted.	
14.	3.2.P.5.2	c) Submit detailed analytical procedures used for testing the drug product in relevant section. d) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.	Submitted.	
15.	3.2.P.6	Submit COA of primary reference standard.		COA of working standard has been submitted.
16.	3.2.P.8.3	d) Submit date of initiation of stability on stability summary data sheets.	Submitted.	

		e) Submit stability summary data sheets as per DRAP CTD guidance document. f) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		
17.	3.2.P.8.3	a) Provide supporting documents of stability for initial testing. b) Submit justification for not performing system suitability before assay at each time point.	Submitted.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.				

Agenda Item No. 02:
Registration applications for local manufacturing of (Human) drugs on Form 5F

a. New cases

170.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Private), Limited 44,45 B,Korangi Creek Road,Karachi, Pakistan.**
	Name, address of Manufacturing site.	**M/s Genix Pharma (Private), Limited 44,45 B,Korangi Creek Road,Karachi, Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10837,02-05-2023
	Details of fee submitted	Slip No:41860774488 PKR 75000/-
	The proposed proprietary name / brand name	Dol-P Tablet 650mg/75mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Film Coated Tablet contains:** **Paracetamol…650mg** **Tramadol Hydrochloride…75mg**
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics ATC Code:N02AJ13
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	AEMPS Approved.
	For generic drugs (me-too status)	New Molecule.

	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	1.5.15 – 1.5.20	Submit signed undertakings.
4.	1.6.5	Submit valid DML issued by the relevant regulatory authority of country of origin or valid Good Manufacturing Practice (GMP) certificate of the Tramadol Hydrochloride manufacturer issued by relevant regulatory authority of country of origin.
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
Tramadol Hydrochloride		
6.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
7.	3.2.S.4.4	Submit justification for any incomplete analyses of the drug substance by drug product manufacturer.
	Paracetamol	
8.	3.2.S.4.2	Submit analytical procedures used for routine testing of the drug substance by drug product manufacturer.
9.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
10.	3.2.S.4.4	Provide results of analysis of relevant batch of drug substance used during product development and stability studies. Moreover, submit justification for any incomplete analyses of the drug substance by drug product manufacturer as per requirements of BP.
11.	3.2.P.3.2	A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis.
12.	3.2.P.3.5	Provide process validation protocol of commercial batches.

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

171.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, 18Km, Mandiali Stop, Lahore.**
	Name, address of Manufacturing site.	**M/s BJ Pharmaceuticals, 18Km, Mandiali Stop, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8071 22-03-2023
	Details of fee submitted	Slip No:43167438563 PKR 30,000/-
	The proposed proprietary name / brand name	Bemol Plus Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** **Paracetamol…325mg** **Tramadol…37.5mg**
	Pharmacotherapeutic Group of (API)	Opioids in combination with non-opioid analgesics ATC Code:N02AJ13
	Reference to Finished product specifications	USP

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
2.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	1.5.4	Provide proposed pack size as it varies from section 3.2.P.7.
4.	1.5.15 – 1.5.20	Submit signed undertakings.
5.	1.6.5	Submit valid DML issued by the relevant regulatory authority of country of origin or valid Good Manufacturing Practice (GMP) certificate of the Tramadol Hydrochloride manufacturer issued by relevant regulatory authority of country of origin.
6.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
Tramadol Hydrochloride		
7.	3.2.S.4.1 3.2.S.4.2	Submit drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
8.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
9.	3.2.S.4.4	Submit justification for any incomplete analyses of the drug substance by drug product manufacturer.
Paracetamol		
10.	3.2.S.4.2	Submit analytical procedures used for routine testing of the drug substance by drug product manufacturer.
11.	3.2.S.4.3	Submit analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
12.	3.2.S.4.4	Provide results of analysis of relevant batch of drug substance used during product development and stability studies. Moreover, submit justification for any incomplete analyses of the drug substance by drug product manufacturer as per requirements of BP.
13.	3.2.P.2	Submit compatibility studies of the Drug Substance(s) with excipients, if the qualitative composition of the formulation is not similar to innovator / reference product.
14.	3.2.P.2.2.1	a) The pharmaceutical equivalence report does not mention the comparison of dissolution. b) Provide the details of product against which pharmaceutical studies have been performed.
15.	3.2.P.3.2	A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis.
16.	3.2.P.3.5	Provide process validation protocol of commercial batches.
17.	3.2.P.5.3	Submit the results of specificity.

18.	3.2.P.6	Submit COA of primary / secondary reference standard including source and lot number.
19.	3.2.P.7	Submit detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume.
20.	3.2.P.8.3	**Documents / Data to be provided along with stability study data:** ➢ Reference of previous approval of applications with stability study data of the firm (if any). ➢ Approval of API/ DML/GMP certificate of both API manufacturers issued by concerned regulatory authority of country of origin. ➢ Documents for the procurement of Tramadol HCl with approval from DRAP (in case of import).

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

172.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s McOlson Research Laboratories Pvt., Ltd**
	Name, address of Manufacturing site.	**M/s McOlson Research Laboratories Pvt., Ltd**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8554: 29-03-2023.
	Details of fee submitted	Slip No:15739021 PKR 30,000/-
	The proposed proprietary name / brand name	Aprin Tablet (Starter Pack)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**APRIN 10MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……10mg **APRIN 20MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……20mg **APRIN 30MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……30mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants L04AA32
	Reference to Finished product specifications	Innovators Specification
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	(not provided)
	Proposed Pack size	14 days starter pack,28 days starter pack. As per SRO.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.1	Submit Me too or fee o new molecule.
2.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.
3.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
4.	1.6	Submit miscellaneous information as per guidance document.
5.	2.3.R.1	Submit production documentation.
6.	3.2.S.4.1 3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.
7.	3.2.S.4.3	Submit analytical test method for assay by drug product manufacturer.
8.	3.2.S.4.4	a) Justification is required for not performing the enantiomeric purity test while analyzing the quality of drug substance by drug product manufacturer. Since, it is the critical test for apremilast because the active substance exhibits stereoisomerism due to presence of a single chiral centre, with the (S)-enantiomer being pharmacologically active. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer.
9.	3.2.P.2.2.1	The dissolution media as per USFDA is 0.15% SLS and paddle speed is 60 rpm whereas, the test method provided by you mentions SLS 0.3 % and paddle speed 75rpm.
10.	3.2.P.5.1	a) The weight of tablets of all three strengths of innovator brand increase with empirical ratio as per the review report of USFDA, while the weight of tablet of all three applied strength varies irrespective of their increase quantity of active ingredient. b) The innovator uses UPLC for the test whereas, you have used HPLC. c) The test of degradation products and microbial limits have not been included.
11.	3.2.P.5.3	a) The detection limit and quantitation limit has not been performed for assay validation. b) The dissolution media as per USFDA is 0.15% SLS and paddle speed is 60 rpm whereas, the test method provided by you mentions SLS 0.3 % and paddle speed 75rpm.
12.	3.2.P.7	The applied starter pack presentation mentioned in section 3.2.P.7 should be as per the innovator brand the starter, pack is of 2 weeks which consist of 13-tablet blister titration pack containing:(4) 10-mg, (4) 20-mg, and (5) 30-mg tablets with an additional (14) 30mg tablets. Justify the rationality of your starter pack presentation with reference to the innovator.

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

173.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma (Pvt)., Ltd.** **Company Address: Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700**
	Name, address of Manufacturing site.	**M/s Helix Pharma (Pvt)., Ltd.** **Company Address: Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7914
	Details of fee submitted	Slip No:608348591404 Rs: 30000/-
	The proposed proprietary name / brand name	Nurosa Oral Solution 10mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Nurosa Oral Solution 10mg/ml**
	Pharmacotherapeutic Group of (API)	Antiepileptic ATC Code: N03AX18
	Reference to Finished product specifications	As per BP.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Not provided.
	Proposed Pack size	100 ml bottle, As per PRC.

Evaluation by PEC:

S. No	Sections	Observations/Deficiencies/ Short-comings
6.	1.3.5.	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
7.	1.5.2	Submit strength of Active ingredient. In case API is in the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.
8.	2.3.R.1	Submit production documentation.
9.	3.2.P.2.2.1	Provide details of reference product against which pharmaceutical studies have been conducted.
10.	3.2.P.5.1	Submit clarification for not performing test of uniformity of mass on drug product.
11.	3.2.P.8.3	Provide supporting documents along with stability data sheets for all tests: ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.	
174.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (PVT.) Ltd, Company Address: 8th Pharma city , 30-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Aptcure (PVT.) Ltd, Company Address: 8th Pharma city , 30-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9200
	Details of fee submitted	Slip No:033913194 Rs: 30000/-

	The proposed proprietary name / brand name	**L-Zid Tablet 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Linezolid…..400mg**
	Pharmacotherapeutic Group of (API)	Antibacterial ATC Code: J01XX08
	Reference to Finished product specifications	Innovator Specs.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Me too is of 600mg.
	Proposed Pack size	100's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Submit production documentation.
3.	3.2.S.3.1	Submit Elucidation of Structure and other Characteristics.
4.	3.2.S.3.2	Submit list of Drug Substance / API-related impurities and process-related impurities with acceptance limits.
5.	3.2.S.4.1 3.2.S.4.2	Submit drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
6.	3.2.S.4.3	Submit proper report for analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
7.	3.2.S.4.4	a) Provide results of assay as both anhydrous and as is basis. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification). c) The reference of specifications in section 3.2.S.4.1 is IP whereas, in 3.2.S.4.4 is USP. Justification is required.
8.	3.2.S.4.5	Submit justification of specifications.
9.	3.2.P.1.1	Submit description of the dosage form as per guidance document.
10.	3.2.P.2	a) Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product or provide the reference product which has similar formulation. b) The test method is not as per USP, justify the pharmaceutical equivalence studies and CDP.. c) Submit following documents for CDP: ✓ Using the mean dissolution values from both curves at each time interval, calculate the difference factor (f1) and similarity factor (f2) .
11.	3.2.P.5.1	The reference of specs mentioned in this section is USP, whereas, Form 5 F mentions innovators.
12.	3.2.P.5.2	The analytical method is not as per USP like chromatographic conditions, dissolution ,rpm etc.
13.	3.2.P.5.3	Submit method verification as per USP.
14.	3.2.P.5.4	Submit complete analysis of at least two batches.
15.	3.2.P.8.3.	a) The date of clearance of linezolid is 24-06-22 whereas, the data of manufacturing of batches in stability summary data sheets is 02-04-2022. Justification is required. b) Justify the batch size 990 tablets.

		c) The injection volume and detector wavelength on chromatograms is different than USP. d) Submit data logger record at long term condition. e) Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing. f) Submit valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. g) Submit dissolution supporting data for stability at each time point.

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

175.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (PVT.) Ltd** **Company Address: 8th Pharma city , 30-km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Aptcure (PVT.) Ltd Company Address: 8th Pharma city , 30-km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10006, 13-04-2023
	Details of fee submitted	Slip No:0407212051 Rs: 30000/-
	The proposed proprietary name / brand name	**L-Zid Tablet 600mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Linezolid…..600mg**
	Pharmacotherapeutic Group of (API)	Antibacterial ATC Code: J01XX08
	Reference to Finished product specifications	Innovator Specs.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Company Name: Maxitech Pharma (Pvt) Ltd. Product Name: Linzo 600mg Tablet Registration Number: 083714
	Proposed Pack size	100's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Submit production documentation.
3.	3.2.S.3.1	Submit elucidation of structure and other characteristics.
4.	3.2.S.3.2	Submit list of Drug Substance / API-related impurities and process-related impurities with acceptance limits.
5.	3.2.S.4.1 3.2.S.4.2	Submit drug substance specifications and analytical procedures used for routine testing of the drug substance by drug product manufacturer.
6.	3.2.S.4.3	Submit proper report for analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.

7.	3.2.S.4.4	a) Provide results of assay as both anhydrous and as is basis. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification). c) The reference of specs in section 3.2.S.4.1 is IP whereas, in 3.2.S.4.4 is USP. Justification is required.
8.	3.2.S.4.5	Submit justification of specification.
9.	3.2.P.1.1	Submit description of the dosage form as per guidance document.
10.	3.2.P.2	a) Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product or provide the reference product which has similar formulation. b) The test method is not as per USP, justify the pharmaceutical equivalence studies and CDP. c) Submit following documents for CDP: ✓ Using the mean dissolution values from both curves at each time interval, calculate the difference factor (f1) and similarity factor (f2) .
11.	3.2.P.5.1	The reference of specs mentioned in this section is USP, whereas, Form 5 F mentions innovators.
12.	3.2.P.5.2	The analytical method is not as per USP like chromatographic conditions, dissolution ,rpm etc.
13.	3.2.P.5.3	Submit method verification as per USP.
14.	3.2.P.5.4	Submit complete analysis of at least two batches.
15.	3.2.P.8.3.	a) Justify the batch size 992 tablets. b) The injection volume and detector wavelength on chromatograms is different than USP. c) Submit data logger record at long term condition. d) Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing. e) Submit valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. f) Submit dissolution supporting data for stability at each time point.

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

176.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cibex (Private) Limited** **Company Address: F-405, S.I.T.E Karachi**
	Name, address of Manufacturing site.	**M/s Cibex (Private) Limited** **Company Address: F-405, S.I.T.E Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12859, 24-05-2023
	Details of fee submitted	Slip No:89128316 Rs: 30000/-
	The proposed proprietary name / brand name	Famobex Dry Suspension 40mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml (after reconstitution) contains:** **Famotidine……40mg**
	Pharmacotherapeutic Group of (API)	H2 Receptors antagonists

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	APSIN (Reg. No.: 046460) manufactured by Safron Pharmaceuticals (19 km Sheikhupura Road Faisalabad Pakistan.)
	Proposed Pack size	60ml,120ml

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit valid DML.
2.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
3.	2.3.R.1.1	Submit production documentation.
4.	3.2.S.4.2 3.2.S.4.3	The 3.2.S.4.1 mentions reference of specifications as USP whereas, 3.2.S.4.2 and 3.2.S.4.3 mentions BP
5.	3.2.S.4.3	Submit proper report for analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.
6.	3.2.S.4.4	a) Provide results of assay as both anhydrous and as is basis. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).
7.	3.2.S.7.3	The shelf life of API is 5 years whereas, stability data is of two years only.
8.	3.2.P.1	Details of accompanying reconstitution diluent shall be submitted
9.	3.2.P.2	Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product or provide the reference product which has similar formulation.
10.	3.2.P.2.5	Submit data for test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter<51>.
11.	3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.
12.	3.2.P.2.2.1	The microbial enumeration tests and tests for Specified microorganisms not included.
13.	3.2.P.5.1	a) The microbial enumeration tests and tests for Specified microorganisms not included. b) Submit Uniformity Of Dosage Units.
14.	3.2.P.8.3.	a) Submit stability data of six months of batch no TR020901. b) The date of manufacturing of TR020901 is 09-2022 whereas, date of initiation of stability studies is 12-12-2022.Justification is required. c) Submission of Volume of diluent for reconstitution along with justification (weight/ml calculation) with reference to innovator/reference product. d) Submission of Stability data of reconstituted suspension up to proposed shelf life is to be submitted for all the three batches. e) Documents for the procurement of famotidine with approval from DRAP (in case of import).

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

177.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt). Ltd.** **Company Address: Plot No. L-20/B, Sector 22, F.B. Industrial Area**

	Name, address of Manufacturing site.	**M/s Tabros Pharma (Pvt). Ltd.** **Company Address: Plot No. L-20/B, Sector 22, F.B. Industrial Area**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13939 , 05-06-2023
	Details of fee submitted	Slip No:3285733040 Rs: 30000/-
	The proposed proprietary name / brand name	**Acetilo Topical Solution 0.01%.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Fluocinolone acetonide….0.1mg**
	Pharmacotherapeutic Group of (API)	Corticosteroid.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	New molecule
	Proposed Pack size	60ml,120ml

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings	Firms Response
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	A valid GMP certificate for the manufacturing unit, issued within the last three years submitted.
2.	2.3.R.1.1	Submit production documentation.	Production documentation submitted.
3.	3.2.S.4.1 3.2.S.4.2	The reference of specifications and analytical method of API of drug substance manufacturer mentions both EP and USP. Clarification is required.	**Fluocinolone Acetonide**, supplied by M/s. Farmabios, Italy, complies with both the (EP) and (USP) standards. The justification of the specification provided by the API manufacturer has been submitted.

Decision: Approved.

178.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth Pharma (Pvt.) Ltd,** **Company Address: plot No. 241, Sector-24, Korangi Industrial Area.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd, Company Address: plot No. 241, Sector-24, Korangi Industrial Area.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14701 , 12-06-2023
	Details of fee submitted	Slip No:85684513159 Rs: 30000/-

	The proposed proprietary name / brand name	**Full Fresh Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Polyvinyl Alcohol…….5mg/ml** **Polyvinyl pyrrolidone….6mg/ml**
	Pharmacotherapeutic Group of (API)	Lubricant
	Reference to Finished product specifications	Manufacturer Specs.
	The status in reference regulatory authorities	Murine Health Canada Approved
	For generic drugs (me-too status)	Provide Me too
	Proposed Pack size	15ml

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	2.3.R.1.1	Submit production documentation.
2.	3.2.P.5.1	a) The reference of specification is in house so submit data as per guidance document regarding application of drug product specifications.
3.	3.2.P.8.3	a) Water loss test not performed. Justification is required. b) Submit reference of previous approval of applications with stability study data of the firm (if any). c) Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. d) Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

179.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth Pharma (Pvt.) Ltd** **Company Address: plot No. 241, Sector-24, Korangi Industrial Area,**
	Name, address of Manufacturing site.	**M/s Ophth Pharma (Pvt.) Ltd** **Company Address: plot No. 241, Sector-24, Korangi Industrial Area,**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14699 , 12-06-2023
	Details of fee submitted	Slip No:542275533 Rs: 75000/-
	The proposed proprietary name / brand name	**Trop M Eye drop**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Tropicamide ..5mg** **Phenylephrine Hydrochloride….5mg**
	Pharmacotherapeutic Group of (API)	Cycloplegics/Mydriatic & Sympathomimetic
	Reference to Finished product specifications	Manufacturer Specs.
	The status in reference regulatory authorities	PMDA Approved

	For generic drugs (me-too status)	Not available.
	Proposed Pack size	10ml, Rs 800.54/-

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	2.3.R.1.1	Submit production documentation.
Tropicamide		
2.	3.2.P.4.2	Submit complete test method as per USP instead of providing monograph.
3.	3.2.P.4.4	a) Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).
Phenylephrine		
4.	3.2.P.4.4	a) Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same bat``ch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification).
5.	3.2.P.5.1	a) The reference of specification is inhouse so submit data as per guidance document regarding application of drug product specifications.
6.	3.2.P.8.3	a) Water loss test not performed. Justification is required. b) The sample name in chromatograms of TB 101,TB 102,TB103 is Mydraine injection. c) The injection volume in chromatograms is also 0. d) Arrange the chromatograms of 0 month,3 months and 6 months. e) Submit reference of previous approval of applications with stability study data of the firm (if any). f) Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. g) Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

180.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Name, address of Manufacturing site.	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15397: 19-06-2023
	Details of fee submitted	Slip No:3729471267 PKR 30,000/-
	The proposed proprietary name / brand name	Atorvi Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Atorvastatin as atorvastatin calcium trihydrate…….10mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Registration Number:023620 Brand Name:Lipitor Tablet 10mg
	Proposed Pack size	As per SRO.,1x30's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate ,structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. b) The test of assay is missing which as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**". c) |Submit evidence of availability of AAS.
6.	3.2.S.4.2	The analytical procedure of drug substance is not as per USP.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) Provide reference for specifications as the tests and specs differ from section 3.2.S.4.1. b) The COA mentions API should be stored at temperature not exceeding 25C whereas, stability studies at long term has been conducted at 30C.
9.	3.2.S.7.3	The stability data of drug substance is not readable.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 10.36 mg whereas, you have applied 10.84mg which is trihydrate form. Justification is required. b) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. c) Justify the use of flavoring agent methionin in the formulation. d) Provide the average weight of core and coated tablet.

		e) The composition mentioned in 3.2.P.1 differs from formulation mentioned in 3.P.2.1.
11.	3.2.P.2.2.1	Submit CDP protocol and supporting documents .
12.	3.2.P.3.5	Submit process validation protocol of commercial batches.
13.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required, which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.5.3	Submit complete analytical method verification report.
16.	3.2.P.6	Submit COA of primary reference standard.
17.	3.2.P.8.3	a) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
18.	3.2.P.8.3	a) Submit justification for not performing system suitability before assay at each time point. b) Submit COA of drug product at each time point.

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

181.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Name, address of Manufacturing site.	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15398: 19-06-2023
	Details of fee submitted	Slip No:47338085437 PKR 30,000/-
	The proposed proprietary name / brand name	Atorvi Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Atorvastatin as atorvastatin calcium trihydrate…….20mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Product Name: Lipitor Tablet 20mg Registration No: 023621
	Proposed Pack size	As per SRO.1x10's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate ,structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. b) The test of assay is missing which as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**". c) |Submit evidence of availability of AAS.
6.	3.2.S.4.2	The analytical procedure of drug substance is not as per USP.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) Provide reference for specifications as the tests and specs. differ from section 3.2.S.4.1. b) The COA mentions API should be stored at temperature not exceeding 25C whereas, stability studies at long term has been conducted at 30C.
9.	3.2.S.7.3	The stability data of drug substance is not readable.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 20.72 mg whereas, you have applied 21.65mg which is trihydrate form. Justification is required. b) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. c) Justify the use of flavoring agent methionin in the formulation. d) Provide the average weight of core and coated tablet e) The composition mentioned in 3.2.P.1 differs from formulation mentioned in 3.P.2.1.
11.	3.2.P.2.2.1	Submit CDP protocol and supporting documents .
12.	3.2.P.3.5	Submit process validation protocol of commercial batches.
13.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.5.3	Submit complete analytical method verification report.
16.	3.2.P.6	Submit COA of primary reference standard.
17.	3.2.P.8.3	a) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
18.	3.2.P.8.3	a) Submit justification for not performing system suitability before assay at each time point. b) Submit COA of drug product at each time point.

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

182.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Name, address of Manufacturing site.	**M/s Weather Folds Pharmaceuticals , Factory:69/2, Phase II, Industrial Area, Hattar , Pakistan.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15399: 19-06-2023
	Details of fee submitted	Slip No:86822916576 PKR 30,000/-
	The proposed proprietary name / brand name	Atorvi Tablet 40mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Atorvastatin as atorvastatin calcium trihydrate…….40mg**
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitor ATC Code: C10AA05
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Lipitor USFDA Approved.
	For generic drugs (me-too status)	Product Name: Lipitor Tablet 20mg Registration No: 023621
	Proposed Pack size	As per SRO.1x10's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.S.1.1	Clarification is required whether its atorvastatin calcium or atorvastatin calcium trihydrate ,structural formula does not mention trihydrate.
4.	3.2.S.1.3	Provide the polymorphic form of the drug substance.
5.	3.2.S.4.1	a) Submit whether propylene glycol has been used as a solvate in manufacturing of API. If yes, then assay specs. should be as per USP. b) The test of assay is missing which as per USP is "**98.0%–102.0% on the anhydrous and solvent-free basis**". c) |Submit evidence of availability of AAS.
6.	3.2.S.4.2	The analytical procedure of drug substance is not as per USP.
7.	3.2.S.4.3	Submit analytical method verification report performed by drug product manufacturer.
8.	3.2.S.4.4	a) Provide reference for specifications as the tests and specs differ from section 3.2.S.4.1.

		b) The COA mentions API should be stored at temperature not exceeding 25C whereas, stability studies at long term has been conducted at 30C.
9.	3.2.S.7.3	The stability data of drug substance is not readable.
10.	3.2.P.2.1	a) The innovator product applied the factor on the basis of anhydrous drug substance 41.44 mg whereas, you have applied 43.3 mg which is trihydrate form. Justification is required. b) Submit compatibility studies of the Drug Substance(s) with excipients as composition of the formulation is not similar to innovator / reference product. Provide the reference product details, if the excipients are similar. c) Justify the use of flavoring agent methionin in the formulation. d) Provide the average weight of core and coated tablet e) The composition mentioned in 3.2.P.1 differs from formulation mentioned in 3.P.2.1.
11.	3.2.P.2.2.1	c) Submit CDP at three pH 1.2, pH 4.5 and pH 6.8.
12.	3.2.P.3.5	Submit process validation protocol of commercial batches.
13.	3.2.P.4	Provide control of excipients as per DRAP CTD guidance document.
14.	3.2.P.5.2	a) Submit detailed analytical procedures used for testing the drug product in relevant section. b) Clarification is required which dissolution USP test firm has adopted Test 1, Test 2 ,Test 3,Test 4 ,Test 5 or Test 6.
15.	3.2.P.5.3	Submit complete analytical method verification report.
16.	3.2.P.6	Submit COA of primary reference standard.
17.	3.2.P.8.3	a) Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
18.	3.2.P.8.3	a) Submit justification for not performing system suitability before assay at each time point. b) Submit COA of drug product at each time point.

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

183.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt), Ltd. Plot No E-127, E-128 & E-129,Karachi**
	Name, address of Manufacturing site.	**M/s Kaizen Pharmaceuticals (Pvt), Ltd. Plot No E-127, E-128 & E-129,Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15683: 21-06-2023
	Details of fee submitted	Slip No:548476207 PKR 75000/-
	The proposed proprietary name / brand name	Imeglim Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains: Imeglimin Hydrocholride…..500mg**
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator

	The status in reference regulatory authorities	PMDA Approved.
	For generic drugs (me-too status)	New molecule
	Proposed Pack size	As per SRO,30's,60's,100's.

Evaluation by PEC-V:

The application has been evaluated in the light of CTD guidance document and found deficient for information/ documents as mentioned against each section.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Provide GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.
3.	3.2.P.2	Justify how your product is qualitatively similar to innovator product. Submit drug-excipient compatibility studies.
4.	3.2.P.5.2	The innovator specs. mentions dissolution on UV whereas,you have performed dissolution on HPLC.
5.	3.2.P.8.3	Provide following supporting documents along with stability data sheets ✓ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. ✓ Documents for the procurement of API with approval from DRAP (in case of import). ✓ Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

Agenda of Dr. Farhadullah

Case No. 01; Routine registration applications of Human Drugs on Form 5F

184.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 6413 dated 07-03-2023
	Details of fee submitted	Rs.30,000/- dated 28-06-2022 (Deposit slip#5187173126)
	The proposed proprietary name / brand name	**Bimsil 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Nimesulide……100mg
	Pharmacotherapeutic Group of (API)	Other antiinflammatory and antirheumatic agents, non-steroids

	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Nimesulide 100 mg tablets, EMA approved.
	For generic drugs (me-too status)	Nims 100mg Tablet by M/s Sami Pharmaceuticals (Reg.No# 26657)
	Proposed Pack size and unit price	10's, 20's, 30's; As per SRO

Evaluation by PEC[XI]:

Registration Board in its 271st meeting keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size for 15 days as per recommendations of EMA only for the following clinical indications as a second-line choice.

a) Treatment of acute pain

b) Primary dysmenorrhea

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall hygienic condition of the firm is satisfactory at the time of inspection.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted License retention certificate issued by Food and Drugs Administration (Maharashtra State) India valid upto 31-12-2026.
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Justification shall be submitted for not performing dissolution test in pharmaceutical equivalence studies of applied product • Justification shall be submitted for not selecting 15minutes time point in CDP studies as recommended by relevant guidelines	• The firm submitted that we performed dissolution test in pharmaceutical equivalence study but unfortunately we mistakenly not mention in report. Now revised pharmaceutical report is submitted containing results of dissolution test • The firm submitted that unfortunately, we mistakenly not select 15 minutes time point when we performed CDP. But our comparative results were complying with the reference product.
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Clarification is required as you have claimed in-house specifications in section 1.5.6 and innovator's specifications in this section	• The firm submitted that we mistakenly not mentioned dissolution time in the finished product specifications and submitted revised finished product specifications in which time of dissolution test has been incorporated • The firm submitted that actually when we worked on these documents, we consider innovator's specifications as in-house specifications

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of commercial invoice cleared dated 07-12-2021 specifying 1000Kg Nimesulide. The invoice is cleared by AD (I&E) DRAP.

Decision: Approved with innovator's specifications

- **Registration Board further decided that Registration letter will be issued after submission of following:**
  - **i. Valid copy of cGMP certificate or GMP inspection report of applicant conducted within last three year**
  - **ii. Submission of fee Rs. 7,500/- for typographical errors**

185.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 6412 dated 07-03-2023
	Details of fee submitted	Rs.30,000/- dated 03-03-2023 (Deposit slip#487933305225)
	The proposed proprietary name / brand name	**BeMox Tablet 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Moxifloxacin HCl…….400mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Avelox 400mg film coated tablets, USFDA approved. Avelox 400mg film coated tablets, MHRA approved
	For generic drugs (me-too status)	Moxitier 400mg Tablet by M/s Brookes Pharma (Reg.No# 92772)
	Proposed Pack size and unit price	10's, 20's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: • The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall

		hygienic condition of the firm is satisfactory at the time of inspection.
1.5.2	• Revise the label claim as per reference formulation considering the salt form along with submission of applicable fee.	• The firm has revised label claim as per reference formulation along with submission of fee Rs.7500/- 98925169. The revised label claim is as under: Each Film Coated Tablet Contains: Moxifloxacin as HCl……400mg • Differential fee Rs. 22500/- is required.
2.3.R.1	• The reference formulation is film coated tablet while the submitted BMR does not indicate coating composition and coating step, clarify	• The firm submitted that we write the composition of film coating in the first page of BMR and the step of the preparation of coating solution also mentioned in the BMR. The firm has submitted revised BLANK BMR.
3.2.S.4	• Justification is required for not including the test for enantiomeric purity in drug substance specifications as per drug substance manufacturer • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Certificate of Analysis (CoA) of the relevant batch of Drug Substance from Drug Substance manufacturer used during product development and stability studies is required	• The firm submitted that we use the result of enantiomeric purity from the manufacturer COA as reference but mistakenly not added in the specifications. We write it and specifications are submitted. • Analytical Method Verification studies is submitted • Certificate of Analysis (CoA) of the relevant batch of Drug Substance from Drug Substance manufacturer is submitted
3.2.P.2	• Justification shall be submitted for not performing dissolution test in pharmaceutical equivalence studies of applied product	• The firm submitted that we performed dissolution test in pharmaceutical equivalence study as per USP specifications but unfortunately we mistakenly not mention in report. Now revised pharmaceutical report is submitted containing results of dissolution test
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Justification shall be submitted for not including uniformity of dosage unit test in finish product specifications • Results of repeatability (method precision) in analytical method verification study is not submitted	• The firm submitted that we mistakenly not mentioned dissolution time in the finished product specifications and submitted revised finished product specifications in which time of dissolution test has been incorporated • The firm revised finish product specifications in which test for uniformity of dosage unit has been included • Results of repeatability (method precision) in analytical method verification study is not submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• The firm has submitted that we get the material from local source (Pharmagen). However, no procurement documents are submitted

Decision: Deferred for submission of following:

i. **Fee of Rs. 22,500/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

ii. Valid copy of cGMP certificate or GMP inspection report of applicant conducted within last three year **iii. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3** **iv. Results of repeatability (method precision) in analytical method verification study for drug product** **v. Documents for the procurement of API with approval from DRAP (in case of import).**

186.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 8069 dated 22-03-2023
	Details of fee submitted	Rs.30,000/- dated 03-03-2023 (Deposit slip#1758398463)
	The proposed proprietary name / brand name	**BeFlox 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ofloxacin……200mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Ofloxacin 200mg film coated tablets, MHRA approved
	For generic drugs (me-too status)	Cinaflox 200mg Tablet by M/s Curatech Pharma (Reg.No# 101668)
	Proposed Pack size and unit price	10's, 20's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: • The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall hygienic condition of the firm is satisfactory at the time of inspection.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of Drug Manufacturing License issued by Zhejiang Medical Product Administration China valid upto 07-10-2024.

2.3.R.1	• The reference formulation is film coated tablet while the submitted BMR does not indicate coating composition and coating step, clarify	• The firm submitted that we write the composition of film coating in the first page of BMR and the step of the preparation of coating solution also mentioned in the BMR. The firm has submitted revised BLANK BMR.
3.2.S.4	• Justification shall be submitted for selecting different limit of assay test (99.0% — 101.0%) by drug product manufacturer than USP monograph (98.5% — 101.5%) • Clarification is required as the drug product manufacturer has utilized simple titration method for assay test while drug substance manufacturer has mentioned potentiometric titration. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• The firm submitted that we select the limit for assay test according to USP monograph as 98.5% to 101.5%. We attached certificate of analysis and standard testing procedure for further clarification. • The firm submitted that we actually perform assay test according to USP monograph and drug substance manufacturer as potentiometrically. But we also randomly perform assay by utilizing simple titration method to compare with potentiometric titration. Therefore, in standard testing method we mistakenly written simple titration method rather than potentiometric assay. Firm has submitted revised testing method. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted
3.2.P.2	• Justification shall be submitted for not performing dissolution test in pharmaceutical equivalence studies of applied product	• The firm submitted that we performed dissolution test in pharmaceutical equivalence study as per USP specifications but unfortunately we mistakenly not mention in report. Now revised pharmaceutical report is submitted containing results of dissolution test
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test and selecting different limits of Q (NLT 85%) in dissolution test in finish product specifications than USP monograph • Justification shall be submitted for not including uniformity of dosage unit test in finish product specifications • Results of specificity test and repeatability (method precision) in analytical method verification study is not submitted	• The firm submitted that we mistakenly not mentioned dissolution time in the finished product specifications and submitted revised finished product specifications in which time of dissolution test has been incorporated. The firm has also revised the limit of dissolution test as NLT 80% as per USP monograph • The firm revised finish product specifications in which test for uniformity of dosage unit has been included • Results of repeatability (method precision) in analytical method verification study is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of commercial invoice dated 22-04-2022 specifying 500Kg Ofloxacin. However, the invoice is not cleared by AD (I&E) DRAP.

Decision: Deferred for submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**
ii. **Valid copy of cGMP certificate or GMP inspection report of applicant conducted within last three year**

iii. **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3**
iv. **Documents for the procurement of API with approval from DRAP (in case of import).**

187.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 15818 dated 22-06-2023
	Details of fee submitted	Rs.30,000/- dated 15-06-2023 (Deposit slip#867852092767)
	The proposed proprietary name / brand name	**B-Clor Dry Powder Suspension 250mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension after Reconstitution Contains: Cefaclor (as Monohydrate)…….250mg
	Pharmacotherapeutic Group of (API)	Cephalosporine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Cefaclor 250mg/5ml Suspension, MHRA approved.
	For generic drugs (me-too status)	Acef 250mg Powder for suspension by M/s English Pharmaceutical Indsutries (Reg.No# 36130)
	Proposed Pack size and unit price	60ml, 90ml, 120ml; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section (Oral Dry powder suspension (cephalosporin) from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter dated 27th September 2019 specifying Oral Dry Powder (Suspension) section. Evidence of approval of required manufacturing facility / Approved Section (Oral Dry powder suspension (cephalosporin) is not submitted. • Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: • The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall hygienic condition of the firm is satisfactory at the time of inspection.

3.2.S.4	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Submit details of comparator product including manufacturer name, manufacturing and expiry date	• Drug excipient compatibility study is submitted. • Firm has submitted details of comparator product; Brand name; Ceclor suspension 250mg/5ml, Manufacturer name; AGP Pakistan Mfg. date; March-22, Exp. Date; March-24
3.2.P.5	• Justification shall be submitted for selecting USP specifications for drug product, the drug substance of which has been tested as per BP monograph by M/s BJ Pharma • Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph	• The firm submitted that we performed drug substance testing as per BP monograph because the drug substance manufacturer claimed BP specifications and we performed drug product testing as per USP monograph because reference product claimed USP specifications. • The firm submitted that we performed uniformity of dosage unit test as per USP monograph but mistakenly not written in finished product specifications. The firm stated that we have revised finish product specifications.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• The firm has submitted copy of invoice dated 20-07-2022 of M/s Pharmagen specifying 10kg cefaclor in the name of M/s BJ Pharmaceuticals

Decision: Deferred for submission of following:

i. **Evidence of approval of required manufacturing facility / Approved Section (Oral Dry powder suspension (cephalosporin) from Licensing Division**
ii. **Valid copy of cGMP certificate or GMP inspection report of applicant conducted within last three year**
iii. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

188.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 15817 dated 22-06-2023
	Details of fee submitted	Rs.30,000/- dated 15-06-2023 (Deposit slip#1021052839)

	The proposed proprietary name / brand name	**B-Clor Dry Powder Suspension 125mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension after Reconstitution Contains: Cefaclor (as Monohydrate)…….125mg
	Pharmacotherapeutic Group of (API)	Cephalosporine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Cefaclor 125mg/5ml Suspension, MHRA approved.
	For generic drugs (me-too status)	Acef 125mg Powder for suspension by M/s English Pharmaceutical Indsutries (Reg.No# 36129)
	Proposed Pack size and unit price	60ml, 90ml, 120ml; As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section (Oral Dry powder suspension (cephalosporin) from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
3.2.S.4	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Submit details of comparator product including manufacturer name, manufacturing and expiry date
3.2.P.5	• Justification shall be submitted for selecting USP specifications for drug product, the drug substance of which has been tested as per BP monograph by M/s BJ Pharma • Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).

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

189.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 15811 dated 22-06-2023
	Details of fee submitted	Rs.30,000/- dated 15-06-2023 (Deposit slip#85255410389)
	The proposed proprietary name / brand name	**B-Clor Dry Powder Suspension Drops 50mg/1ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Suspension after Reconstitution Contains: Cefaclor (as Monohydrate)……..50mg
	Pharmacotherapeutic Group of (API)	Cephalosporine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Cefaclor 250mg/5ml Suspension, MHRA approved.

	For generic drugs (me-too status)	Acef 50mg drops by M/s English Pharmaceutical Indsutries (Reg.No# 36131)
	Proposed Pack size and unit price	15ml; As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section (Oral Dry powder suspension (cephalosporin) from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.9	• Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
3.2.S.4	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Submit details of comparator product including manufacturer name, manufacturing and expiry date
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).

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

190.	Name, address of Applicant / Marketing Authorization Holder	**M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 15809 dated 22-06-2023
	Details of fee submitted	Rs.30,000/- dated 15-06-2023 (Deposit slip#3806894084)
	The proposed proprietary name / brand name	**B-Clor Capsule 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefaclor (as Monohydrate)……500mg
	Pharmacotherapeutic Group of (API)	Cephalosporine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Cefaclor 500mg capsule, MHRA approved.
	For generic drugs (me-too status)	Acef 500mg capsule by M/s English Pharmaceutical Indsutries (Reg.No# 36133)
	Proposed Pack size and unit price	12's, 24's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response

1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter dated 27th September 2019 specifying Capsule (Cephalosporin) section. • Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: • The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall hygienic condition of the firm is satisfactory at the time of inspection.
3.2.S.4	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Justification shall be submitted for not performing dissolution test in pharmaceutical equivalence studies	• Drug excipient compatibility study is submitted. • The firm submitted that we performed dissolution test in pharmaceutical equivalence study as per USP specifications but unfortunately we mistakenly not mention in report. Now revised pharmaceutical report is submitted containing results of dissolution test
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph	• The firm submitted that we mistakenly not mentioned dissolution time in the finished product specifications and submitted revised finished product specifications in which time of dissolution test has been incorporated • The firm submitted that we performed uniformity of dosage unit test as per USP monograph but mistakenly not written in finished product specifications. The firm stated that we have revised finish product specifications.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• The firm has submitted copy of invoice dated 20-07-2022 of M/s Pharmagen specifying 10kg cefaclor in the name of M/s BJ Pharmaceuticals

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid copy of cGMP certificate or GMP inspection report of applicant conducted within last three year**
ii. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

191.	Name, address of Applicant / Marketing Authorization Holder	M/s Arsons Pharmaceutical Industries (Pvt.) Ltd., 2.5km Defence Road, off Multan Road, Lahore

	Name, address of Manufacturing site.	M/s Arsons Pharmaceutical Industries (Pvt.) Ltd., 2.5km Defence Road, off Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 6410 dated 07-03-2023
	Details of fee submitted	Rs.30,000/- dated 18-10-2022 (Deposit slip#00907444)
	The proposed proprietary name / brand name	**Voltrex 2% Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Gel Contains: Diclofenac Diethylamine Eq. to Diclofenac Sodium……20mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Diclofenac Diethylamine 2.32% w/w Gel, MHRA approved
	For generic drugs (me-too status)	Swiso 2% Gel by M/s Swiss Pharmaceuticals (Reg.No# 66888)
	Proposed Pack size and unit price	1's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and letter submitted for renewal of DML dated 03-05-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 05-10-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Control Adminstration Gujarat State India valid upto 22-11-2025
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Not submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. However, results specificity and accuracy test is not submitted
3.2.S.7	• Stability study data of drug substance from M/s Cubic analytical solution is submitted instead of API manufacturer. Stability study data of drug substance at zone VI-A conditions till claimed shelf life shall be submitted	• Stability study data of drug substance from M/s Cubic analytical solution is submitted again instead of API manufacturer.

3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	• Not submitted
3.2.P.5	• Results of accuracy tests in analytical method verification study is not submitted	• Results of accuracy tests in analytical method verification study is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of clearance certificate dated 03-08-2022 specifying 100Kg Diclofenac Diethylamine. The invoice is cleared by AD (I&E) DRAP.

Decision: Deferred for submission of following:

i. **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer**
ii. **Results of specificity and accuracy in analytical method verification studies performed by the Drug Product manufacturer for drug substance**
iii. **Stability study data of drug substance from API manufacturer at zone VI-A conditions till claimed shelf life**
iv. **Results of drug excipient compatibility study**

192.	Name, address of Applicant / Marketing Authorization Holder	M/s Islam Pharmaceuticals., 7 km, Pasrur Road, Sialkot
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals., 7 km, Pasrur Road, Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 7615 dated 16-03-2023
	Details of fee submitted	Rs.30,000/- dated 13-02-2023 (Deposit slip#21439537275)
	The proposed proprietary name / brand name	**Isoxin 550mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Naproxen Sodium……550mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Crysanal naproxen sodium 550mg tablet blister pack, TGA approved
	For generic drugs (me-too status)	Synflex 550mg Tablet by M/s Martin Dow Limited (Reg.No# 10197)
	Proposed Pack size and unit price	20's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and letter submitted for renewal of DML dated 11-08-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 08-02-2023.

1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs Control Administration, Government of Andhra Pradesh valid upto 25-06-2027
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications as per USP monograph	• The firm submitted that time of dissolution test is written in SAP for finished product and submitted copy of SAP.
3.2.P.8	• Stability study data for applied product at 6th month time point shall be submitted	• Stability study data for applied product at 6th month time point is submitted

Decision: Approved.

193.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 7910 dated 20-03-2023
	Details of fee submitted	Rs.75,000/- dated 01-03-2023 (Deposit slip#871842487809)
	The proposed proprietary name / brand name	**Codopa 12.5+50 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Carbidopa eq. to anhydrous carbidopa……..…12.5mg Levodopa……..50mg
	Pharmacotherapeutic Group of (API)	Carbidopa….decarboxylase inhibitors Levodopa…..central nervous system agents
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Carbidopa/Levodopa Orion 12.5 mg/50 mg tablets Ireland Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size & proposed unit price	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.5.2	• Revise the label claim as per reference formulation considering the hydrated form in case of carbidopa along with submission of applicable fee.	• The firm has revised the label claim as per reference formulation along with submission of fee Rs. 75,000/- on deposit slip No. 800402518741. The revised label claim is as under: Each Tablet Contains: Carbidopa monohydrate equivalent to carbidopa……..……12.5mg Levodopa……..50mg
1.5.5	• Indicate Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) with proper reference	• The firm has submitted the Pharmacotherapeutic group of Carbidopa and Levodopa i.e. ATC: N04B Dopaminergic Agents with reference.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by	• Firm has submitted copy of Drug product License (license#ZHe20060667) of API manufacturer

	relevant regulatory authority of country of origin is required	issued by Zhejiang Drug Administration valid upto 20-09-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa shall be submitted.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Cabidopa and Levodopa by Drug Product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Carbidopa and Levodopa is submitted.
3.2.P.2	• Pharmaceutical Equivalence and CDP studies of applied product against innovator product shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Sinemet 12.5mg/50mg tablet by M/s Organon Pharma (UK) Ltd. • Firm has submitted CDP results of their product against the product Sinemet 12.5mg/50mg tablet by M/s Organon Pharma (UK) Ltd.
3.2.P.5	• Results of accuracy test are not submitted in analytical method verification studies	• Results of accuracy test in analytical method verification studies are submitted
3.2.P.8	• Submit readable copy of commercial invoice of API cleared by AD (I&E) DRAP	• Firm has submitted copy of commercial invoice cleared dated 02-07-2021 specifying 25Kg Levodopa and 03kg Carbidopa. The invoice is cleared by AD (I&E) DRAP.

Decision: Approved with following label claim:
Each Tablet Contains:
Carbidopa monohydrate equivalent to carbidopa……12.5mg
Levodopa……...50mg

194.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt.) Ltd., 44-45B, Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B, Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 8553 dated 29-03-2023
	Details of fee submitted	Rs.30,000/- dated 17-03-2023 (Deposit slip#458870925)
	The proposed proprietary name / brand name	**Sitensa 3mg/3ml Concentrate for solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Solution for Injection (with 3ml fill) Contains: Granisetron (as HCl)……3mg
	Pharmacotherapeutic Group of (API)	Antiemetics
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Granisetron, 1mg/ml, solution for injection (1ml, 3ml) MHRA Approved
	For generic drugs (me-too status)	Vomitron 3mg/3ml Injection by M/s Helix Pharma (Reg# 86056)

	Proposed Pack size & proposed unit price	1's, 5's, 10's,: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023.
1.5.2	• Clarify the applied label claim with respect to volume as the submitted label claim contains two volumes along with submission of applicable fee	• The firm has revised the label claim along with submission of Rs. 30,000/- on deposit slip#31365136253. The revised label claim is as under: Each ml Contains: 1.12 mg Granisetron HCl equivalent to granisteron 1mg OR Each 3ml Contains: 3.36 mg Granisetron HCl equivalent to granisteron 3mg
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML of API manufacturer issued by Zhejiang Drug Administration China valid upto 17-09-2025
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Submitted

Decision: Approved with following label claim:
Each 3ml Contains:
3.36 mg Granisetron HCl equivalent to granisteron 3mg

195.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt.) Ltd., 44-45B, Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B, Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 12905 dated 25-05-2023
	Details of fee submitted	Rs.75,000/- dated 12-05-2023 (Deposit slip#097586542)
	The proposed proprietary name / brand name	**Sitensa 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Granisetron (as HCl)……2mg
	Pharmacotherapeutic Group of (API)	Antiemetics, Serotonin (5HT3) antagonists
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Kytril 2mg film-coated tablets Netherland Approved Kytril 2mg film-coated tablets MHRA Approved

	For generic drugs (me-too status)	Not applicable since this is a new drug
	Proposed Pack size & proposed unit price	1's, 2's, 5's, 7's, 10's, 14's, 20's, 28's, 30's: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 06-06-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML of API manufacturer issued by Zhejiang Drug Administration China valid upto 17-09-2025
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Submitted
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications	• The firm submitted that we mistakenly not mentioned the time of dissolution test in finished product specifications. We hereby submitting the finished product specification with dissolution test.

Decision: Approved.

196.	Name, address of Applicant / Marketing Authorization Holder	M/s Ray Pharma (Pvt.) Ltd., Rahimtoola House No. 38/C, Khayaban-E-Shahbaz, Phase-6, D.H.A., Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Ray Pharma (Pvt.) Ltd., S-58, S.I.T.E Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 9672 dated 11-04-2023
	Details of fee submitted	Rs.30,000/- dated 06-03-2023 (Deposit slip#3303535662)
	The proposed proprietary name / brand name	**Multigesic Gel Double Strength**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100gm Gel Contains: Diclofenac Diethylamine Eq. to Diclofenac Sodium……..…2%
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Diclofenac Diethylamine 2.32% w/w Gel, MHRA approved Voltarol Emulgel Extra Strength 2% w/w gel Ireland Approved

	For generic drugs (me-too status)	Voltral Emulgel 2% by M/s GlaxoSmithKline Consumer Health Care (Reg.No# 89372)
	Proposed Pack size and unit price	20gm, 30gm, 40gm, 50gm; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.1	• Manufacturing Site Address of the applicant as per submitted DML shall be submitted	• The manufacturing site address of the applicant as per submitted DML is submitted M/s Ray Pharma (Pvt.) Ltd., S-58, S.I.T.E Karachi,
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and copy of letter dated 04-09-2023 applied for renewal of DML
1.5.2	• Standardize the label claim as per reference formulation along with submission of applicable fee.	• Firm has standardize the label claim as per reference formulation along with submission of Rs. 7500/- on deposit slip#100748303443. The revised label claim is as under: Multigesic 2% w/w Gel Contains: Diclofenac Diethylamine 2.32% w/w corresponding Eq. to Diclofenac Sodium…..…2% w/w (20mg/g). Differential fee Rs. 22,500/- shall be submitted
1.6.5	• cGMP certificate of different manufacturing site of API manufacturer is submitted, clarify	• Firm has corrected address of API manufacturer in section 1.6.5 and submitted valid copy of cGMP certificate of API manufacturer issued by Food and Drugs Administration M.S. Mumbai India valid upto 06-09-2025.
2.3.R.1	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life	• Complete details for batch size of trial batches against the number of units required for complete testing of drug product is submitted
3.2.P.2	• Drug excipient compatibility study of applied product shall be submitted as the qualitative composition of applied product is not similar to reference product	• Drug excipient compatibility study of applied product is submitted
3.2.P.8	• Stability study data of applied product at 6th month time point shall be submitted • Submit documents for the procurement of relevant batch of API used in product development and stability study along with approval from DRAP.	• Stability study data of applied product at 6th month time point is submitted • Firm has submitted copy of form 6 issued dated 02-09-2022 specifying 1kg Diclofenac Diethylamine. The invoice is issued by AD (I&E) DRAP.

Decision: Approved with following label claim:
Multigesic 2% w/w Gel Contains:
Diclofenac Diethylamine 2.32% w/w corresponding Eq. to Diclofenac Sodium…..…2% w/w (20mg/g).
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Differential fee of Rs. 22,500/- for correction/pre-approval change in composition (correction/change of strength of the applied formulation), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

197.	Name, address of Applicant / Marketing Authorization Holder	M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 10766 dated 28-04-2023
	Details of fee submitted	Rs.30,000/- dated 05-04-2023 (Deposit slip#852569889814)
	The proposed proprietary name / brand name	**Momento Topical Solution 0.1% w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm Contains: Mometasone Furoate……..1mg
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Elocon 0.1% w/w Scalp Lotion MHRA Approved
	For generic drugs (me-too status)	Momate 0.1% Lotion by Maxitech Pharma (Reg#83744)
	Proposed Pack size and unit price	30ml, 20ml; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• The name of API manufacturer mentioned in GMP certificate is M/s Shakti Lifescineces Private Limited while name mentioned in this section is M/s Shakti Industries, clarify	• Firm has submitted declaration from API manufacturer stating that the company has successfully renamed from Shakti Industries to Shakti Lifesciences Private Limited on 09th December 2021 and submitted documents.
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Submit copy of clearance certificate or commercial invoice for the procurement of API along with approval from DRAP.	• The firm has submitted sampling plan for complete testing. The firm submitted that total of 65 bottles are required for complete testing of drug product during stability study. • Firm has again submitted copy of form 6 issued dated 08-06-2022 specifying 210gm Mometasone Furate, issued by AD (I&E) DRAP.

Decision: Approved.

198.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 12097 dated 17-05-2023
	Details of fee submitted	Rs.75,000/- dated 04-04-2023 (Deposit slip#589869791)
	The proposed proprietary name / brand name	**Delaflox 450mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Delafloxacin Meglumine eq. to Delafloxacin…….450mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Reference to Finished product specifications	Innovator's specifications

	The status in reference regulatory authorities	Quofenix 450mg tablets MHRA Approved Baxdela 450mg tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	14's, 20's, 28's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Chongqing Drug & Chemical Administration China valid upto 23-08-2026
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
3.2.S.7	• Stability study data of drug substance at real time conditions till claimed shelf life shall be submitted	• Stability study data of drug substance at real time conditions till claimed shelf life is submitted
3.2.P.5	• Justification shall be submitted for not including test for water content in finished product specification as per innovator's product review document • The dissolution specifications of innovator product is NLT Q in 10 minutes while you have selected limit of dissolution specification NLT Q in 30 minutes. Revise your dissolution specifications as per innovator's product review document and submit dissolution data as per revised specifications	• The firm submitted that we could not find any mention of water content test for the finished product in the innovator's product review document. The water or moisture content in granules of the finished product (for tablets) should be between 1% and 3# for better and smoother tablet compression process. This moisture content test is a regular part of in-process testing. We checked the moisture content during the in-process stage, and it was 2.3% according to our batch manufacturing record. According to the routine requirements of pharmacopeia, there is no need to test the water or moisture content in the tablet unless the product is highly prone to microbial growth or contains a high amount of water or moisture in the API. Neither of these scenarios applies to delafloxacin meglumine. That's why we did not include the test of water content of the finished product. • The firm submitted that we already found out the same issue in past. Therefore, we have manufactured one more trial batch having batch No TF-04. This batch was manufactured on dated: 02-2024. The dissolution test was performed on 10-minutes time point. The results were found satisfactory and passes the limit of NLT Q in 10 minutes. The batch was kept on stability and also passes the 6th month's stability data for dissolution test. A complete report of dissolution data is submitted. Firm has also submitted revised finished product specifications.
3.2.P.8	• Submit copy of clearance certificate or commercial invoice for the procurement of API along with approval from DRAP.	• Firm has submitted copy of commercial invoice cleared dated 30-12-2021 specifying 1.5Kg Delafloxacin Meglumine. The invoice is cleared by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

199.	Name, address of Applicant / Marketing Authorization Holder	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals., Plot No. 23 & 24, Phase S-1, RCCI, Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 12213 dated 18-05-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#128181087419)
	The proposed proprietary name / brand name	**Sulrid 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……100mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 100mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Nexpride 100mg Tablet by M/s Medicraft Pharmaceutical (Reg.No# 95949)
	Proposed Pack size and unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for chloride content and sulphated ash in batch analysis of drug substance by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Complete comparative dissolution studies shall be submitted
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finished product specifications • Description of test for identification test in finished product specifications shall be submitted • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test by UV method. • Analytical method validation protocols shall be submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).

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

200.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 13513 dated 31-05-2023
	Details of fee submitted	Rs.30,000/- dated 11-05-2023 (Deposit slip#5393271323)
	The proposed proprietary name / brand name	**Linaglu 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin …….. 5mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor (Treatment for type 2 Diabetes Mellitus)
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tradjenta 5mg film coated tablets USFDA Approved.
	For generic drugs (me-too status)	Linvesta 5mg Tablet by M/s Wilshire Laboratories (Reg#110608)
	Proposed Pack size and unit price	10's, 14's, 20's, 28's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML of API manufacturer issued by Anhui Provincial Drug Administration valid upto 31-12-2025
3.2.P.5	• Justify the use of USP apparatus-II (Paddle) instead of USP Apparatus-I (Basket) in dissolution test as recommended by innovator's product review document • The copies of complete analysis of at least two batches shall be provided	• The firm submitted that we have adopted the same parameters mentioned in innovator product review document except of Apparatus-I (Basket). Reason behind that we follow FDA guidance for industry "Dissolution testing of immediate release solid oral dosage form" which mention in section A "Approaches for Setting Dissolution Specifications for a New Chemical Entity stated Dissolution testing should be carried out under mild test conditions, basket method at 50/100 rpm or paddle method at 50/75 rpm at 15 minutes interval to generate a dissolution profile. • During dissolution method development for Linagliptin tablets we select paddle method at 50 rpm and conduct comparative dissolution profile studies of our product in comparison with reference product and found similar drug release profile in physiological buffers including QC release media. On the basis of this we have selected paddle apparatus for dissolution method. • However, to have compliance with innovator dissolution method we have also conducted dissolution studies on basket method in comparison

		with innovator product as on today's basis and found satisfactory results same as obtained in paddle method previously. Raw data reports/calculations sheets are submitted. • Moreover we have revised finished product specifications enclosed for dissolution method mentioning Apparatus-I (Basket) instead of paddle apparatus to comply with innovator's dissolution specifications for QC release commercial batches. • Copies of complete analysis of stability batches are submitted

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021

201.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14 km Adyala Road, Post Office Daghal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14 km Adyala Road, Post Office Daghal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 15389 dated 19-06-2023
	Details of fee submitted	Rs.30,000/- dated 11-04-2023 (Deposit slip#26168320107)
	The proposed proprietary name / brand name	**Lina 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin …….. 5mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor (Antidiabetic)
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tradjenta 5mg film coated tablets USFDA Approved.
	For generic drugs (me-too status)	Linvesta 5mg Tablet by M/s Wilshire Laboratories (Reg#110608)
	Proposed Pack size and unit price	2x10's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter of renewal of DML dated 27-04-2020 specifying Tablet (General) section. • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-02-2024.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of Pharmaceutical production license of API manufacturer issued by Liaoning Province Drug Administration China valid upto 17-11-2024.

3.2.S.4	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required.	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted.
3.2.P.5	• Justification is required for not including the test for loss on drying in finished product specifications as recommended by innovator's product review document	• Firm has submitted revised finished product specifications in which test for loss on drying has been incorporated. • Firm has also submitted batch analysis report of all three batches of drug product in which test for loss on drying has been performed
3.2.P.8	• Submit stability study data at 6th month time point of applied product • Submit AD (I&E) DRAP attested documents for procurement of API	• Stability study data at 6th month time point of applied product is submitted • Firm has submitted copy of form 6 issued dated 01-08-2022 specifying 500g of Linagliptin. The form 6 is issued by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 02; Deferred Routine Registration applications of Human Drugs on Form 5F

202.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 29615 dated 18-10-2022
	Details of fee submitted	Rs.30,000/- dated 17-08-2022 (Deposit slip#6245701768)
	The proposed proprietary name / brand name	**Cetazol 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Acetazolamide……..250mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Carbonic anhydrase inhibitors
	Reference to Finished product specifications	USP

	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	DIAMOX 250mg Tablets MHRA Approved
	For generic drugs (me-too status)	Getacet Tablets by M/s Getz Pharma (Reg. No#98716)
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 72 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Acemox tablets 250mg by M/s Vega Pharmaceuticals Pvt. Ltd. CDP has been performed against a comparator product AZM 250mg tablet by M/s Ethical Laboratories in HCl buffer pH 1.2, acetate buffer pH 4.5, Phosphate Buffer pH 6.8.

	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd., Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, India		
API Lot No.	AC183015		
Description of Pack (Container closure system)	Alu-PVC blister packed in a bleach board unit carton 3x10's.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	25-05-2021	26-05-2021	27-05-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of M/s CTX Lifesciences Pvt. Ltd., Block No. 251/P, 252/P, 253 TO 255, 256/P, 258/P, 276/P, 277, 278/P, 279 TO 282, 283/P, 284/P, GIDC, City: Sachin, District; Surat – Gujarat state, INDIA issued by Food & Drugs Control Administration Gujarat State India valid upto 29-05-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted copy of Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Acetazolamide 1.6gm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)

1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
3.2.S.4	• Clarification shall be submitted for not selecting the test for residue on ignition, chloride and sulphate by drug product manufacturer as per drug substance manufacturer specifications and USP monograph
3.2.P.5	• Clarification is required for not mentioning the limits of dissolution test in finished product specifications • Clarification is required for not selecting the test for uniformity of dosage units in finished product specifications as per USP monograph • Analytical method for dissolution test is not submitted • Numerical values of dissolution test shall be mentioned in batch analysis of finished product instead of complies.
3.2.P.8	• Submit commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP • Results of dissolution test are not reported in the submitted stability study • In stability study, chromatograms for standard solutions are not submitted. Furthermore, chromatograms for batch # T01 are submitted only

Previous Decision (M-336th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Valid copy of Drug Manufacturing License (DML) is submitted
1.3.5	• Submit Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. • Submit copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter of renewal of DML dated 08-12-2022 specifying Tablet section (General). • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 13-10-2023 and 07-11-2023.
3.2.S.4	• Clarification shall be submitted for not selecting the test for residue on ignition, chloride and sulphate by drug product manufacturer as per drug substance manufacturer specifications and USP monograph	• Firm has submitted revised drug substance specifications in which test for residue on ignition, chloride and sulphate has been incorporated
3.2.P.5	• Clarification is required for not mentioning the limits of dissolution test in finished product specifications • Clarification is required for not selecting the test for uniformity of dosage units in finished product specifications as per USP monograph • Analytical method for dissolution test is not submitted • Numerical values of dissolution test shall be mentioned in batch analysis of finished product instead of complies.	• Firm has revised finished product specifications in which limits of dissolution test has been incorporated and test for uniformity of dosage units has been included. • Analytical method for dissolution test is submitted • Numerical values of dissolution test is submitted in batch analysis of finished product

3.2.P.8	• Submit commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP • Results of dissolution test are not reported in the submitted stability study • In stability study, chromatograms for standard solutions are not submitted. Furthermore, chromatograms for batch # T01 are submitted only	• Commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP is not submitted • Firm has submitted revised stability summary sheets in which results of dissolution test are reported • No reply is submitted

Decision: Deferred for submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**
ii. **Commercial invoice or clearance certificate for procurement of API attested by AD (I&E) DRAP**
iii. **Submit chromatograms for standard solutions. Furthermore, submit chromatograms for other two batches in stability study**

203.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 25-06-2019 specifying Sachet General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 25514 dated 08-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-05-2022 (Deposit slip#15669313366)
	The proposed proprietary name / brand name	**Cadotril Sachet 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Racecadotril……..…10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Anti-secretory enkephalinase inhibitor
	Reference to Finished product specifications	Not Applicable (Product is JPL)
	Proposed Pack size	16 Sachets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Hidrasec Infants 10mg, Granules for oral suspension MHRA Approved
	For generic drugs (me-too status)	Hidrasec 10mg Sachet by M/s Abbott Laboratories

		(Reg. No# 87082)
	Name and address of API manufacturer.	M/s Symed Labs Limited., India, 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad-500034, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including Accuracy, Precision, Specificity, linearity, LOD, LOQ, robustness.

STABILITY STUDY DATA	
Manufacturer of API	M/s Symed Labs Limited., India, 8-2-293/174/3, Beside BN Reddy Colony, Road No. 14, Banjara Hills, Hyderabad-500034, Telangana, India.
API Lot No.	2KA0100519
Description of Pack (Container closure system)	White granular powder with characteristic apricot odor for oral suspension filled in a unit dose sachet, finally packed in a bleach board unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	5000 Sachet	5000 Sachet	5000 Sachet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	27-10-2021	28-10-2021	29-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M), Medchal - Malkajgiri District, Telangana State, India., issued by Drugs Control Administration Telangana State India valid upto 03-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing Racecadotril 15gm issued by AD (I&E) DRAP Lahore
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference
1.5.6	• Clarification is required for term "***Product is JPL***" in Pharmacopoeial Status of applied formulation
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate

3.2.S.4	• The drug substance manufacturer has selected gradient chromatographic method for assay of drug substance upto 50 minutes while you have selected gradient chromatographic method only upto 35 minutes, clarify. • Provide results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.
3.2.P.2	• Pharmaceutical equivalence studies against the innovator/reference product shall be submitted
3.2.P.5	• The applied product is racecadotril sachet while test for identification and assay for strontium ranelate is mentioned in specification, clarification is required. • Submit complete analytical methods for all the tests mentioned in finished product specifications
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • Submit real time stability data documents including chromatograms, Raw data sheets, COA of applied product

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Valid copy of Drug Manufacturing License (DML) is submitted
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 13-10-2023 and 07-11-2023.
1.5.5	• Indicate Pharmacological class of the API (drug substance) with proper reference	• Antidiarrheals
1.5.6	• Clarification is required for term "***Product is JPL***" in Pharmacopoeial Status of applied formulation	• Firm submitted product complies innovator's specifications
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • Address of API manufacturer mentioned in section 1.6.5 is different than that given in submitted GMP certificate	• Firm has again submitted copy of GMP certificate in the name of M/s Symed Labs Limited., Plot No. 25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M), Medchal - Malkajgiri District, Telangana State, India., issued by Drugs Control Administration Telangana State India valid upto 03-03-2022. • Firm has revised address of API manufacturer in section 1.6.5 as per submitted cGMP certificate
3.2.S.4	• The drug substance manufacturer has selected gradient chromatographic method for assay of drug substance upto 50 minutes while you have selected gradient chromatographic method only upto 35 minutes, clarify. • Provide results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	• The firm submitted that there is no peak observed after 19 minutes of run and continue till 50minutes, co we used 35 minutes for that reason instead of 50 minutes. • COA of relevant batch of drug substance from drug substance manufacturer is submitted. However, COA of drug substance from drug product manufacturer is not submitted

3.2.P.2	• Pharmaceutical equivalence studies against the innovator/reference product shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Hidrasec 10mg sachet by M/s Vega Pharmaceuticals Pvt. Ltd.
3.2.P.5	• The applied product is racecadotril sachet while test for identification and assay for strontium ranelate is mentioned in specification, clarification is required. • Submit complete analytical methods for all the tests mentioned in finished product specifications	• The firm has submitted revised finished product specifications for applied product racecadotril sachet • Analytical methods for all the tests mentioned in finished product specifications is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for procurement of API with approval from DRAP • Submit real time stability data documents including chromatograms, Raw data sheets, COA of applied product	• Documents for procurement of API is not submitted. • Real time stability data documents including chromatograms, Raw data sheets, COA of applied product after 9th month time point is submitted, while Real time stability data documents of first 6th month is not submitted

Decision: Deferred for submission of following:

i. **COA of relevant batch of Drug Substance from Drug Product manufacturer used during product development and stability studies**
ii. **Documents for procurement of API with approval from DRAP (in case of import)**
iii. **Real time stability data documents including chromatograms, Raw data sheets, COA of applied product**

204.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 2607 dated 27-01-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#8156471400)
	The proposed proprietary name / brand name	**L-prid 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levosulpiride Aristo 50 mg tablets, AIFA Italy approved.
	For generic drugs (me-too status)	Levopaid 50mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99724)
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Chromatograms of stability study for applied product are not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 30-03-2022.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Administration Gujarate State India valid upto 23-04-2025.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • The firm submitted that we have performed both analytical methods by potentiometric titration and by HPLC. As HPLC method give more information about purification and impurities. So we have also performed method of analysis by HPLC. Moreover its subsequent test were performed by HPLC that is

		why we perform method of analysis by HPLC as well potentiometric titration.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies	• Firm has submitted details of marketing authorization holder of comparator product Manufacturer Name; Genom Pharmaceuticals Hattar Brand Name; Levoma tablets 50mg • Firm has submitted revised pharmaceutical equivalence report in which dissolution studies has been performed
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)	• According to Chinese Pharmacopeia 2010
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Chromatograms of stability study for applied product are not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets and COA. • Firm has submitted copy of form 6 issued dated 28-01-2022 specifying 5Kg Levosulpiride. The form 6 is issued by AD (I&E) DRAP. • Submitted

Decision: Approved.

205.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3926 dated 10-02-2023
	Details of fee submitted	Rs.30,000/- dated 26-01-2023 (Deposit slip#9818258520)
	The proposed proprietary name / brand name	**L-prid 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated Tablet Contains: Levosulpiride……25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Levopraid 25mg Tablet AIF Italy Approved
	For generic drugs (me-too status)	Levopaid 25mg Tablet by M/s Wimits Pharmaceuticals (Reg.No# 99723)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Deferment Reason	Firm's Response
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 30-03-2022.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Administration Gujarate State India valid upto 23-04-2025.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted as you have submitted analytical method verification studies by HPLC method while drug substance manufacturer has submitted analytical method for assay by potentiometric titration method.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • The firm submitted that we have performed both analytical methods by potentiometric titration and by HPLC. As HPLC method give more information about purification and impurities. So we have also performed method of analysis by HPLC. Moreover its subsequent test were performed by HPLC that is why we perform method of analysis by HPLC as well potentiometric titration.

3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.2	• Details of marketing authorization holder of comparator product in pharmaceutical equivalence and CDP studies shall be submitted • Justification shall be submitted for not performing dissolution studies in pharmaceutical equivalence studies	• Firm has submitted details of marketing authorization holder of comparator product Manufacturer Name; Genom Pharmaceuticals Hattar Brand Name; Levoma tablets 25mg • Firm has submitted revised pharmaceutical equivalence report in which dissolution studies has been performed
3.2.P.5	• Justification shall be submitted for selection of dissolution parameters i.e. medium, volume, apparatus and rpm (0.1N HCl, 900ml, apparatus 2, 50rpm,)	• According to Chinese Pharmacopiea 2010
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of form 6 issued dated 28-01-2022 specifying 5Kg Levosulpiride. The form 6 is issued by AD (I&E) DRAP. • Submitted

Decision: Approved.

206.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 33016 dated 17-11-2022
	Details of fee submitted	Rs.30,000/- dated 08-09-2022 (Deposit slip#408771720)
	The proposed proprietary name / brand name	**Roxaban 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Rivaroxaban……2.5mg
	Pharmacotherapeutic Group of (API)	Antithrombotic Agents, Direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Xarelto (2.5 mg, 10 mg, 15 mg, or 20 mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Zonabax 2.5mg Tablet by M/s Horizon Healthcare (Reg# 108120)
	Proposed Pack size	20's
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's response
3.2.S.4	• Copies of the Drug substance specifications of Drug substance manufacturer is required. • Clarification is required as the declared drug substance specifications is in-house while monograph for the drug substance is available both in USP and BP • The assay method of drug product manufacturer (isocratic method) is different than drug substance manufacturer (gradient method), clarify • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Submit readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis of the same batch from Drug Substance manufacture.	• Copies of the Drug substance specifications of Drug product manufacturer is submitted instead of drug substance manufacturer • The firm submitted that at the time of Product Development and Stability Studies API was not available in any pharmacopeia. However now Rivaroxaban API is available in BP pharmacopeia, we have revised our Method & Specifications accordingly. Also Analytical Method Verification has been performed and submitted. • As API was not available in Pharmacopoeia at the time of Product Development. The API testing method was developed according to the Article of Brazilian journal. Link is given below and for your reference documents of article are submitted https://www.scielo.br/j/bjps/a/p8RzWwkTsrMRwNGVZTcDdDg/ Now API is available in BP so, we have performed testing as per British Pharmacopoeia and revised method is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted. • Certificate of Analysis of the same batch of drug substance from Drug Substance manufacture is submitted. However, Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies is not submitted.
3.2.P.5	• You have applied for in house specification in this section and innovator's specifications in section 1.5.6 while the monograph for the applied product is available both in USP and BP. Clarification is required	• The firm submitted that at the time of Product Development and Stability Studies rivaroxaban tablets were not available in any pharmacopeia. • However now it is available in BP & we have revised our Method of Analysis & Specifications accordingly. Also Analytical Method Verification of Rivaroxaban 2.5mg Tablet is submitted
3.2.P.8	• Raw data sheets of stability testing for applied product is not submitted	• Raw data sheets of stability testing for applied product is not submitted

Previous Decision (M-336th-DRB): Deferred for submission of following:

- Copies of the Drug substance specifications of Drug substance manufacturer
- Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies
- Raw data sheets of stability testing for applied product
- Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021

Firm's Response:

S No.	Deferment Reason	Firm's response
1	• Copies of the Drug substance specifications of Drug substance manufacturer	• Copies of the Drug substance specifications of Drug substance manufacturer is submitted

2	• Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer used during product development and stability studies	• Readable copy of results of analysis of relevant batch of Drug Substance performed by Drug Product manufacturer is submitted
3	• Raw data sheets of stability testing for applied product	• Raw data sheets of stability testing for applied product is submitted
4	• Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021	• Firm has submitted fee Rs. 7500/- on deposit slip#237610862 for correction/pre-approval change/ in product specifications,

Decision: Approved.

207.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 34284 dated 28-11-2022
	Details of fee submitted	Rs.30,000/- dated 30-09-2022 (Deposit slip#765328177565)
	The proposed proprietary name / brand name	**Savelo 800mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sevelamer Carbonate……800mg
	Pharmacotherapeutic Group of (API)	Phosphate Binders
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Sevelamer carbonate 800mg film-coated tablets MHRA Approved Renvela 800mg film coated Tablets USFDA Approved
	For generic drugs (me-too status)	Renvela 800mg Tablets by M/s sanofi-aventis Pakistan Limited (Reg#85252)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of application applied for renewal of DML dated 12-04-2022
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Control Administration Gujarat State India valid upto 05-05-2023

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Not submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications shall be submitted • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer • Submit certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture used during product development and stability studies.	• Copies of the Drug substance specifications for drug substance by product manufacturer is submitted. However, analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is not submitted • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications is not submitted • Analytical Method Verification studies for drug substance by drug product manufacturer is submitted • No justification is submitted • Certificate of analysis of relevant batch of Drug Substance from Drug Substance manufacture is submitted
3.2.P.2	• Pharmaceutical equivalence and CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted	• Firm has submitted pharmaceutical equivalence of their product against the product Renvela 800mg Tablet by M/s Genzyme Ireland ltd. Waterford Ireland • The firm submitted that sevelamer carbonate 800mg tablets dissolution test can't be performed like the conventional film coated tablets. Because this product till now is not available in any official monograph like USP, BP, JP etc. furthermore, the afore said product dissolution in FDA dissolution guidance is mentioned to be done by disintegration method. • So the exemption of the dissolution and comparative dissolution may be granted for the product
3.2.P.5	• Justification shall be submitted for not including the test for loss on drying, uniformity of mass, disintegration, potency, microbial purity, titratable amines, soluble oligomers in finished product specifications as per innovator's product review document • Description of test for identification test in finished product specifications shall be submitted	• The firm submitted that titratable amines and soluble oligomers test is done raw material and these are not required in finished product. • Description of test for identification test in finished product specifications is submitted • Analytical procedure for all the tests given in finished product specifications is submitted • Firm has submitted revised batch analysis report in which test for loss on drying, uniformity of mass, disintegration, potency has been performed. However test for titratable amines and soluble oligomers in

	• Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for not performing the test for loss on drying, uniformity of mass, disintegration, potency, microbial purity, titratable amines, soluble oligomers in finished in batch analysis of drug product as per innovator's product review document	finished product batch analysis is not performed and firm submit that titratable amines and soluble oligomers test is done raw material and these are not required in finished product.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Justification of applying UV Spectrophotometric method for Assay analysis of applied formulation in stability study instead submitted HPLC method. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of form 6 issued dated 21-10-2021 specifying 03Kg Sevelamer Carbonate. The invoice is issued by AD (I&E) DRAP. • The firm submitted that HPLC method is not applicable for phosphate binding capacity so it is performed on UV. However no UV method has been submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted

Previous Decision (M-336th-DRB): Deferred for submission of following:

- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
- Analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer
- Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications
- Justification for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer
- Justification for not performing the test for microbial purity, titratable amines, soluble oligomers in finished in batch analysis of drug product
- Analytical method for applied drug product

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
2	• Analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer	• Analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted
3	• Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications	• Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications is not submitted
4	• Justification for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer	• Firm has submitted revised batch analysis of drug substance in which test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index has been incorporated. However, firm submitted that they rely on COA of supplier
5	• Justification for not performing the test for microbial purity, titratable amines, soluble	• Firm has submitted revised batch analysis of drug product in which the test for titratable amines and soluble oligomers has been performed

	oligomers in finished in batch analysis of drug product	
6	• Analytical method for applied drug product	• Analytical method for applied drug product is submitted

Decision: Deferred for clarification for not performing the test for total titratable amine, carbonate content, limit of soluble oligomers, limit of allylamine, residue on ignition, limit of chloride, swell index in batch analysis of drug substance by drug product manufacturer

208.	Name, address of Applicant / Marketing Authorization Holder	M/s Faas Pharmaceuticals (Pvt.) Ltd., Plot# F-748 L, S.I.T.E Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Safe Pharmaceuticals (Pvt.) Ltd., Plot# C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	**M/s Safe Pharmaceuticals:** Firm has submitted copy of cGMP certificate date 13-08-2020 based on inspection conducted on 13-03-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 30-06-2020 specifying Dry Powder Injectable (Cephalosporin) of M/s Safe Pharmaceuticals
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 10624 dated 26-04-2022
	Details of fee submitted	Rs.50,000/- dated 28-04-2021 (Deposit slip#9115296832) Rs.25,000/- dated 24-12-2021 (Deposit slip#1184490481)
	The proposed proprietary name / brand name	**Faascef 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Ceftriaxone sodium 250mg
	Pharmaceutical form of applied drug	Dry powder Injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1x250mg
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin 250mg Powder for solution for injection MHRA Approved
	For generic drugs (me-too status)	Arizon Injection 250mg IV by M/s Aries Pharmaceuticals (Reg.No# 100241)
	Name and address of API manufacturer.	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD

		template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batches: 11302001, 11302002, 11302003)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Cefxone Injection 250mg by M/s Bosch Pharmaceutical Company by performing quality tests (Description, identification, water, pH, sterility test, BET, particulate matter, assay).
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Specificity, Linearity and range, system suitability

STABILITY STUDY DATA	
Manufacturer of API	M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., First Medical Zone, Economic & Technological Development Zone, Datong, Shanxi, China
API Lot No.	Q011801001, Q011712039, ***Q011802027***
Description of Pack (Container closure system)	White or almost white crystalline powder filled in clear glass vial of 10ml sealed with grey rubber stopper & AI/PI (dark blue) flap (5ml WFI is also supplied in white PVC tray) along with leaflet.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	DI-659 ***(API Q011712039)***	DI-710 (API Q011801001)	DI-740 (API Q011802027)
Batch Size	33333 vials	33333 vials	33333 vials
Manufacturing Date	02-2018	05-2018	08-2018
Date of Initiation	23-02-2018	23-05-2018	15-08-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of cGMP certificate of M/s Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China issued by Shanxi Provincial Food and Drug Administration China valid upto 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No#W180507 dated 07-05-2018 for import of 700kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011802027, Q011802044, Q011802045) in name of M/s Safe Pharmaceuticals attested by AD (I&E) DRAP Karachi dated 28-06-2018. Firm has submitted copy of another commercial invoice No#W180347 dated 28-03-2018 for import of 500kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011712037, ***Q011712039***, Q011712100, ***Q011801001***) in name of M/s Safe Pharmaceuticals. *However, the invoice is not attested by AD (I&E) DRAP office.*
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like Raw data sheets, COA, chromatogram and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Clarification is required as the fee Rs. 50,000/- is submitted on 28-04-2021while R&I date of submitted application is 26-04-2022. (almost 1 year before R&I date)	• The primary reason for the delayed submission of required documents was the discovery of a deficiency in the dossier during pre-screening process. Additionaly we acknowledge that the stability data provided in the initial submission was incomplete.
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years	Firm has submitted cGMP certificate of applicant M/s Faas Pharmaceuticals: Details are: Firm has submitted copy of cGMP certificate date 08-05-2018 based on inspection

		conducted on 04-05-2018. However, the cGMP in not valid.
1.4.3	• The firm has submitted application to Deputy Director General (R-II) DRAP Islamabad for change of contract manufacturer from M/s PharmEvo (Pvt) Ltd to M/s Safe Pharmaceuticals (Pvt) Ltd. Clarification is required whether it is application for new registration or change of contract manufacturer	• The firm submitted that the application for this product from M/s Safe Pharmaceuticals is for new registration on contract manufacturing with M/s Faas Pharmaceuticals.
1.5.2	• Submit your label claim as per reference formulation along with submission of applicable fee	• Not submitted
1.6.5	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Not submitted
3.2.S.4	• Justification shall be submitted for not including the test for constituted solution, particulate matter, bacterial endotoxin, sterility in drug substance specification by drug product manufacturer as recommended by drug substance manufacturer • Justification shall be submitted for selecting different limits of assay test by drug product manufacturer (≥79%) than drug substance manufacturer (NLT84%)	• Firm has submitted revised drug substance specificatins in which test for particulate matter, bacterial endotoxin, sterility are included • The firm submitted that assay limit as specified by drug substance manufacturer NLT 84% is according to Chinese Pharmacopiea 2010 as provided by Sinopharm. While QC department of M/s Safe Pharmaceuticals has followed USP 36 which specifies assay limit NLT 79.5%
3.2.P.1	• You have submitted the use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection, clarify	• Firm submitted that sterile WFI is complemenatry for parenteral products. We provide 5ml WFI ampoule with our product Faascef 250mg injection although the reconstitution volume required is 2.5ml to prepae the exact dose in accordance with innovator's product.
3.2.P.2	• Justification shall be submitted for not performing pharmaceutical equivalence studies against the innovator product • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the reference product including the tests recommended by USP monograph (uniformity of dosage unit and test for water determination)	• Firm has submitted pharmaceutical equivalence of their product against the product Rocephin 250mg Injection by M/s Roche Laboratories Inc. by performing quality tests (Description, identification, water, pH, uniformity of dosage unit, assay and reconstituted solution). However details of innovator product i.e batch No#, manufacturing date and expiry date is not provided. Furthermore, test for sterility test, BET, particulate matter are also not performed in pharmaceutical equivalence study.
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units as per USP monograph • Justification shall be submitted using different length column in chromatographic method for assay test (15cm) than USP (25cm).	• Firm has submitted revised finished product specifications in which test for uniformity of dosage units are included. • Firm has submitted revised analytical method for assay test with column length 25cm as per USP

	• Results for accuracy and precision studies in analytical method verification for applied product shall be submitted	• Results for accuracy and precision studies in analytical method verification for applied product is submitted
3.2.P.8	• Submit documents of relevant batches for procurement of API with approval from DRAP • As per submitted COA of API (***Q011712039,*** Q011801001) by drug product manufacturer the analysis date of API is subsequent to the manufacturing date of trial batches clarify • As per submitted stability summary sheet and commercial invoice the manufacturing date of trial batch DI-659 is prior to the import of API, clarify • Clarification shall be submitted as the brand name mentioned in BMR is Safetrazone 250mg injection while analytical record (raw data sheet, stability summary sheet, chromatograms) in batch analysis and stability study for Faascef injection 250mg is provided • Clarification shall be submitted as the submitted chromatograms does not show the batch number, sample number, standard or sample solution, time point or storage conditions of stability study and wavelength	• Firm has submitted copy of another commercial invoice No#WQD201704114 dated 26-12-2017 for import of 300kg of Ceftriaxone Sodium Sterile USP (Batch No# *Q011801001, Q011802027, Q011712039*) in name of M/s Safe Pharmaceuticals. *However, the invoice is not attested by AD (I&E) DRAP office.* • No clarification is submitted • No clarification is submitted. However, another invoice is submitted and the invoice is not attested by AD (I&E) DRAP office. • No clarification is submitted. However, the firm has submitted new BMR with applied brand name of drug product i.e. Faascef 250mg injection and same batch number. • No clarification is submitted. However, the firm has submitted new chromatograms that contains the batch number, sample number, standard or sample solution, time point or storage conditions of stability study

Previous Decision (M-331st-DRB): Deferred for submission of following:

- Differential fee Rs. 25000/- for contract manufacturing application
- Submit your label claim as per reference formulation along with submission of applicable fee
- Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Clarification for use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection
- Complete testing of the applied drug product and the reference product in pharmaceutical equivalence including the tests recommended by USP monograph
- Documents of relevant batches for procurement of API with approval from DRAP
- Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039,* Q011801001)] is subsequent to the manufacturing date of trial batches
- Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)
- Clarification for submission of new BMR with change of brand name

Response of firm:

S No.	Deferment Reason	Firm's Response
1	• Differential fee Rs. 25000/- for contract manufacturing application	• Firm has submitted differential fee Rs. 25000/- on deposit slip#240618745 for contract manufacturing
2	• Submit your label claim as per reference formulation along with submission of applicable fee	• The firm has revised the label claim as per reference formulation. The revise label claim is as under: Each vial of dry substance contains: Ceftriaxone sodium equivalent to ceftriaxone……250mg
3	• Valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Not submitted

4	• Clarification for use of 5ml sterile water for injection while innovator product recommends the use of 2.5ml water for injection	• I/we hereby justifies that the required volume to reconstitute Faascef (Ceftriaxone sodium) 250mg injection vial is 2.5ml. We provided 5ml water for injection instead of 3ml water for injection because we have not registered WFI with 3ml and it fulfils the requirement of reconstitution.
5	• Complete testing of the applied drug product and the reference product in pharmaceutical equivalence including the tests recommended by USP monograph	• Firm has submitted pharmaceutical equivalence of their product against the product Cefxone Injection 250mg by M/s Bosch Pharmaceutical
6	• Documents of relevant batches for procurement of API with approval from DRAP	• Firm has submitted copy of commercial invoice No#W180347 dated 28-03-2018 for import of 500kg of Ceftriaxone Sodium Sterile USP (Batch No#Q011712037, ***Q011712039***, Q011712100, ***Q011801001***) in name of M/s Safe Pharmaceuticals. attested by AD (I&E) DRAP Karachi dated 09-04-2018.
7	• Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches	• No clarification is submitted
8	• Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)	• No clarification is submitted
9	• Clarification for submission of new BMR with change of brand name	• No clarification is submitted

Previous Decision (M-336th-DRB): Deferred for submission of following:

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin
- Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches
- Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)
- Clarification for submission of new BMR with change of brand name

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted notice of Good manufacturing practice compliance inspection results stating that the firm meet the requirements of Drug Production Quality management standard (ver: 2010) issued by Shanxi Medical products Administration dated 30-03-2023
2	• Clarification as the analysis date of API by drug product manufacturer [COA of API (*Q011712039*, Q011801001)] is subsequent to the manufacturing date of trial batches	The firm submitted that COA of API which is submitted in dossier is standardization of secondary standard, while the COA of API is attached to this query by which batches have manufactured
3	• Clarification as manufacturing date of trial batch DI-659 is prior to the import of API (as per submitted stability summary sheet and commercial invoice)	The firm submitted that COA of API which is submitted in dossier is standardization of secondary standard, while the COA of API is

		attached to this query by which batches have manufactured
4	• Clarification for submission of new BMR with change of brand name	Proper BMR with applied brand name of drug product i.e. Faascef 250mg Injection is provided

Decision: Approved with following label claim:
Each vial of dry substance contains:
Ceftriaxone sodium equivalent to ceftriaxone……250mg
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin**
ii. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 03; Deferred Registration applications of Human drugs on Form 5-F (New Section)

209.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd., 14Km Adyala Road Post office Dahgal Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F UM6-1B3-2QYX dated 23-04-2024
	Details of fee submitted	Rs.30,000/- dated 11-11-2023 (Deposit slip#74238026)
	The proposed proprietary name / brand name	Simalvia Soft Gelatin Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Alverine citrate……..…..60mg Simethicone…….300mg
	Pharmacotherapeutic Group of (API)	Musculotropic Antispasmodics / Antiflatulents
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[XI]:

Section	Observations	Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for both drug substances issued by relevant regulatory authority of country of origin is required	**Simethicone:** Firm has again submitted copy of cGMP certificate of different manufacturing site of API manufacturer issued by Food and Drugs Administration (Maharashtra State) India valid upto 23-11-2024. (Elkay Chemicals Pvt Ltd, Plot No. F-5, Lote MIDC Area., Lote , Tal-Khed, Ratnagiri - 415722 , Dist – Ratnagiri, District: Ratnagiri India) **Alverine citrate** • Firm has again submitted copy of cGMP certificate of API manufacturer issued by Italian Medicine Agency valid upto 2 end 2022
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is	• Submitted

	provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance alverine citrate by Drug Product manufacturer is required. • Copies of the Drug substance specifications of the Drug substance simethicone by Drug substance manufacturer is required. • Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer shall be submitted • Justification shall be submitted for not including the test for silicon dioxide content and defoaming activity in specification of drug substance by drug product manufacturer as per USP monograph	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance alverine citrate by Drug Product manufacturer is submitted. • Copies of the Drug substance specifications of the Drug substance simethicone by Drug substance manufacturer is submitted. • Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer is not submitted • Firm has submitted revised batch analysis report of drug substance simethicone in which test for silicon dioxide content and defoaming activity has been performed
3.2.S.5	• COA of primary / secondary reference standard of alverine citrate including source and lot number shall be provided.	• COA of primary / secondary reference standard of alverine citrate is submitted
3.2.S.7	• Stability study data of simethicone at real time conditions till claimed shelf life shall be submitted	• Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions till 18 months only
3.2.P.5	• Analytical method validation study reports for simethicone in drug product shall be submitted.	• Analytical method validation study reports for simethicone in drug product is submitted.
3.2.P.6	• COA of primary / secondary reference standard of simethicone including source and lot number shall be provided	• COA of secondary reference standard of simethicone is submitted. However it mentioned on the COA that it is to be used before 12-10-2012
3.2.P.8	• Submit documents for the procurement of API Simethicone with approval from DRAP (in case of import).	• Firm has submitted copy of clearance certificate issued dated 21-07-2022 specifying 1000kg of Simethicone USP. The clearance certificate is issued by AD (I&E) DRAP.

Previous Decision M-336th-DRB): Deferred for submission of following:

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for both drug substances issued by relevant regulatory authority of country of origin is required
- Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer
- Stability study data of simethicone at real time conditions till claimed shelf life
- COA of primary / secondary reference standard of simethicone including source and lot number

Firm's Reponse:

S No	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for both drug	**Simethicone:** • Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs

	substances issued by relevant regulatory authority of country of origin is required	Administration (Maharashtra State) India valid upto 23-11-2024. • Firm has submitted details of API manufacturer in section 3.2. S.2 as Elkay Chemicals Pvt Ltd, Plot No. F-5, Lote Parshuram, MIDC., Tal-Khed, Dist – Ratnagiri, Maharashtra, India) **Alverine citrate** • Firm has submitted copy of cGMP certificate of API manufacturer issued by Italian Medicine Agency valid upto 21-12-2026
2	• Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer	• Certificate of Analysis (COA) of relevant batch of drug substance alverine citrate used in product development and stability study from drug substance manufacturer is submitted
3	• Stability study data of simethicone at real time conditions till claimed shelf life	• Stability study data of simethicone at real time conditions till claimed shelf life is submitted
4	• COA of primary / secondary reference standard of simethicone including source and lot number	• COA of primary reference standard of simethicone including source and lot number is submitted

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 04: Deferred Registration applications of Human Drugs on form 5F (New DML):

210.	Name, address of Applicant / Marketing Authorization Holder	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30255; dated 05/11/2021
	Details of fee submitted	PKR 30,000/-: dated 27/10/2021
	The proposed proprietary name / brand name	Emeton Injection 4mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ondansetron (as ondansetron HCl Dihydrate)……..4mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) Antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 2mg base/ml injection USFDA Approved **Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**** Ondansetron 2mg/ml Solution for Injection MHRA Approved (2ml, 4ml)
	For generic drugs (me-too status)	Zofran Injection 4mg/2ml by M/s GSK (Reg#052259)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSS DC, Industrial Estate, Doddaballapur, Banglore, Karnataka, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed Pharmaceutical Equivalence studies against the Zofran injection by M/s GSK
	Analytical method validation/verification of product	Method verification studies have submitted.

STABILITY STUDY DATA	
Manufacturer of API	M/s Anugraha Chemicals No D-47 to D-50, C-62 and C-63, KSS DC, Industrial Estate, Doddaballapur, Banglore, Karnataka, India
API Lot No.	AOND-18006

Description of Pack (Container closure system)	Colorless liquid filled in ***2ml / 5cc clear glass vial*** labeled and packed in standard unit carton (1 x 1'c) and leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T1/21	T2/21	T3/21
Batch Size	2000 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	01-2021	01-2021	01-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15 – 1.5.20	Commitments not submitted	Firm has submitted commitments as per form 5-F
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	***GMP certificate is not submitted***
2.3.R.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4.1. - 3.2.S.4.2	Submit signed analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.	Firm have submitted analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug substance manufacturer is not submitted.***

3.2.S.4.3	Clarify whether the Analytical Method Verification studies of drug substance have been performed by drugs substance manufacturer or drug product manufacturer	***No clarification is submitted***
3.2.S.6	Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component and other information on the container closure system(s) (e.g. suitability studies) may be submitted.	***No details submitted***
3.2.S.7	The submitted stability study is performed by M/s CTX Lifesciences while the manufacturer of drug substance is Anugraha Chemicals, clarification is required?	***No clarification is submitted***
3.2.P.1	You have not performed the tests of identification, bacterial endotoxin test and particulate matter in pharmaceutical equivalence, justify?	***No justification is submitted***
3.2.p.3.3.	Submit the flowchart of manufacturing outline since the submitted manufacturing outline is not clearly visible.	***No reply submitted***
3.2.P.5.1	• You have not mentioned the tests of identification, bacterial endotoxin test and particulate matter, justify? • Revise your specifications in line with USP specifications along with submission of applicable fee	***No justification is submitted***
3.2.P.5.3	Analytical Method Verification studies of drug product is same as that of drug substance. Clarification is required	***No clarification is submitted***
3.2.P.7	Specify the container closure system of your product including details whether ampoule or vial, filled volume and type of glass, since both ampoule and vials and different volumes have been mentioned in different sections	***No details are submitted***
3.2.P.8.3	• The stability batches have been manufactured on 01-2021 while the stability chromatograms are acquired in 2019, justify? • COA of 3rd month stability study data not submitted? • The ph values given in stability data sheet and raw data sheet is different at all time point? • COA and raw data sheet at 6th month time point is not submitted	• ***No justification is submitted*** • ***COA of 3rd month stability study data not submitted*** • ***No clarification is submitted*** • Firm has submitted raw data sheet at 6th month time point. ***However, COA at 6th month time point is still not submitted***
	• Audit trail reports on product testing is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import).	***No document/record is submitted***

	• Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated)	
	• In submitted reply the BMR shows that batch size is 1500 ampoule, while raw data sheet shows 2000 ampoule	

Decision: Deferred for following:

- Submission of valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer
- Clarification is required since the submitted stability study is performed by M/s CTX Lifesciences while the manufacturer of drug substance is Anugraha Chemicals.
- Justification for not including the tests of identification, bacterial endotoxin test and particulate matter in product specifications.
- Clarification for submission of same Analytical Method Verification studies for drug product as that of drug substance.
- Specify the container closure system of your product including details whether ampoule or vial, filled volume and type of glass, since both ampoule and vials and different volumes have been mentioned in different sections
- Justification since the stability batches have been manufactured on 01-2021 while the stability chromatograms are acquired in 2019.
- Clarification since the pH values given in stability data sheet and raw data sheet is different at all-time point.
- Submission of COA and raw data sheet at 6th month time point.
- Submission of documents for the procurement of API with approval from DRAP (in case of import).
- Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Firm's Response:

S No#	Deferment Reason	Firm's Response
1	• Submission of valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	• Valid GMP certificate of M/s Anugraha Chemicals, D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangalore, India issued by Drug Control Department Government of Karnatak valid upto one year from the date of issue. (Date of issue 10-04-2023.
2	• Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is submitted
3	• Clarification is required since the submitted stability study is performed by M/s CTX Lifesciences while the manufacturer of drug substance is Anugraha Chemicals.	• Stability study of three batches of drug substance at both accelerated as well as real time conditions by M/s Anugraha Chemicals is submitted. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
4	• Justification for not including the tests of identification, bacterial endotoxin test and particulate matter in product specifications.	• Firm has submitted that tests of identification, bacterial endotoxin test and particulate matter in product specifications is included and revised specifiactions are submitted

5	• Clarification for submission of same Analytical Method Verification studies for drug product as that of drug substance.	• Analytical method verification studies for drug product is submitted
6	• Specify the container closure system of your product including details whether ampoule or vial, filled volume and type of glass, since both ampoule and vials and different volumes have been mentioned in different sections	• Glass ampoule is the container closure system
7	• Justification since the stability batches have been manufactured on 01-2021 while the stability chromatograms are acquired in 2019.	• The firm has submitted that it's drafting mistake and the values stated in the raw data sheets may be considered valid
8	• Clarification since the pH values given in stability data sheet and raw data sheet is different at all-time point.	• Firm has submitted stability data sheets
9	• Submission of COA and raw data sheet at 6th month time point.	• COA and raw data sheet at 6th month time point is not submitted
10	• Submission of documents for the procurement of API with approval from DRAP (in case of import).	• Not submitted
11	• Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Previous Decision (M-331st-DRB): Deferred for submission of following:

- Chromatograms for the Assay analysis performed during stability studies of all three batches
- Clarification since the pH values given in stability data sheet and raw data sheet is different at all-time point.
- COA and raw data sheet at 6th month time point.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021

Firm's Response:

The firm has submitted revised stability data including details of drug substance manufacturer, Module III (Drug Substance), Stability Studies of Drug Substance, Module-III (Drug Product), Pharmaceutical equivalence, Analytical method validation/verification of product. The details of reply are given below:

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ondansetron hydrochloride dihydrate eq. to Ondansetron……...4mg
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Zofran Inj by M/s GSK
STABILITY STUDY DATA	
Manufacturer of API	M/s Anugraha Chemicals No D-47 to D-50, C-62 and C-63, KSS DC, Industrial Estate, Doddaballapur, India
API Lot No.	AOND-23005
Description of Pack (Container closure system)	Clear, colourless or almost colourless, solution filled in type-I glass ampoule.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)

Batch No.	T004	T005	T006
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	01-2024	01-2024	01-2024
Date of Initiation	01-2024	01-2024	01-2024
No. of Batches	03		

Administrative Portion	
Reference of previous approval of applications with stability study data of the firm (if any)	N/A
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of cGMP certificate of API manufacturer issued by Drug Control Department Government of Karnataka Gujarat State India valid upto 02-04-2025
Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted that we have taken loan from Caliph Pharmaceuticals. All the relevant document are submitted.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The HPLC system is 21 CFR compliant but Audit trail has not yet been activated.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with following label claim:
Each 2ml ampoule contains:
Ondansetron hydrochloride dihydrate eq. to Ondansetron……...4mg
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 30,000/- for revision in stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

211.	Name, address of Applicant / Marketing Authorization Holder	M/s, Carer Pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s, Carer Pharmaceuticals Industries. Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29204 dated 26/10/2021
	Details of fee submitted	PKR 30,000/-: dated 18/10/2021
	The proposed proprietary name / brand name	Capliva 200mg /5ml Dry Powder Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API)	Each 5ml of reconstituted suspension contains: Azithromycin as dihydrate……..200mg

	per unit	
	Pharmaceutical form of applied drug	Dry Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's (15ml, 30ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax powder for oral suspension 200mg/5ml by M/s Pfizer Ltd MHRA Approved
	For generic drugs (me-too status)	Zetro oral suspension 200mg by M/s Getz Pharma (Reg#047145)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceutical Co, Ltd., No 9 Xingye street, Shiiazhuang Economic and Technological Development Zone, Hebei Province, China. Tel: 0086-575-82736468 Fax: 0086-575-82735575
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (U129-141124-1, U129-141125-1, U129-141126-1)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed Pharmaceutical Equivalence against the Azomax suspension 200mg/5ml by M/s Novartis Pharma.
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA	
Manufacturer of API	M/s Hebei Guolong Pharmaceutical Co, Ltd., No 9 Xingye street, Shiiazhuang Economic and Technological Development Zone, Hebei Province, China Tel: 0086-575-82736468 Fax: 0086-575-82735575
API Lot No.	210507019

Description of Pack (Container closure system)	White to off-white granular powder filled in amber color glass bottle, with white Aluminium cap, is packed in a printed unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	16-01-2021	16-01-2021	16-01-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15 – 1.5.20	Commitments not submitted	Firm has submitted commitments as per form 5-F
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	***GMP certificate is not submitted***
2.3.R.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4.1. - 3.2.S.4.2	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required. • Submit signed analytical procedures used for routine testing of the Drug substance	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is not submitted*** • Firm have submitted analytical procedures used for routine testing of the Drug

<table>
<tr><td></td><td>/Active Pharmaceutical Ingredient by Drug product manufacturer is required.
• Justify the declared potency of drug substance on COA as it is given on dried basis while in pharmacopeia it is given on anhydrous basis?</td><td>substance /Active Pharmaceutical Ingredient by Drug product manufacturer.
• The firm submitted that potency of API has been calculated on anhydrous basis, whereas the term “on dried basis” was inadvertently mentioned considering it a broader term</td></tr>
<tr><td>3.2.S.4.3</td><td>Analytical Method Verification studies of drug substance(s) for specificity study by the Drug Product manufacturer shall be submitted.</td><td>No reply submitted</td></tr>
<tr><td>3.2.S.4.4</td><td>Batch number of submitted batch analysis by drug product manufacturer (201507019) is different from the batch number submitted by drug substance manufacturer given in batch analysis (210507019)</td><td>The firm have again submitted same COA of drug substance provided by drug substance manufacturer and drug product manufacturer having different batch number and no clarification is provided.</td></tr>
<tr><td>3.2.S.5</td><td>COA of primary standard including source and lot number is submitted. Clarify whether the same reference standard is used by the drug substance manufacturer or drug product manufacturer?</td><td>Firm has submitted COA of primary reference standard and stated that the same is used by drug product manufacturer.</td></tr>
<tr><td>3.2.P.2.1.1</td><td>Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.

<table>
<tr><td>Applied product</td><td>ZITHROMAX for oral suspension USFDA</td></tr>
<tr><td>Azithromycin as dihydrate</td><td>Azithromycin as dihydrate</td></tr>
<tr><td>Sucrose (Extra Fine)</td><td>Sucrose</td></tr>
<tr><td>Mannitol</td><td>Hydroxypropyl cellulose</td></tr>
<tr><td>Xanthan gum</td><td>Xanthan gum</td></tr>
<tr><td>Trisodium phosphate anhydrous</td><td>Sodium phosphate, tribasic, anhydrous</td></tr>
<tr><td>Colloidal anhydrous silica (Aerosil 200)</td><td>FD&C Red #40; spray dried artificial cherry, creme de vanilla, and banana flavors</td></tr>
<tr><td>Sodium benzoate</td><td></td></tr>
<tr><td>Tutti Frutti powder (PDF 245)</td><td></td></tr>
</table></td><td>• The excipients used in the applied formulation are complying with current pharmacopeial monograph. These excipients are pharmaceutically inert substance and we have used these excipients below the IIG limit of FDA orange book as well as we have done extensive analysis of the product after formulation and found satisfactory result of the assay.
• Also, we have done stability study during development stage and found satisfactory result of the product. So, we can conclude that these excipients are not incompatible with API.</td></tr>
</table>

3.2.P.2.2.1	• In Description of formulation development, you have submitted manufacturing outline. In manufacturing outline, you have mentioned Sodium hydroxy methyl benzoate and sodium propyl hydroxy benzoate, Saccharine sodium, citric acid monohydrate, glycerin, maltitol sodium, strawberry flavor which are not part of applied formulation, clarify? • Furthermore, you have submitted manufacturing outline for liquid suspension while the applied product is dry suspension, clarify?	The firm have submitted corrected composition table and manufacturing outline.
3.2.P.3.2	In batch formula the amount of azithromycin is mentioned without considering the hydrated form clarify?	The firm have submitted revised batch formula and stated that dihydrate will be adjusted by actual potency (on as is basis) given by QC.
3.2.P.5.1	The USP monograph for azithromycin suspension has given the test for dissolution while you have not mentioned the dissolution test in specification, clarify?	The firm submitted that they followed USP-37 monograph of azithromycin oral suspension which did not include dissolution test. The firm further submitted that now they have included dissolution test in specifications and had also performed it on recent time point of long-term stability studies. The firm have submitted revised specifications.
3.2.P.5.2	Submit detailed signed analytical procedures used for testing the drug product shall be provided.	Firm have submitted analytical procedures used for testing of drug product
3.2.P.5.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Firm have submitted Analytical Method Verification studies. ***However, results of repeatability (method precision) is not submitted***
3.2.P.5.4	You have not performed dissolution test as per USP monograph of the applied product, clarify?	Reply submitted as above in section 3.2.P.5.1
3.2.P.8	• The results of assay of Batch #01, Batch #02, Batch #03 mentioned in COA of accelerated and real time stability study is different from the assay result given in raw data sheet • Two different method used for sample preparation mentioned in submitted raw data sheet of Batch #T01, clarify? • The results of stability study data of all the three batches at real time and accelerated conditions given in raw data sheet and chromatogram reflects the same value for all the three batches, clarify?	• The firm submitted that there had been an erroneous drafting error in stability sheets, corrected stability summary sheets are submitted again. ***Further it is submitted that dissolution test results at initial time point, 3rd month time point and 6th month time point of real time and accelerated stability study were given in stability summary sheets which were neither included in specifications and not performed previously.*** • ***No clarification is submitted*** • ***No clarification is submitted. The submitted raw data sheets reflect that same standard peak area value has been applied for the calculation of Assay results at all time points of stability studies for all three batches.***

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• ***No document/details are submitted*** • ***No document/details are submitted*** • ***No document/details are submitted***

Previous Decision (M-321st-DRB): Deferred for following:

- Submission of valid GMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Submission of Copies of the Drug substance specifications and analytical procedures used for testing of the Drug substance by Drug substance manufacturer.
- Submission of results of specificity test in Analytical Method Verification studies of drug substance performed by the Drug Product manufacturer.
- Clarification since Batch number of drug substance mentioned in batch analysis by drug product manufacturer (201507019) is different from the batch number mentioned by drug substance manufacturer given in batch analysis (210507019)
- Submission of results of repeatability (method precision) test in method verification studies for drug product
- Clarification since results of dissolution test were included at initial time point, 3rd month time point and 6th month time point of real time and accelerated stability study in stability summary sheets which were neither included in specifications and not performed previously.
- Clarification for considering same standard peak area value for the calculation of Assay results at all-time points of stability studies for all three batches.
- Submission of documents for the procurement of API with approval from DRAP (in case of import).
- Submit record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Firm's Response:

The firm has submitted revised stability data including details of drug substance manufacturer, Module III (Drug Substance), Stability Studies of Drug Substance, Module-III (Drug Product), Pharmaceutical equivalence, Analytical method validation/verification of product. The details of reply are given below:

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Azithromycin as Dihydrate …….200mg
Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence of their product against the product Zithromax 200mg/5ml DS by M/s Pfizer Laboratories Firm has submitted CDP results of their product against the product Zithromax 200mg/5ml DS by M/s Pfizer Laboratories

STABILITY STUDY DATA

Manufacturer of API	Ningxia Taiyicin Biotech Co., Ltd., Pacific Road No.1.Nuanquan Economic Zone, Helan County, Yinchuan, Ningxia, (China)
API Lot No.	I231109014
Description of Pack (Container closure system)	White to off-white powder filled in amber glass bottle
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated: 06 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)

Batch No.	T004	T005	T006
Batch Size	250 bottles	250 bottles	250 bottles
Manufacturing Date	01-2024	01-2024	01-2024
Date of Initiation	01-2024	01-2024	01-2024
No. of Batches	03		
Administrative Portion			
Reference of previous approval of applications with stability study data of the firm (if any)	Nil		
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of API manufacturer issued by Ningxia Hui Autonomous Region Food and Drug Administration valid upto 24-01-2027		
Documents for the procurement of API with approval from DRAP (in case of import).	The firm submitted that we have borrowed azithromycin from M/s Caliph Pharmaceuticals. All the relevant document are submitted.		
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The HPLC system is 21 CFR compliant but Audit trail has not yet been activated.		
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Decision: Approved with following label claim: **Each 5ml of reconstituted suspension contains:** **Azithromycin as Dihydrate…….……200mg** **Registration Board further decided that Registration letter will be issued after submission of following:** **i. Fee of Rs. 30,000/- for revision in stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**			

Case No.; 05 Deferred Registration application on Form 5F (Import)

Registration applications of M/s Al-Habib Pharmaceuticals, Plot #81, block B, S.M.C.H.S., Karachi were deferred in 336th meeting of Registration Board with following decision.

Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email".

In response Mr. **Prasad Parelkar GM Business Development Export**, M/s Naprod Life Sciences Pvt. Ltd. India has sent email with following details;

"From: Prasad Parelkar <prasad.parelkar@naprodgroup.com>
Date: Mon, Jul 29, 2024 at 12:14 PM
Subject: RE: Verification of Sole Agency Agreement Between Naprod Life Sciences and Al-Habib Pharmaceuticals
To: dir.pe.reg@dra.gov.pk <dir.pe.reg@dra.gov.pk>
Cc: aasifjalildrap@gmail.com <aasifjalildrap@gmail.com>, zeeshan_moh@hotmail.com <zeeshan_moh@hotmail.com>, AHP BD <intl.bd@ahp.com.pk>, Azeem Ullah Khan <azeem@ahp.com.pk>, Sushama Lokhande <sushama.lokhande9013@naprod.onmicrosoft.com>

To
Director
PE & R Division,
Chairman Registration Board

DRAP Islamabad

Dear Sir / Madam,
We (Naprod Life Sciences Pvt. Ltd) are the Manufacturer and Direct Exporter having registered office at 304, Town center 1, Andheri Kurla Road, Andheri (E) , Mumbai, 400708, India, and Factory at G-17/1, MIDC, Tarapur, Boiser, Dist. Thane- 401506, India, like to reconfirm that we have Authorized Al Habib Pharmaceuticals having registered office at Plot 81 , Block B, SMCHS, 74400, Karachi, Pakistan as our ***sole agent*** *for following mentioned products.*

- *Capecitabine 500mg Tablet (Naprocap-500) ,*
- *Methotrexate 2.5mg Tab (Alltrex) ,*
- *Doxorubicin HCL 50mg inj (Naprodox 50),*
- *Doxorubicin HCL 10mg inj, (Naprodox 10),*
- *Bicalutamide 50mg Tab (MACABI)*
- *Fluorouracil Inj 500mg (FLUONCO)*
- *Leucovorin calcium inj 300mg (Cafonate)*

Please find enclosed official letter re issued (Dt. 14/07/23) by Naprod for your records against the Query raised by you in registration board meeting dated 4th to 6th June 2024

Also Please note that; Miles Intl. India and their partner Lab Diagnostic System (SMC) Pvt Ltd Rawalpindi, has been authorized by Naprod to export following Products only;

S.NO	***Product Name***	***Strength***	***Dosage Form***
1	*Bendamustine*	*100mg*	*Injection*
2	*Bortezomib*	*2mg and 3.5mg*	*Injection*
3	*Carboplatin*	*150mg and 450mg*	*Injection*
3	*Cisplatin*	*10mg and 50mg*	*Injection*
4	*Dacarbazine*	*200mg*	*Injection*
5	*Docetaxel*	*20mg,80mg and 120mg*	*Injection*
6	*Epirubicin*	*10mg and 50mg*	*Injection*
7	*Gemcitabine*	*200mg and 1gm*	*Injection*
8	*Lenalidomide*	*10mg and 25mg*	*Injection*
9	*Posaconazole*	*300mg*	*Injection*
10	*Voriconazole*	*200mg*	*Injection*

In case of any query feel free to contact us
Thanks and Regards"

212.	Name, address of Applicant / Importer	M/s. Al-Habib Pharmaceuticals, **Address:** Plot # 81, Block B, SMCHS, Karachi – Pakistan
	Details of Drug Sale License of importer	**License No:** 0230 **Address:** Plot # 81, Block B, SMCHS, Karachi – Pakistan **Address of Godown:** NA **Validity:** 18-05-2024 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name, address of manufacturer(s)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# COPP/CERT/KD/100457/2021/11/34994/172799) Valid up to 03-04-2022 by , Food and Drug control administration Gujrat state india **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Yearly. (Section of Tablet cytotoxic mentioned in GMP certificate)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from NAPROD LIFE SCIENCES PVT. LTD. (304, Town Center-1 Andheri Kurla Road, Andheri , Mumbai.The letter specifies that the manufacturer appoints M/s. Al Habib Pharmaceuticals to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5226 dated: 24-02-2022
	Details of fee submitted	PKR 150,000/- deposit Slip # 47789098702
	The proposed proprietary name / brand name	NAPROCAP Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Capecitabine USP…… 500mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic (Colorectal) WHO ATC code: (L01BC06) (capecitabine) is a nucleoside metabolic inhibitor with antineoplastic activity indicated for: • Adjuvant Colon Cancer – Patients with Dukes' C colon cancer. • Metastatic Colorectal Cancer– First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred • Metastatic Breast Cancer– In combination with docetaxel after failure of prior anthracyclinecontaining therapy – As monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XELODA® 500mg of USFDA approved.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	Mac- Chem Products (India) Pvt. Ltd. N-211/2/10. MIDC, Boisar, District- Thane, Pin - 401 506, Maharashtra, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months Batches: (CAP0210002, CAP0210001, CAP0210003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against XELODA Tablet 500mg manufactured by Hoffmann-La-Roche Inc. USA by performing quality tests (Identification, Assay, Dissolution, Hardness, Disintegration Time). The firm has submitted CDP with of XELODA Tablet 500mg manufactured by Hoffmann-La-Roche Inc. USA (Reference Drug Product) in in water, Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	PVC film coated with PVDC and printed Aluminium foil

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months. Batches:(NT1131, NT1132, NT1133)

Remarks of Evaluator:

Previous Decision(M-324): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023
"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.
Regarding our email Dated June 6th 2023 about about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

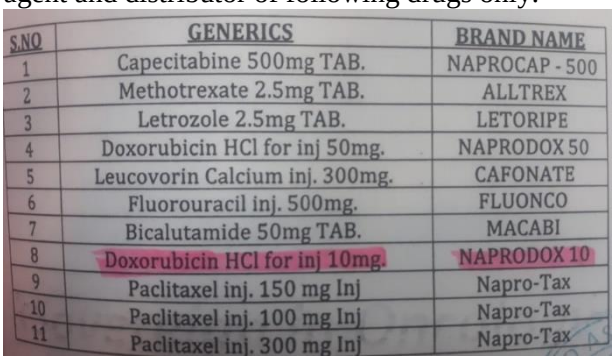
S. No	Generics	Brand Name
1.	Capecitabine 500mg TAB	NAPROCAP -500
2.	Methotrexate 2.5mg TAB	ALLTREX
3.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
4.	Leucovorin Calcium inj. 300mg	CAFONATE
5.	Fluorouracil inj. 500mg	FLUONCO
6.	Bicalutamide 50mg TAB	MACABI
7.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Previous Decision (M-336th-DRB): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email.

Decision: Approved as per Policy for inspection of Manufacturer abroad.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid, original, legalized CoPP certificate**
ii. **Valid copy of Drug Sale License**

213.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot #81, block B, S.M.C.H.S., Karachi.
	Details of Drug Sale License of importer	**DSL No**.: 1245 **Address**: Al-Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** 1. Plot No. 10 Sector 25 KIA Karachi 2. HT-8, Landhi Industrial Area, Karachi **Validity:** 18/05/2022 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Thane–401506, Mahrashtra State India.
	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd., G-17/1, M.I.D.C. Tarapur, Boisar, Distt – Thane – 401506 India.
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COPP/CERT/KD/83867/2019/11/27845/143336 dated 02/05/2019 issued by Food and Drug Administration Mahrashtra State Mumbai India for Doxorubicin Hydrochloride for Injection BP 10mg (lyophilszed). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The CoPP is valid upto 03/04/2022. The name of importing country mentioned on annexure attached with CoPP is mentioned as Pakistan. **GMP:** Firm has submitted notarized copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 dated 04/04/2019 issued by Food and Drug Administration Mahrashtra Estate Mumbai India The GMP certificate is valid upto 03/04/2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of letter of authorization from M/s Naprod Life Sciences Pvt. Ltd 304, Town Centre-1, Andheri Kurla Road, Andheri (East), Mumbai, India., The letter species that the manufacturer authorizes M/s Al Habib Pharmaceuticals, Plot #81, block B, SMCHS., 74400 Karachi., Pakistan as sole agent and distributor of following drugs only. 
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5228: dated; 24-02-2022
	Details of fee submitted	PKR 150,000 ; Dated: 26-01-2022 (Deposit slip#976636166)
	The proposed proprietary name / brand name	**NAPRODOX 10mg lyophilized powder for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Doxorubicin HCl ……. 10 mg
	Pharmaceutical form of applied drug	Lyophilized powder for Injection

S.NO	GENERICS	BRAND NAME
1	Capecitabine 500mg TAB.	NAPROCAP - 500
2	Methotrexate 2.5mg TAB.	ALLTREX
3	Letrozole 2.5mg TAB.	LETORIPE
4	Doxorubicin HCl for inj 50mg.	NAPRODOX 50
5	Leucovorin Calcium inj. 300mg.	CAFONATE
6	Fluorouracil inj. 500mg.	FLUONCO
7	Bicalutamide 50mg TAB.	MACABI
8	Doxorubicin HCl for inj 10mg.	NAPRODOX 10
9	Paclitaxel inj. 150 mg Inj	Napro-Tax
10	Paclitaxel inj. 100 mg Inj	Napro-Tax
11	Paclitaxel inj. 300 mg Inj	Napro-Tax

	Pharmacotherapeutic Group of (API)	Antineoplastic and Immunomodulating Agents; Anthracyclines and related substances WHO ATC Code: L01DB01
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Doxorubicin Hydrochloride 10mg/vial for Injection by M/s Hikma USFDA Approved
	For generic drugs (me-too status)	Astrodox Lyophilized Powder for Injection 10mg by M/s Aster Life Sciences (Reg. No# 78110)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated study is conducted at 40±2°C/75± 5%RH for 6 months and the real time stability study is conducted at 25 ± 2°C/ 60 ± 5 % RH till 24 months. (Batches: 71203715, 71204715, 71204915)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product ADRIAMYCIN RD 10 mg/vial injection by performing quality tests (Description, Identification, pH, Assay, particulate matter, reconstitution time).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, precision, linearity and range, accuracy and solution stability for the applied product.
	Container closure system of the drug product	5ml 20mm Flint Tubular-USP Type-I Glass vial with Rubber stopper 20mm Grey Bromo Butyl Slotted Siliconised by Silicon & Alu. Seal Lacq.20mm F/O Top Red Plain

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C / 75% ± 5% RH for 06 months and real time stability study is conducted at 30° C ± 2° C / 75% ± 5% RH for 36 months.

Batches	Mfg date	Batch size
NN7196	May 2017	18160 vials
NN7232	Jun 2017	18160 vials
NN7233	Jun 2017	18160 vials

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	• Submit valid Certificate of Pharmaceutical Product (CoPP) and GMP certificate of the drug product Manufacturer issued by relevant regulatory authority in the country of origin	• The firm submitted that the COPP that we submitted with CTD dossier has a validity till April 2022, as it gets expire during its period in R&I that's why as per the rule it will be considered as valid as we received R&I attested letter on 24th-Februray-2022.
1.3.4	• Submit copy of valid Drug Sale License (DSL) issued by relevant licensing authority	Firm has submitted valid copy of DSL. **DSL No**.: 0230 **Address**: Al Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi **Validity:** 18/05/2024 **Status:** Drug License by way of wholesale
1.3.5	• Submit evidence of approval of manufacturing facility / Approved Section from Licensing Authority	Firm submitted cGMP certificate in name of Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, District Palghar–401506, Mahrashtra State India showing lyophilized / Powder injectable cytotoxic section
1.6.5	• Submit Name and address of API manufacturer., • Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	• Firm has submitted details of API Manufacturer: M/s Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India. • Firm has submitted cGMP certificate in name of M/s Intas Pharmaceuticals Ltd., Plot No. 2702/A, GIDC Estate, Ankleshwar-393 002, District: Bharuch, Gujarat State India issued by Commissioner Food and Drug Administration Gandhinagar India valid upto 05-09-2025
3.2.S.4	• Justification is required for selecting different limits of specification of total impurities (Not more than 2.0%) by drug product manufacturer than drug substance manufacturer (Not more than 1.0%)	• Please note that we are following the BP monograph for analysis of finished product. BP Monograph of Doxorubicin for injection mentions limit of total impurities - Not more than 2.0%. BP monograph of finished product is submitted.
3.2.P.1	• Justify the role of methyl paraben in the applied formulation	• Methyl paraben is used as Solubilizing agent in the formulation of Doxorubicin for injection 10 mg. • Methyl paraben occurs as colorless crystals or a white crystalline powder. It is odorless or almost odorless and has a slight burning taste. Methyl paraben is widely used as an antimicrobial preservative in cosmetics, food products, and pharmaceutical formulations. Aqueous solutions at pH 3–6 are stable The WHO has set an estimated

Applied product	Reference pr
Doxorubicin HCl	Doxorubicin
Lactose monohydrate	Lactose Mon
Methyl paraben	
HCl	
NaOH	
Water for injection	

	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug	total acceptable daily intake for methyl-, ethyl-, and propyl parabens at up to 10 mg/kg body weight and official monograph available in BP. • However as per Innovator Literature, for Doxorubicin Hydrochloride for Injection particularly used as solubilizing agent which improved or give rapid dissolution of powder in final lyophilized product. Methyl paraben was used in formulation to improve solubilization by reducing the gel formation during reconstitution. Being generic drug of existing Innovator all excipients used as per Innovator and comply as per generic drug definition. • No information provided
3.2.P.2	• Submit details of comparator product including name of manufacturer, Batch No#, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator/comparator product including the tests recommended by BP (Bacterial endotoxin, Water)	• Information not provided • Pharmaceutical equivalence was proved on the basis of enclosed comparison of important physicochemical characteristic of innovator product and drug product. Also the proposed Drug product contains same active substance and excipient in similar quantity as that of innovator product. Complete testing as per the any specific pharmacopeia is not necessary during product development as we develop product for global supply with different pharmacopeia. As the results of critical Physicochemical parameters are similar and comparable, therefore both the drug product and innovator product are pharmaceutically equivalent. • Moreover Naprod ensure to perform complete analysis of drug product inline with the BP pharmacopoeia during release of every batch & Submitted stability study.
3.2.P.5.4	• In batch analysis the manufacturing date mentioned on COA of one batch No. NN7233 is Jun 2017 while batch release date is October 2017, clarify the gap between manufacturing date and batch release date.	• Please Note that the batch was manufactured in the end of June 2017. Subsequently the Mother batch was released in July-2017 as per the common pharmacopoeia grades (IP/BP). • Refer enclosed COA of mother batch with common IP/BP pharmacopoeia. Then this batch was charged on the stability study in August 2017. • Later as per export requirement, we have packed and released some quantity from same mother batch as per only BP specification in October-2017. • Since we are proposing the BP grade for finished product in Pakistan registration, we have submitted the same finished product COA which was released as per BP in October-2017 as per Pakistan requirement
3.2.P.8	• Batch release date mentioned in COA of drug product is subsequent to date of initiation of stability study mentioned in stability summary sheets, clarify • The manufacturing date mentioned on COA of batch No. NN7233 is Jun 2017and batch release date is October 2017 while date of initiation of stability study is 24-08-2017, clarify?	• Naprod had manufactured and initially released batch as per common pharmacopoeia (IP/BP) & then charged for stability study to meet domestic as well as export registration requirements. • Later as per Export requirement, we have released some quantity from these batches to export market as per BP pharmacopoeia grade. Since we are proposing the BP grade for finished product in Pakistan registration, we have submitted the same finished product COA which were released subsequently.

		• Hence COA of these batches have subsequent release date, after stability initiation date.

Remarks of Evaluator: Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Previous Decision (M-324-DRB): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Response of the Firm:
Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023
"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK **B** SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.
Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt Ltd beside the below mentioned products.
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

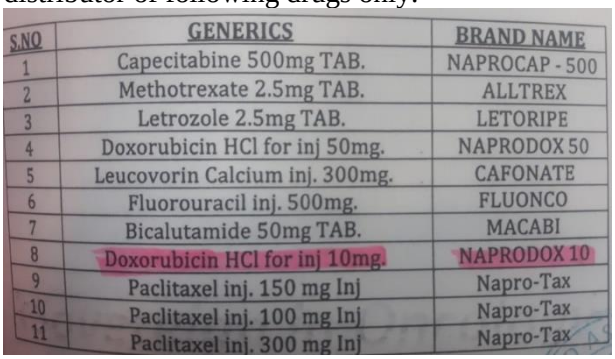
S.No	Generics	Brand Name
8.	Capecitabine 500mg TAB	NAPROCAP -500
9.	Methotrexate 2.5mg TAB	ALLTREX
10.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
11.	Leucovorin Calcium inj. 300mg	CAFONATE
12.	Fluorouracil inj. 500mg	FLUONCO
13.	Bicalutamide 50mg TAB	MACABI
14.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Previous Decision (M-336th-DRB): Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email".

Decision: Approved as per Policy for inspection of Manufacturer abroad.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid, original, legalized CoPP certificate**
ii. **Valid copy of Drug Sale License**

214.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot #81, block B, S.M.C.H.S., Karachi.
	Details of Drug Sale License of importer	**DSL No**.: 1245 **Address**: Al-Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** 1. Plot No. 10 Sector 25 KIA Karachi 2. HT-8, Landhi Industrial Area, Karachi **Validity:** 18/05/2022 **Status:** Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Thane–401506, Mahrashtra State India.
	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd., G-17/1, M.I.D.C. Tarapur, Boisar, Distt – Thane – 401506 India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No.

		COPP/CERT/KD/104901/2021/11/37012/179916 dated 16/08/2021 issued by Food and Drug Administration Mahrashtra State Mumbai India for Fluonco (Fluorouracil Injection BP 50mg (5ml, 10ml). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The CoPP is valid upto 03/04/2022. The name of importing country mentioned on annexure attached with CoPP is mentioned as Pakistan. **GMP:** Firm has submitted notarized copy of GMP certificate (No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 dated 04/04/2019 issued by Food and Drug Administration Mahrashtra Estate Mumbai India The GMP certificate is valid upto 03/04/2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of letter of authorization from M/s Naprod Life Sciences Pvt. Ltd 304, Town Centre-1, Andheri Kurla Road, Andheri (East), Mumbai, India., The letter species that the manufacturer authorizes M/s Al Habib Pharmaceuticals, Plot #81, block B, SMCHS., 74400 Karachi., Pakistan as sole agent and distributor of following drugs only. 
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5225: dated; 24-02-2022
	Details of fee submitted	PKR 150,000 ; Dated: 26-01-2022 (Deposit slip#24358311719)
	The proposed proprietary name / brand name	**Fluonco injection BP 500mg/10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Fluorouracil injection BP……. 500mg/10ml

S.NO	GENERICS	BRAND NAME
1	Capecitabine 500mg TAB.	NAPROCAP - 500
2	Methotrexate 2.5mg TAB.	ALLTREX
3	Letrozole 2.5mg TAB.	LETORIPE
4	Doxorubicin HCl for inj 50mg.	NAPRODOX 50
5	Leucovorin Calcium inj. 300mg.	CAFONATE
6	Fluorouracil inj. 500mg.	FLUONCO
7	Bicalutamide 50mg TAB.	MACABI
8	Doxorubicin HCl for inj 10mg.	NAPRODOX 10
9	Paclitaxel inj. 150 mg Inj	Napro-Tax
10	Paclitaxel inj. 100 mg Inj	Napro-Tax
11	Paclitaxel inj. 300 mg Inj	Napro-Tax

	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antimetabolites; Pyrimidine analogues WHO ATC Code: L01BC
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fluorouracil 500mg/10ml (50mg/ml) Injection by Accord Healthcare USFDA Approved
	For generic drugs (me-too status)	Flurosol Injection 500mg/10ml by M/s Pharmasol (Pvt) Ltd (Reg. No# 107202)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Nantong Jinghua Pharmaceutical Co., Ltd., No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated study is conducted at 40±2°C/75± 5%RH for 6 months and the real time stability study is conducted at 25 ± 2°C/ 60 ± 5 % RH till 48 months. (Batches: FLU2012001-RD, FLU2012002-RD, FLU2012003-RD)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product Fluorouracil Injection 50mg/ml by M/s Accord Pharmaceutical Ltd., by performing quality tests (Description, pH, Assay, particulate matter, bacterial endotoxin, test for urea, test for related substances).

	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including specificity, precision, linearity and range, accuracy for the applied product.
	Container closure system of the drug product	10ml 20mm Amber coloured Type-I vial with 20mm Grey Bromo Butyl Rubber stopper with aluminium seal
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40° C ± 2° C / 75% ± 5% RH for 06 months and real time stability study is conducted at 30° C ± 2° C / 75% ± 5% RH for 36 months. **Batches** / **Mfg date** / **Batch size** NN9308-B inverted…LT / Jul 2019 / 22828 vials NN9358-A upright….LT / Aug 2019 / 22828 vials NN9359-A inverted…..LT / Aug 2019 / 22828 vials Firm submitted accelerated stability study data at both orientation (inverted, upright)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.3	• Submit valid Certificate of Pharmaceutical Product (CoPP) and GMP certificate of the drug product Manufacturer issued by relevant regulatory authority in the country of origin	• The firm submitted that the COPP that we submitted with CTD dossier has a validity till April 2022, as it gets expire during its period in R&I that's why as per the rule it will be considered as valid as we received R&I attested letter on 24th-Februray-2022. • Firm has submitted cGMP certificate of M/s Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, Dist. Palghar–401506, Mahrashtra State India issued by Comissioner Food and Drug Administration Maharashtra state India valid upto 27-04-2025
1.3.4	• Submit copy of valid Drug Sale License (DSL) issued by relevant licensing authority	• Firm has submitted valid copy of DSL. **DSL No**.: 0230 **Address**: Al Habib Pharmaceuticals, 81-B, block B, S.M.C.H.S., Karachi. **Godown:** Plot No. 393/7 & 393/8 Sector 7-A KIA Karachi **Validity:** 18/05/2024 **Status:** Drug License by way of wholesale
1.3.5	• Submit evidence of approval of manufacturing facility / Approved Section from Licensing Authority	Firm submitted cGMP certificate in name of Naprod Life Sciences Pvt. Ltd., Plot No. G-17/1, M.I.D.C. Tarapur, Boisar, District Palghar–401506, Mahrashtra State India showing lyophilized / Powder injectable cytotoxic section
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned as per reference formulation along with submission of applicable fee	Fluorouracil injection BP 500mg/10ml (50mg/ml)
1.6.5	• Submit Name and address of API manufacturer.,	Nantong Jinghua Pharmaceutical Co., Ltd., No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China.

<table>
<tr><td>3.2.P.1</td><td>• Justify the role of Tris Buffer (tromethamine) in the applied formulation<table><tr><th>Applied product</th><th>Reference pr</th></tr><tr><td>Fluorouracil</td><td>Fluorouracil</td></tr><tr><td>Sodium Hydroxide</td><td>Sodium Hydr</td></tr><tr><td>Tris Buffer (tromethamine)</td><td>Water for inje</td></tr><tr><td>Water for injection</td><td></td></tr></table></td><td>Based on information and rationale; Tris Buffer used as buffering agent and Sodium Hydroxide as pH adjustifier along with Water for Injection. Selected excipients are very conventional and normally used in Injection manufacturing for their particular function like buffering agent and pH adjuster.</td></tr>
<tr><td>3.2.P.2</td><td>• Submit details of comparator product including name, manufacturing date, expiry date etc. against which pharmaceutical equivalence is submitted</td><td>• The firm submitted details of reference / comparator product. The details of reference product are:
Name: Fluorouracil Injection 50mg/ml; B. No: N03889, Mfg Date: 16-06-2015, Expiry Date: 15-06-2017
Manufacturer by: Accord Pharmaceutical Ltd.</td></tr>
<tr><td>3.2.P.8</td><td>• Clarification is required as submitted long term stability summery sheets of drug product conclude as: the product meets the prescribed standards of quality after completion of 18 months long term stability study as per stability indicating specifications, while stability study data upto 36 months is submitted.
• The submitted long term stability summary sheets include both the conditions 40° C ± 2° C / 75% ± 5% RH and 30° C ± 2° C / 75% ± 5%, clarify?</td><td>• The firm submitted that 36 months stability data submitted but the proposed shelf life mentioned in Stability summary sheet is 24 months. (Stability summary sheet attached)

• In the sheet three conditions and temperature are mentioned but the long term and only 30°C ± 2°C and 75% ± 5%RH is marked (✓) which clearly shows the long term stability conducted on 30°C ± 2°C and 75% ± 5%RH (Sheet attach for clarification)</td></tr>
</table>

Remarks of Evaluator: Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Previous Decision (M-324th-DRB): Deferred for the Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Response of the Firm:

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK **B** SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.

Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt Ltd beside the below mentioned products.

We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
1.	Capecitabine 500mg TAB	NAPROCAP -500
2.	Methotrexate 2.5mg TAB	ALLTREX
3.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
4.	Leucovorin Calcium inj. 300mg	CAFONATE
5.	Fluorouracil inj. 500mg	FLUONCO
6.	Bicalutamide 50mg TAB	MACABI
7.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Previous Decision (M-336th-DRB): Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email".
Decision: Approved as per Policy for inspection of Manufacturer abroad. **Registration Board further decided that Registration letter will be issued after submission of following:** **i. Valid, original, legalized CoPP certificate** **ii. Valid copy of Drug Sale License**

215.	**Name, address of Applicant / Importer**	**M/s Al Habib Pharmaceuticals**
	Details of Drug Sale License of importer	**License No:** 0230 **Address:** 81-B Block B, S.M.C.H.S., Karachi **Address of Godown:** 393/7,393/8 Sector 7-A KIA Karachi **Validity:** 19/05/2022 till 18/05/2024 **Status:** License to sell drugs as distributor **Renewal:** Valid
	Name and address of marketing authorization holder (abroad)	Naprod Life Sciences Pvt. Ltd. Plot no. G-17/1,MIDC,Tarapur,Boisar,Thane 401506 Maharashtra State, India
	Name, address of manufacturer(s)	Naprod Life Sciences Pvt. Ltd. Plot no. G-17/1,MIDC,Tarapur,Boisar,Thane 401506 Maharashtra State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COPP/CERT/KD/104901/2021/11/1799901) dated 16 August, 2021 (valid till 03-April,2022) issued by Food & Drug Administration Maharashtra State, Mumbai for Macabi (Bicalutamide Tablets USP 50mg). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. Certificate of renewal of Licence to Manufacture of M/s. NAPROD LIFE SCIENCES PVT. LTD valid from 01-01-2017 to 31-12-2021. Certificate of Good Manufacturing Practices of M/s. Naprod Life Sciences Pvt. Ltd. Maharashtra State, India certificate no. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 DATED 04-April,2019 valid till 03-April,2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Authorization from M/s. Naprod Life Sciences Pvt. Ltd. authorize to M/s. Al Habib Pharmaceuticals, Karachi as a sole agent and distributor of Macabi (Bicalutamide) Tablet 50mg.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import

		☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5227 dated 24-02-2022
	Details of fee submitted	PKR 150,000/-: dated 26-01-2022
	The proposed proprietary name / brand name	**MACABI Tablets 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Bicalutamide……50mg ATC Code L02BB03
	Pharmaceutical form of applied drug	1 × 10's in Alu-Alu Blister
	Pharmacotherapeutic Group of (API)	ATC Code L02BB03 (Anti Androgens)
	Reference to Finished product specifications	USP
	Proposed Pack size	As per policy
	Proposed unit price	As per policy
	The status in reference regulatory authorities	USFDA (Casodex 50mg Tablet)
	For generic drugs (me-too status)	Casodex 50mg Tablet of M/s. ICI Pakistan Ltd., Hattar (Reg.no. 027380)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Mac Chem Products (India) Pvt. Ltd. N-211/2/10.Tarapur MIDC,Biosar,District Thane, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30°C ± 2°C,60%±5% RH (60 months) and accelerated time stability study conducted at 40°C±2°C,75%±5% RH (6 months) of following batches: BCL0211001,BCL0211002,BCL0211003
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or

		materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has established against the innovator product casodex 50mg Tablet (M/s. AstraZeneca Pvt. Ltd.) Batch no. 60022647. Comparative dissolution has performed in all three recommended physiological medium against the innovator brand.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu foil & PVC film coated with PVDC Blister foil.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of 10,000 tablets batch size. The accelerated stability study is conducted at 40°C/75%RH and data of 6 months has submitted. The real time stability study is conducted at 30°C±2°C/75%±5%RH. The real time stability study data of 24 months has been submitted. Batch no. NT1160,NT1161,NT1162

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Drug substance Bicalutamide is a racemate mixture, please provide the detail along with quantitative results, that which enantiomeric form of API has been used in the manufacturing of drug product.	Bicalutamide is racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.as single enantiomeric form is not used, enantiomeric purity is not applicable. *CASODEX is a racemate with its antiandrogenic activity being almost exclusively exhibited by the R-enantiomer of bicalutamide; the S-enantiomer is essentially inactive.*
2.	Justify for keeping the water content limit NMT 7.0% comparing the water content of active ingredient NMT 0.2%.	Firm replied that our product complies with the current USP monograph of bicalutamide tablet 50mg ,drug product monograph in USP does not contain water content test ,hence the limit of water content was given in-house based on the water content of API ,excipients and manufacturing process.
3.	justify, for submitting the validation report of 150mg strength instead of applied 50mg strength.	Submitted

Registration Board was apprised regarding an e. mail received to Director PE&R Division from M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Decision of 324th meeting of Registration Board:

Deferred for following:

- Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.
- Scientific justification regarding declaration of Bicalutamide as racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.

Response of the Firm:

- **Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.**

Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, as a sole agent and distribution of following drugs only. Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs.

S.No	Generics	Brand Name
15.	Capecitabine 500mg TAB	NAPROCAP -500
16.	Methotrexate 2.5mg TAB	ALLTREX
17.	Doxorubicin HCl for inj 50mg	NAPRODOX 50
18.	Leucovorin Calcium inj. 300mg	CAFONATE
19.	Fluorouracil inj. 500mg	FLUONCO
20.	Bicalutamide 50mg TAB	MACABI
21.	Doxorubicin HCl for inj 10mg	NAPRODOX 10

- **Scientific justification regarding declaration of Bicalutamide as racemic mixture i.e. a mixture of equal quantities (50:50) of two enantiomers.**

Firm replied that drug substance is a racemic mixture of S-enantioner and R-enantiomer in a ratio of 50:50, as the review literature of innovator product also claimed that the drug substance is racemic mixture of both enantiomers.

Previous Decision (M-336th-DRB): Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through email.

Decision: Approved as per Policy for inspection of Manufacturer abroad.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid, original, legalized CoPP certificate**
ii. **Valid copy of Drug Sale License**

216.	Name, address of Applicant / Importer	M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.
	Details of Drug Sale License of importer	DSL No.: 1245 Address: M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.. Godown: Plot No. 10 Sector 25, K I A Karachi HT-8, Landhi Industrial Area, Karachi. Validity: 18/05/2022 Status: Drug License by way of wholesale
	Name and address of marketing authorization holder (abroad)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name, address of manufacturer(s)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Original legalized CoPP (certificate No. CoPP/CERT/KD/83894/2019/11/27844/143353) valid till 03-04-2022 issued by Food and Drug Administration Mahrashtra Estate Mumbai for Methotrexate Tablets 2.5mg . The CoPP confirms free sale status of the

		product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. GMP: Firm has submitted GMP certificate No. NEW-WHO-GMP/CERT/KD/80691/2019/11/27530 issued by Food and Drug Administration Mahrashtra Estate Mumbai. Valid till 03.04.2022
	Details of letter of authorization / sole agency agreement	Firm has submitted Original Authorization letter from Naprod Life Sciences Pvt. Ltd. The letter species that the manufacturer appoints M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi as a sole agent and distributor to register their products in Pakistan .
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 5224: 24-02-2022
	Details of fee submitted	PKR 150,000/-: 26-01-2022
	The proposed proprietary name / brand name	ALLTREX (Methotrexate) 2.5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Methotrexate ……. 2.5 mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Anti-Metabolite (L04AX03)
	Reference to Finished product specifications	BP
	Proposed Pack size	As per Policy
	Proposed unit price	As per Policy
	The status in reference regulatory authorities	Methotrexate Orion 2.5 mg tablets by Orion Pharma UK MHRA approved
	For generic drugs (me-too status)	Methotrexate Tablet 2.5mg by Werrick Pharmaceuticals (025084)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Mac Chem Products (India) Pvt. Ltd. N-211/2/10. MIDC, Boisar Thane 401506 MAHARASHTRA state India. GMP: Firm has submitted GMP certificate No. NEW-WHO-GMP/CERT/KD/74238/2018/11/24897 by Food and Drug Administration Mahrashtra Estate Mumbai. Valid till 10.09.2021
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: MTX0213042, MTX0213043, MTX0213044,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against the reference product (Methotrexate Tabs 2.5mg Mfg. By Orion Pharma, UK). Quality parameters such as Disintegration time, hardness, dissolution, average weight, thickness etc were compared. Firm has submitted Comparative Dissolution Profile for the applied product as follows Test Product Naprod Methotrexate tablet 2.5mg Reference product Orion methotrexate tablet 2.5mg Medium Water,Acid media (pH 1.0-1.2) in Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). On the basis of similarity factor (f2) result i.e NLT 50 of dissolution profile of API in test product and reference product, both products are similar.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu-Alu Blister

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches 24 months real time stability data at 30°C ± 2°C / 75% ± 5%RH of 03 batches 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches NT8132. NT8133, NT8134

Remarks of AD (PECXX):
USFDA approved Box warning for methotrexate tablet is as follows:

METHOTREXATE tablets, for oral use
Initial U.S. Approval: 1953

WARNING: EMBRYO-FETAL TOXICITY, HYPERSENSITIVITY REACTIONS, and SEVERE ADVERSE REACTIONS

See full prescribing information for complete boxed warning.

- **Methotrexate Tablets can cause embryo-fetal toxicity, including fetal death. For non-neoplastic diseases, Methotrexate Tablets are contraindicated in pregnancy. For neoplastic diseases, advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception. (4, 5.1, 8.1, 8.3)**
- **Methotrexate Tablets are contraindicated in patients with a history of severe hypersensitivity reactions to methotrexate, including anaphylaxis. (4, 5.2)**
- **Serious adverse reactions, including death, have been reported with methotrexate. Closely monitor for adverse reactions of the bone marrow, gastrointestinal tract, liver, lungs, skin, and kidneys. Withhold or discontinue Methotrexate Tablets as appropriate. (5.3, 5.4, 5.5, 5.6, 5.7, 5.8)**

Sr.#	Observation	Reply	Remarks
1.	RRA approved formulations are Methotrexate sodium/disodium (eq to Methotrexate) while applied product is in base form. Clarify it or provide reference regarding applied formulation (base form) in any reference country.	Relevant reference is provided by the firm as follows: MHRA approved product Methotrexate tablet 2.5mg by Sandoz Ltd	Verified MHRA approved product Methotrexate tablet 2.5mg by Sandoz Ltd is also approved in base form. Each tablet contains methotrexate 2.5 mg
2.	Compatibility of the Drug Substance(s) with excipients (Sodium Lauryl Sulphate, sodium starch glycolate, colloidal silicon dioxide) is not provided	Excipients used in formulation do not influence physicochemical property of Drug product and are routinely used in pharmaceutical industry	Sodium starch glycolate is found in RRA (MHRA) approved formulation By Cipla (EU) Limited However Compatibility of the Drug Substance(s) with Sodium Lauryl Sulphate and colloidal silicon dioxide is required.
	Registration Board was apprised regarding an e. mail received to Director PE&R Division form M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.		

Decision 324th meeting: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Updated status:
Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023 wherein it has been mentioned that:
"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.
Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products.
We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs."

S. No	Generics	Brand Name
	Capecitabine 500mg TAB	NAPROCAP -500
	Methotrexate 2.5mg TAB	ALLTREX
	Doxorubicin HCl for inj 50mg	NAPRODOX 50
	Leucovorin Calcium inj. 300mg	CAFONATE
	Fluorouracil inj. 500mg	FLUONCO
	Bicalutamide 50mg TAB	MACABI
	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Previous Decision (M-336th –DRB): Deferred for following requirements:

- Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through e-mail.
- Compatibility of the Drug Substance(s) with excipients such as Sodium Lauryl Sulphate and colloidal silicon dioxide.

Decision: Approved as per Policy for inspection of Manufacturer abroad.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Valid, original, legalized CoPP certificate**
ii. **Valid copy of Drug Sale License**
iii. **Compatibility of the Drug Substance(s) with excipients such as Sodium Lauryl Sulphate and colloidal silicon dioxide**

Case No. 06; Deferred Registration applications of Human Drugs on Form 5

217.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 10/40mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…10mg Telmisartan…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41200 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 10mg/40mg (USFDA Approved)
	Me-too-status	Amtas 10mg + 40mg Tablet of M/s Sami Pharmaceuticals (Reg. # 066945)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Previous Decision (M-296th-DRB)	• Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.
	Firms Response	• Firms has submitted routine inspection report dated 15-02-2024 by area FID in which Bi-layered tablets compression and Co-blistering facility is verified in general tablet section
	Decision: Approved.	
218.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 5/80mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..5mg Telmisartan……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41202 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 5mg/80mg (USFDA Approved)
	Me-too-status	Telmipin 5mg + 80mg Tablet of M/s Schazoo Zaka (Reg. # 0090511)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Previous Decision (M-296th-DRB)	• Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.
	Firms Response	• Firms has submitted routine inspection report dated 15-02-2024 by area FID in which Bi-layered tablets compression and Co-blistering facility is verified in general tablet section

	Decision: Approved.	
219.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 5/40mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..5mg Telmisartan…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41201 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 5mg/40mg (USFDA Approved)
	Me-too-status	Telmipin 5mg + 40mg Tablet of M/s Schazoo Zaka (Reg. # 0090514)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 and undertaking is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Previous Decision (M-296th-DRB)	• Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.
	Firms Response	• Firms has submitted routine inspection report dated 15-02-2024 by area FID in which Bi-layered tablets compression and Co-blistering facility is verified in general tablet section
	Decision: Approved.	
220.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart AM Tablet 10/80mg
	Composition	Each bilayered tablet contains: Amlodipine Besylate eq to Amlodipine…..10mg Telmisartan…..80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41199 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA Tablets 10mg/80mg (USFDA Approved)
	Me-too-status	Telmipin 10mg + 80mg Tablet of M/s Schazoo Zaka (Reg. # 0090512)

	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• 1st page of form 5 is missing. Submit complete form 5. • Evidence of availability of bilayered compression tablet facility • Master formulation is missing
	Previous Decision (M-296th-DRB)	• Deferred for confirmation of installation and operational qualification of bilayered compression machine by the area FID.
	Firms Response	• Firms has submitted routine inspection report dated 15-02-2024 by area FID in which Bi-layered tablets compression and Co-blistering facility is verified in general tablet section
	Decision: Approved.	

Agenda of Mr. Shahid Nawaz

Case 01: Registration applications Locally manufactured (Human) drugs Routine cases on Form 5F.

221.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to 149, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145 to 149, North Western Industrial Zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 12907 dated 25-05-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 5273402807 dated 28-04-2023.
	The proposed proprietary name / brand name	**Brivact 10mg/ml Oral Solution.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Brivaracetam …… 10mg
	Pharmacotherapeutic Group of (API)	Antiepileptic. ATC code N03AX23
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	BRIVIACT® (Brivaracetam) 10mg/ml oral solution, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	As per PRC.
	Proposed unit price	As per PRC.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm

1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-1698616/DD/DCA/VSP/2024 dated 21-05-2024 issued by DCA, Andhra Pradesh, India. Certificate is valid for one year.
2.	3.2.P.2.2.1	Details of the innovator product shall be submitted against which the PE studies are performed.	Firm has submitted pictorial evidence of the innovator product Briviact 10mg/ml oral solution, B. No. 299738 manufactured by UCB Pharma Limited.

Decision: Approved.

222.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9205 dated 05-04-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 434775895 dated 21-02-2023.
	The proposed proprietary name / brand name	**Caripride 1.5mg Capsule.**
	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)	Antipsychotic. ATC code N05AX15.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	VRAYLAR® (Cariprazine) 1.5 capsules, USFDA approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 14's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-1628564/DD/DCA/VSP/2023 dated 07-08-2023 issued by DCA Visakhapatnam Andhra Pradesh, India. Certificate is valid for one year.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.

4.	3.2.S.4.4	Chloride content test is not performed by the drug product manufacturer. Clarification shall be submitted.	Firm has submitted that chloride test was conducted on the drug substance, but it was mistakenly not included in the raw material report. They now included the chloride test in the method of analysis and report.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated in the stability portion.

Decision: Approved.

223.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9206 dated 05-04-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 88336208 dated 21-02-2023.
	The proposed proprietary name / brand name	**Caripride 3mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cariprazine HCl eq. to Cariprazine …… 3mg
	Pharmacotherapeutic Group of (API)	Antipsychotic. ATC code N05AX15.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	VRAYLAR® (Cariprazine) 3mg capsules, USFDA approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 14's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-1628564/DD/DCA/VSP/2023 dated 07-08-2023 issued by DCA Visakhapatnam Andhra Pradesh, India. Certificate is valid for one year.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.

3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Chloride content test is not performed by the drug product manufacturer. Clarification shall be submitted.	Firm has submitted that chloride test was conducted on the drug substance, but it was mistakenly not included in the raw material report. They now included the chloride test in the method of analysis and report.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated in the stability portion.

Decision: Approved.

224.		
	Name, address of Applicant / Marketing Authorization Holder	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9202 dated 05-04-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 1805019704 dated 21-02-2023.
	The proposed proprietary name / brand name	**Caripride 4.5mg Capsule.**
	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)	Antipsychotic. ATC code N05AX15.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	VRAYLAR® (Cariprazine) 4.5mg capsules, USFDA approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 14's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-1628564/DD/DCA/VSP/2023 dated 07-08-2023 issued by DCA Visakhapatnam Andhra Pradesh, India. Certificate is valid for one year.

2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Chloride content test is not performed by the drug product manufacturer. Clarification shall be submitted.	Firm has submitted that chloride test was conducted on the drug substance, but it was mistakenly not included in the raw material report. They now included the chloride test in the method of analysis and report.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated in the stability portion.

Decision: Approved.

225.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9208 dated 05-04-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 50650351 dated 21-02-2023.
	The proposed proprietary name / brand name	**Caripride 6mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cariprazine HCl eq. to Cariprazine …… 6mg
	Pharmacotherapeutic Group of (API)	Antipsychotic. ATC code N05AX15.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	VRAYLAR® (Cariprazine) 6mg capsules, USFDA approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 14's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-1628564/DD/DCA/VSP/2023 dated 07-08-2023 issued by DCA Visakhapatnam Andhra Pradesh, India.

			Certificate is valid for one year.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Chloride content test is not performed by the drug product manufacturer. Clarification shall be submitted.	Firm has submitted that chloride test was conducted on the drug substance, but it was mistakenly not included in the raw material report. They now included the chloride test in the method of analysis and report.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number, batch size and date of initiation shall be submitted.	Submitted and updated in the stability portion.

Decision: Approved.

226.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7690 dated 17-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 16729860 dated 13-03-2023.
	The proposed proprietary name / brand name	**Zavibac 2.5gm injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime….2gm Avibactam Sodium eq. to Avibactam…….. 0.5gm
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotics.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion, MHRA approved.
	For generic drugs (me-too status)	Zavicefta 2.5gm injection, Pfizer Pakistan, Reg. No. 106848.
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**
1.	1.3.4	Valid copy of GMP certificate of the drug product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. F.11-6/24-DRAP-302 dated 10-05-2024 issued on the basis of inspection conducted on 03-05-2024.

2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	Copy of GMP certificate No. GD20180909 dated 06-12-2018 issued by CFDA valid till 05-12-2023 is submitted by the firm. Firm has also submitted copy of DML No. Yue20160262 valid till 28-10-2025.
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
4.	3.2.P.1	Description of accompanying reconstitution diluent shall be submitted.	The powder Vial reconstituted with 10ml of water for injection (WFI) and the resulting concentrate must then be immediately diluted prior to use. The reconstituted solution is a Colorless to yellowish or greenish yellowish solution visually free from foreign particles.
5.	3.2.P.8.3	• Stability data sheets with inclusion of API lot number and batch size as per decision of registration Board in its 293 shall be submitted. • Six moth stability studies for all the three batches at both real time and accelerated condition shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted and updated in the stability portion. Submitted. N/A.

Decision: Approved.

227.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 14527 dated 09-06-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 952973757 dated 29-05-2023.
	The proposed proprietary name / brand name	**Rosca V 10/80mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 10mg Valsartan ……... 80mg
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents in combination with other drugs. (C10BX10)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Valsaros 10 mg/80 mg Film-Coated Tablets, CIMA Spain approved.

	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's & 100's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.4.3	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 41/2023-DRAP (K) dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023.
2.	1.6.5	Valid copy of GMP certificates of both the drug substances issued by concerned/relevant authority shall be submitted.	Rosuvastatin: Firm has submitted copy of DML No. Yue20160622 issued by Guangdong FDA, China valid till 07-10-2026. Valsartan: Firm has submitted copy of DML No. Zhe20000311 issued by Zhejiang Provincial Drug Administration valid till 12-01-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that they have mentioned the limit of water content NMT 6% and the same was mentioned in supplier COA. Furthermore, the same limit is also present in USP monograph. However, in the initially submitted documents water content of less than or equal to 3.5% was mentioned.
4.	3.2.S.4.2	Assay test provided by the drug substance manufacturer for Valsartan is different from USP. Clarification shall be submitted.	Firm has submitted that supplier has revised its method and its validated. They also attached the updated method.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted pictures of innovator product i.e. Valsaros, B. No. S72724 manufactured by KRKA.
6.	3.2.P.8	Stability summary data sheets have mentioned API lot No. 1081 for Rosuvastatin while 3.2.S.4.4 has mentioned 1082. Clarification shall be submitted.	Firm has submitted that it was typographical mistake and stability summary sheets with API lot No. 1082 are submitted by the firm.

Decision: Approved.
Firm will submit 7500/- fee for typo error as per decision of the Registration Board.

228.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16132 dated 26-06-2023.

	Details of fee submitted	Rs.75,000/- vide slip No. 948516395 dated 08-06-2023.
	The proposed proprietary name / brand name	**Rosca V 10/160mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 10mg Valsartan ……... 160mg
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents in combination with other drugs. (C10BX10)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Valsaros 10 mg/160 mg Film-Coated Tablets, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's & 100's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.4.3	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 41/2023-DRAP (K) dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023.
2.	1.6.5	Valid copy of GMP certificates of both the drug substances issued by concerned/relevant authority shall be submitted.	Rosuvastatin: Firm has submitted copy of DML No. Yue20160622 issued by Guangdong FDA, China valid till 07-10-2026. Valsartan: Firm has submitted copy of DML No. Zhe20000311 issued by Zhejiang Provincial Drug Administration valid till 12-01-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that they have mentioned the limit of water content NMT 6% and the same was mentioned in supplier COA. Furthermore, the same limit is also present in USP monograph. *However, in the initially submitted documents water content of less than or equal to 3.5% was mentioned.*
4.	3.2.S.4.2	Assay test provided by the drug substance manufacturer for Valsartan is different from USP. Clarification shall be submitted.	Firm has submitted that supplier has revised its method and its validated. They also attached the updated method.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted pictures of innovator product i.e. Valsaros, B. No. V45675 manufactured by KRKA.

Decision: Approved.

229.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**

	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 14528 dated 09-06-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 1670846540 dated 29-05-2023.
	The proposed proprietary name / brand name	**Rosca V 20/80mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 20mg Valsartan …….... 80mg
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents in combination with other drugs. (C10BX10)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Valsaros 20 mg/80 mg Film-Coated Tablets, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's & 100's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.4.3	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 41/2023-DRAP (K) dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023.
2.	1.6.5	Valid copy of GMP certificates of both the drug substances issued by concerned/relevant authority shall be submitted.	Rosuvastatin: Firm has submitted copy of DML No. Yue20160622 issued by Guangdong FDA, China valid till 07-10-2026. Valsartan: Firm has submitted copy of DML No. Zhe20000311 issued by Zhejiang Provincial Drug Administration valid till 12-01-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that they have mentioned the limit of water content NMT 6% and the same was mentioned in supplier COA. Furthermore, the same limit is also present in USP monograph. However, in the initially submitted documents water content of less than or equal to 3.5% was mentioned.

4.	3.2.S.4.2	Assay test provided by the drug substance manufacturer for Valsartan is different from USP. Clarification shall be submitted.	Firm has submitted that supplier has revised its method and its validated. They also attached the updated method.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted pictures of innovator product i.e. Valsaros, B. No. T57425 manufactured by KRKA.
6.	3.2.P.8	Stability summary data sheets have mentioned API lot No. 1081 for Rosuvastatin while 3.2.S.4.4 has mentioned 1082. Clarification shall be submitted.	Firm has submitted that it was typographical mistake and stability summary sheets with API lot No. 1082 are submitted by the firm.

Decision: Approved.
Firm will submit 7500/- fee for typo error as per decision of the Registration Board.

230.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16131 dated 26-06-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 53502402 dated 08-06-2023.
	The proposed proprietary name / brand name	**Rosca V 20/160mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 20mg Valsartan ……... 160mg
	Pharmacotherapeutic Group of (API)	Lipid Modifying Agents in combination with other drugs. (C10BX10)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Valsaros 20 mg/160 mg Film-Coated Tablets, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's & 100's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.4.3	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 41/2023-DRAP (K) dated 13-06-2023 issued on the basis of inspection conducted on 06-06-2023.
2.	1.6.5	Valid copy of GMP certificates of both the drug substances issued by	Rosuvastatin:

		concerned/relevant authority shall be submitted.	Firm has submitted copy of DML No. Yue20160622 issued by Guangdong FDA, China valid till 07-10-2026. Valsartan: Firm has submitted copy of DML No. Zhe20000311 issued by Zhejiang Provincial Drug Administration valid till 12-01-2025.
3.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer for rosuvastatin has mentioned water content of less or equal to 3.5% while that of the drug product manufacturer has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted that they have mentioned the limit of water content NMT 6% and the same was mentioned in supplier COA. Furthermore, the same limit is also present in USP monograph. *However, in the initially submitted documents water content of less than or equal to 3.5% was mentioned.*
4.	3.2.S.4.2	Assay test provided by the drug substance manufacturer for Valsartan is different from USP. Clarification shall be submitted.	Firm has submitted that supplier has revised its method and its validated. They also attached the updated method.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted pictures of innovator product i.e. Valsaros, B. No. Y52638 manufactured by KRKA.

Decision: Approved.

231.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma (Pvt.) Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur.**
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3-Km, Head Balloki Road, Phool Nagar, Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 6542 dated 08-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7017924605 dated 04-01-2023.
	The proposed proprietary name / brand name	**Askprol Women Tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol …… 500mg. Hyoscine Butyl bromide ……. 10mg.
	Pharmacotherapeutic Group of (API)	NSAIDs/Antispasmodic.
	Reference to Finished product specifications	In-house Specifications.
	The status in reference regulatory authorities	Buscopan Plus Tablets approved by Germany.
	For generic drugs (me-too status)	Buscopan Plus Tablets, Martin Dow, Reg. No. 008358.
	Proposed Pack size	10 x 10's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.	
2.	1.5.9	Provide evidence of approval of applied formulation i.e. uncoated tablets in reference regulatory authorities as decided by the Registration Board in its 275th meeting.	
3.	1.6.5	Valid copy of GMP certificate for both the drug substances issued by concerned/relevant authority shall be submitted.	
4.	3.2.S.4.1	Specifications of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.2	Analytical procedures of both the drug substances i.e. paracetamol & Hyoscine from drug substance manufacturer shall be submitted.	
6.	3.2.S.4.3	Verification studies of both the drug substances i.e. paracetamol & Hyoscine performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.4.4	COA of both the drug substances i.e. paracetamol & Hyoscine with same batch number from both the drug substance and drug product manufacturer.	
8.	3.2.P.5.1	This section has mentioned In-house specifications, however, each separate test has mentioned BP specifications. Clarification shall be submitted.	
9.	3.2.P.5.2	Analytical procedures of the drug product shall be submitted.	
10.	3.2.P.8.3	• Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. • Raw data sheets for calculation of assay and dissolution shall be submitted for both real time and accelerated at each interval. • Chromatograms for each time with values of resolution, theoretical plates & tailing factor shall be submitted. • Submitted chromatograms has revealed retention time for both the substances as of 1.01 and 1.426 while the actual value on the scale is of 0.2 and 0.6. clarification shall be submitted. • Justification shall be submitted for two extra peaks other than the peaks of interest in chromatograms. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.	

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

232.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Ltd., F-216, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	**M/s Macter International Ltd.,** F-216, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7091 dated 10-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 081730065862 dated 30-08-2022.
	The proposed proprietary name / brand name	**Tamlomac 0.4mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tamsulosin hydrochloride as modified release pellets ……..……..0.4mg
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists. ATC code G04CA02
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	FLOMAX® (Tamsulosin hydrochloride, USP) Capsules, USFDA approved.
	For generic drugs (me-too status)	Sintam 0.4mg Capsule, Hilton Pharma, Reg. No. 061842.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.	
2.	1.5.6	Pharmacopoeial reference / Status of applied formulation shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate for the drug substance manufacturer shall be submitted.	
4.	2.3	Table for literature references shall be submitted.	
5.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
6.	3.2.S.4.2	Analytical procedures of the drug substances from drug product manufacturer shall be submitted.	
7.	3.2.S.4.3	Verification studies of the drug substances from drug product manufacturer shall be submitted.	
8.	3.2.S.4.4	COA of the drug substances i.e. with same batch number from both the drug substance and drug product manufacturer.	
9.	3.2.P.8.3	• Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. • Documents for the procurement of API shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

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

233.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7697 dated 17-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 30810134648 dated 27-01-2023.
	The proposed proprietary name / brand name	**Thiofold 4mg/2ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Thiocolchicoside …… 4mg
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	ANSM France approved.
	For generic drugs (me-too status)	Chicowin 4mg/2ml Injection, Wnsfield Pharmaceuticals, Reg. No. 093890.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	Analytical record submitted has shown run time of 6 minutes and retention time of 3 minutes while analytical procedure for assay and potential impurities has mentioned approximate retention time of 15.4 minutes. Clarification shall be submitted.	
7.	3.2.S.7.3	Complete real time stability data as per Zone Iva shall be submitted.	
8.	3.2.P.2.2.1	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE & CDP studies against the innovator product.	
9.	3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	
10.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.	
11.		Batch No. L-01 & L-03 at 0-month time point has volume variation test out of specification. Limit is 1.8 to 2.2 while the results are 2.3ml. clarification shall be submitted.	
12.	3.2.P.8.3	• Chromatograms does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.	

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

234.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7698 dated 17-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 8064730870 dated 27-01-2023.
	The proposed proprietary name / brand name	**Thiofold 4mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Thiocolchicoside …… 4mg
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	ANSM France approved.
	For generic drugs (me-too status)	Wodlink 4mg tablets, Martin Dow, Reg. No. 081138.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	• Specifications provided by the drug substance manufacturer for drug substance has mentioned assay limit of 98.0% - 102% while COA provided by the drug substance manufacturer for drug substance has mentioned NLT 95%. Clarification shall be submitted. • Value of sulphated Ash in specification is NMT 0.1% while COA has mentioned NMT 0.2%. Clarification shall be submitted.	
7.	3.2.S.7.3	Stability data sheets for the drug substance are from Sarv Biolabs while the drug substance manufacturer in all the three modules is M/s India Glycols. Clarification shall be submitted.	
8.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	
9.	3.2.P.2.2.1	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE & CDP studies against the innovator product.	

10.	3.2.P.8.3	• Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.	

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

235.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 13519 dated 31-05-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 1618481557 dated 08-02-2023.
	The proposed proprietary name / brand name	**Dewa 40mg injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Drotaverine HCl …… 40mg
	Pharmacotherapeutic Group of (API)	Papaverine and derivatives. (A03AD)
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	NO- SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) & NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) Approved in 3 European countries (Hungary, Minutes of 330th meeting of Registration Board (24th to 26th July, 2023) 90 Romania, Bulgaria)
	For generic drugs (me-too status)	Hi-Spa 40mg injection, Helix pharma, Reg. No. 073604.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	

3.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	• Justification shall be submitted regarding the results of pH test (5.1) in the submitted COA by the drug product manufacturer while the limit for pH test is 3.5 – 5.0. • Most of the specifications submitted in the COA by drug product manufacturer are different than the specifications submitted by drug substance manufacturer i.e. Assay test, loss on drying, sulphated Ash etc. Justification shall be submitted. • Justification shall be submitted regarding HPLC chromatograms with respect to the analytical procedure.	
7.	3.2.P.5.3	Analytical method submitted has mentioned UV method for analysis while the analytical method verification studies provided are for HPLC method. Clarification shall be submitted.	
8.	3.2.P.7	Details of the container for finished product shall be submitted.	
9.	3.2.P.8.3	• Justify the submitted chromatograms with respect to the analytical procedures submitted in 3.2.P.5.2. • Also justify the raw data submitted with respect to analytical procedure submitted in 3.2.P.5.2.	

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

236.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 10000 dated 13-04-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7033546224 dated 07-03-2023.
	The proposed proprietary name / brand name	**Cefzect 2.5gm injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftazidime as pentahydrate ……. 2000mg Avibactam as Sodium salt …….. 500mg
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotics.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion, MHRA approved.
	For generic drugs (me-too status)	Zavicefta 2.5gm injection, Pfizer Pakistan, Reg. No. 106848.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	• Justification shall be submitted for not performing most of the test as recommended by the drug substance manufacturer such as pyridine content, visible particles & related substances. • Justification shall be submitted for assay limits as drug substance has mentioned NLT 68.5% of Ceftazidime and NLT 17.1% of Avibactam while drug product manufacturer has mentioned 90% 110% for both the substances.	
7.	3.2.S.7.3	Real time stability studies data is only for 6 months. Provide real time stability data for the drug substance till claimed shelf life.	
8.	3.2.P.1	Description of accompanying reconstitution diluent shall be submitted.	
9.	3.2.P.2.2.1	Justification shall be submitted for not performing most of the tests in PE studies such as sterility, BET and content uniformity etc. as recommended by the innovator product.	
10.	3.2.P.8.3	• Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Stability data sheets have mentioned that for both physical and chemical testing, 252 injections are required while total batch size of the trial batches is 200 vials each. Clarification shall be submitted. • Justification shall be submitted for run time of the submitted chromatograms (6 minutes) while the analytical procedures have mentioned 10 minutes run time. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay as per calculation formula shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Firm has submitted their reply that the same data has already been approved in 330th meeting of the Registration Board where it was applied under contract manufacturing by M/s Welmark pharmaceuticals, Hattar.
Firm has also submitted copy of the minutes of 330th meeting of the Registration Board.

Decision: Approved.

237.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 13765 dated 02-06-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 519422242 dated 08-05-2023.
	The proposed proprietary name / brand name	**Tear Actual (Sterile ophthalmic solution).**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dextran 70 ……1mg Hypromellose …… 3mg
	Pharmacotherapeutic Group of (API)	Pharmaceutical Aid (Non-toxic, Nonirritant.)
	Reference to Finished product specifications	Manufacturer Specifications.
	The status in reference regulatory authorities	Could not be confirmed.
	For generic drugs (me-too status)	Ashk eye drops, M/s Ray pharma, Reg. No. 076593.
	Proposed Pack size	15ml.
	Proposed unit price	Rs: 325.50.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.5	Reference to the submitted Pharmacotherapeutic group shall be submitted.	
2.	1.5.9	RRA for the applied formulation in reference regulatory authorities shall be submitted as the submitted one could not be verified and is discontinued.	
3.	1.6.5	Valid copies of GMP certificate of both the drug substance manufacturer issued by relevant/concerned regulatory authorities shall be submitted.	
4.	2.3	• Table for literature references has mentioned that drug product is available in USP, BP etc. while 1.5.6 has mentioned manufacturer specification. Clarification shall be submitted.	
5.	3.2.S.2 & 3.2.S.3	Detailed information of these sections for both the drug substances shall be submitted.	
6.	3.2.S.4.2	• Analytical procedures of the drug substance Dextran from both the drug substance and drug product manufacturer shall be submitted. • Analytical procedure submitted for HPMC by both drug substance manufacturer and drug product manufacturer are different than USP monograph for assay test. USP monograph has HPLC method while drug substance and product manufacturer has applied UV method. Clarification shall be submitted.	
7.	3.2.S.4.3	• Analytical method verification of both the drug substance performed by the drug product manufacturer shall be submitted.	
8.	3.2.S.4.4	• COA of both the drug substances from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of both the drug substance shall be submitted.	
9.	3.2.P.2.2	• Justification shall be submitted for conducting only pH and appearance test in pharmaceutical equivalence studies.	

		• Pictorial evidence of the innovator product shall be submitted.	
10.	3.2.P.5.1	Justification shall be submitted for assay limits of 80% to 120% for HPMC.	
11.	3.2.P.5.2	Justification shall be submitted for using UV method for the analysis of drug product.	
12.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.	
13.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the values of absorbance of UV spectrophotometric reported above "1", in Assay analysis of Dextran in submitted raw data sheets. • Justify the calculation formula applied for Assay analysis of Dextran against the standard and sample preparation methods submitted in Drug product analytical procedure. • Justify the performance of Assay analysis of drug substance by UV spectrophotometric method. • Justification shall be submitted for use of 65% ± 5% RH in real time stability studies of the applied formulation. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Justification shall be submitted for over writing the procurement documents with fake attestation of DRAP. • Documents for procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

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

238.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Dy. No. and date of submission	Dy. No. 8798 dated 30-03-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 7896314072 Dated 15-03-2023.
	The proposed proprietary name / brand name	**Falamox 600mg for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Amoxicillin as Sodium …… 500mg. Potassium Clavulanate eq. Clavulanic Acid……. 100mg.
	Reference to Finished product specifications	BP specifications.

	The status in reference regulatory authorities	Co-Amoxiclav 500/100mg Powder solution for injection or infusion, MHRA approved.
	For generic drugs (me-too status)	Co Amoxi Injection 0.6 gm, Macter International Ltd., Reg. No. 070881.
	Proposed Pack size	1's (One vial packed with 10ml of WFI).
	Proposed unit price	As per SRO.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.1	First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. DC/Mfg.-25/E-01761/GMP/2023/4069 dated 06-10-2023 valid for three years.
3.	2.3	Revised table for literature references with correct information regarding the drug substance and finished product with applicable fee shall be submitted.	Firm has submitted revised table for literature references without submission of applicable fee.
4.	3.2.S.4.1	• Both USP and BP specs are mentioned at different parts of the dossier. Justification shall be submitted. • Justification shall be submitted for the specification of the drug substance provided by the drug substance manufacturer wherein BP specifications are mentioned while there is no monograph for the drug substance. And also most of the tests are with in-house specifications.	Firm has submitted that it is to clarify that drug substance manufacturer has provided ready to fill powder of amoxicillin sodium and potassium Clavulanate (Sterile powder 5:1), which complies with BP specifications of drug product. Since drug substance manufacturer is using Clavulanate potassium and amoxicillin trihydrate as starting material for the manufacturing of Sterile powder combination of amoxicillin sodium and potassium Clavulanate 5:1, so drug substance manufacturer adopted USP specifications for Clavulanate potassium and IP specifications for amoxicillin trihydrate as BP monograph for these starting material are not available.
5.	3.2.S.4.2	Justify the injection volume, concentration of standard solution, sample solution in the analytical procedures provided by the drug product manufacturer with respect to that provided by the drug substance manufacturer as they are changed from drug substance manufacturer.	Firm has submitted revised analytical procedures in line with that of the drug substance manufacturer.

Role	Material	Specs
Starting material	Amoxicillin trihydrate	IP
	Clavulanate potassium	USP
Ready to fill powder (5:1)	amoxicillin sodium and potassium Clavulanate	BP

6.	3.2.S.4.4	Specifications of the drug substance provided by the drug substance manufacturer has mentioned BP while the COA of the drug substance provided by the drug substance manufacturer has mentioned IP specification. Justification shall be submitted.	Firm has submitted that specification limit and testing technique in both monograph is same. Updated COA with BP specification had been attached.
7.	3.2.S.7	Clear and readable copies of the stability data sheets of the drug substance shall be submitted.	Firm has submitted stability data sheets for drug substance as per zone Iva in readable form.
8.	3.2.P.2.2	• Justification shall be submitted for not performing most of the test applied on dry powder injections i.e. identification, particulate matter, clarity of solution etc. • Justification for not performing pharmaceutical equivalence against the innovator product shall be submitted.	Firm has submitted that identification, particulate matter and clarity of solution has been performed and results are well within the limits. They also submitted revised PE studies with inclusion of results of the above mentioned test. Firm has submitted that as per guidance document, they performed PE studies with the locally available brand.
9.	3.2.P.5.2	Justify the sample solution and reference solution for amoxicillin with reference to BP monograph.	Firm has submitted revised analytical procedures as per BP monographs.
10.	3.2.P.8	• Raw data sheets for calculation of assay at each time interval shall be submitted. • Justification regarding the quantity of drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of two strengths of Falamox Dry powder injection.	Submitted. Firm has submitted that 1kg of API was imported vide clearance certificate No. (E-1393520227361) dated 07-06-2022 and was used for product development. For stability batches, 5kg of API was taken as loan from Stallion pharmaceuticals.

Decision: Approved.

239.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Dy. No. and date of submission	Dy. No. 8797 dated 30-03-2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 236340013 Dated 15-03-2023.
	The proposed proprietary name / brand name	**Falamox 1.2gm for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Amoxicillin as Sodium …… 1000mg. Potassium Clavulanate eq. Clavulanic Acid……. 200mg.
	Reference to Finished product specifications	BP specifications.
	The status in reference regulatory authorities	Co-Amoxiclav 1000/200mg Powder solution for injection or infusion, MHRA approved.
	For generic drugs (me-too status)	Co Amoxi Injection 1.2 gm, Macter International Ltd., Reg. No. 070882.
	Proposed Pack size	1's (One vial packed with 20ml of WFI).
	Proposed unit price	As per SRO.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		First page of Form 5 is not submitted by the firm.	Submitted.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. DC/Mfg.-25/E-01761/GMP/2023/4069 dated 06-10-2023 valid for three years.
3.	2.3	Revised table for literature references with correct information regarding the drug substance and finished product with applicable fee shall be submitted.	Firm has submitted revised table for literature references without submission of applicable fee.

<table>
<tr>
<td>4.</td>
<td>3.2.S.4.1</td>
<td>

Both USP and BP specs are mentioned at different parts of the dossier. Justification shall be submitted.
Justification shall be submitted for the specification of the drug substance provided by the drug substance manufacturer wherein BP specifications are mentioned while there is no monograph for the drug substance. And also most of the tests are with in-house specifications.

</td>
<td>
Firm has submitted that it is to clarify that drug substance manufacturer has provided ready to fill powder of amoxicillin sodium and potassium Clavulanate (Sterile powder 5:1), which complies with BP specifications of drug product.

Since drug substance manufacturer is using Clavulanate potassium and amoxicillin trihydrate as starting material for the manufacturing of Sterile powder combination of amoxicillin sodium and potassium Clavulanate 5:1, so drug substance manufacturer adopted USP specifications for Clavulanate potassium and IP specifications for amoxicillin trihydrate as BP monograph for these starting material are not available.
<table>
<tr><th>Role</th><th>Material</th><th>Specs</th></tr>
<tr><td rowspan="2">Starting material</td><td>Amoxicillin trihydrate</td><td>IP</td></tr>
<tr><td>Clavulanate potassium</td><td>USP</td></tr>
<tr><td>Ready to fill powder (5:1)</td><td>amoxicillin sodium and potassium Clavulanate</td><td>BP</td></tr>
</table>
</td>
</tr>
<tr>
<td>5.</td>
<td>3.2.S.4.2</td>
<td>Justify the injection volume, concentration of standard solution, sample solution in the analytical procedures provided by the drug product manufacturer with respect to that provided by the drug substance manufacturer as they are changed from drug substance manufacturer.</td>
<td>Firm has submitted revised analytical procedures in line with that of the drug substance manufacturer.</td>
</tr>
<tr>
<td>6.</td>
<td>3.2.S.4.4</td>
<td>Specifications of the drug substance provided by the drug substance manufacturer has mentioned BP while the COA of the drug substance provided by the drug substance manufacturer has mentioned IP specification. Justification shall be submitted.</td>
<td>Firm has submitted that specification limit and testing technique in both monograph is same. Updated COA with BP specification had been attached.</td>
</tr>
<tr>
<td>7.</td>
<td>3.2.S.7</td>
<td>Clear and readable copies of the stability data sheets of the drug substance shall be submitted.</td>
<td>Firm has submitted stability data sheets for drug substance as per zone Iva in readable form.</td>
</tr>
<tr>
<td>8.</td>
<td>3.2.P.2.2</td>
<td>

Justification shall be submitted for not performing most of the test applied on dry powder injections i.e. identification, particulate matter, clarity of solution etc.
Justification for not performing pharmaceutical equivalence against the innovator product shall be submitted.

</td>
<td>Firm has submitted that identification, particulate matter and clarity of solution has been performed and results are well within the limits. They also submitted revised PE studies with inclusion of results of the above mentioned test.
Firm has stated that as per guidance document, they perform PE studies with the locally available brand.</td>
</tr>
</table>

9.	3.2.P.5.2	Justify the sample solution and reference solution for amoxicillin with reference to BP monograph.	Firm has submitted revised analytical procedures as per BP monographs.
10.	3.2.P.8	• Raw data sheets for calculation of assay at each time interval shall be submitted. • Justification regarding the quantity of drug substance shall be submitted with respect to the total quantity of the drug substance imported and total quantity used in manufacturing and testing of two strengths of Falamox Dry powder injection.	Submitted. Firm has submitted that 1kg of API was imported vide clearance certificate No. (E-1393520227361) dated 07-06-2022 and was used for product development. For stability batches, 5kg of API was taken as loan from Stallion pharmaceuticals.

Decision: Approved.

Case 02: Registration applications Locally manufactured (Human) drugs Deferred cases on Form 5F.

240.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan Pharmaceuticals (Pvt.) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceuticals (Pvt.) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 33968 dated 24-11-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 0727272806 dated 28-10-2022.
	The proposed proprietary name / brand name	**Lozar 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…50mg
	Pharmacotherapeutic Group of (API)	Anti hypertensive.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Cozzar 50mg Tablet, M/s OBS Pakistan limited, Reg. No. 022067.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	

3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.P.2.2	• Assay specifications has mentioned 94.5% - 105% in this section while USP has mentioned 95% - 105%. Clarification shall be submitted. • CDP studies of the applied formulation with innovator/comparator product shall be submitted.	
5.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	
6.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board shall be submitted with inclusion of API lot number. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has request for issuance of cGMP certificate dated 19-12-2022. However, they have not provided any updated GMP certificate.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.2.2	• Assay specifications has mentioned 94.5% - 105% in this section while USP has mentioned 95% - 105%. Clarification shall be submitted. • CDP studies of the applied formulation with innovator/comparator product shall be submitted.	Firm has submitted that it was a typographical mistake and is regretted. Firm has submitted CDP studies with Cozzar 50mg tablets, B. No. U020634 manufactured by M/s Merck Sharp & Dohme Pharmaceutical. F2 values are in acceptable ranges.
5.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	Firm has not submitted any clarification/justification regarding this point. However, they just submitted revised analytical method.
6.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board shall be submitted with	Firm has submitted revised stability data sheets with inclusion of API lot No. 10102-200918.

		inclusion of API lot number. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.

Decision: Approved.

- **Registration letter will be issued after submission of 7500/- fee for typo error as per decision of Registration Board and submission of valid copy of GMP certificate.**

241.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35345 dated 06-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 74692864338 dated 30-11-2022.
	The proposed proprietary name / brand name	**Losartan 25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Losartan Potassium ……..…25mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Losmart Tablet 25mg, M/s Scilife Pharma, Reg. No. 096990.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply submitted by the firm.**
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.5.2	This section has not mentioned film coating while the reference product is film coated tablet. Clarification shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
4.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	

		• Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
6.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
7.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	
8.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
9.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
10.	3.2.P.2.2	Justification shall be submitted for not performing CDP & PE studies against the innovator product.	
11.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply by the firm:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. F.3-3/2018-Addl. Dir. (QA&LT-I)-70 dated 24-11-2022.
2.	1.5.2	This section has not mentioned film coating while the reference product is film coated tablet. Clarification shall be submitted.	Firm has submitted that the product is film coated as mentioned in FPP's COA and test protocol. However, neither revised label claim is provided nor any fee is submitted by the firm.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. IT/E/API/10/2019 rev. 1 issued by AIFA Italy in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Diqiao, Linhai, Zhejiang China valid till 13-03-2022. *The submitted certificate is not valid. Furthermore, the source of drug substance*

			mentioned in the dossier was M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City instead of M/s Zhejiang Huahai Pharmaceutical Co., Ltd.
4.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 59 of DMF of API manufacturer.
5.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 60-64 of DMF of API manufacturer. Firm has submitted Equivalence study for comparing In-house HPLC assay and related substances analytical method to USP for losartan potassium.
6.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted that refer to page No. 65-260 page of DMF of API manufacturer. *Firm was asked to provide Analytical method verification studies of the drug substance performed by the drug product manufacturer, however, they didn't provide the same.*
7.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	Firm has stated that it is responded at serial No. 4 and it is the same query.
8.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	Submitted.
9.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	Firm has submitted that for this product they follow dissolution test 1. According to official monograph, test 1 should be performed on UV method. *Dissolution test 1in the official monograph has mentioned both the UV and HPLC method.*
10.	3.2.P.2.2	Justification shall be submitted for not performing CDP & PE studies against the innovator product.	Firm has submitted that innovator's brand i.e. Cozzar in 25mg is not available in the market, therefore, alternate and well established brand A2A of Wilson pharma was used as reference.
11.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph	Already justifies at point No. 09.

		has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted proforma invoice and DHL slip only. *However, no clearance certificate attested by DRAP is submitted by the firm for procurement of API.* N/A Submitted. Submitted.

Decision: Registration Board deferred the instant case and decided to give last chance to the applicant for submission the following deficiencies;

- **Submission of 7500/- fee for revision of label claim in 1.5.2 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.**
- **Specifications of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.**
- **Documents for the procurement of API with approval from DRAP shall be submitted.**

242.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35346 dated 06-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 3173706031 dated 30-11-2022.
	The proposed proprietary name / brand name	**Losartan 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…50mg

	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Losmart Tablet 50mg, M/s Scilife Pharma, Reg. No. 096991.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
8.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. F.3-3/2018-Addl. Dir. (QA&LT-I)-70 dated 24-11-2022.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. IT/E/API/10/2019 rev. 1 issued by AIFA Italy in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Diqiao, Linhai, Zhejiang China valid till 13-03-2022. *The submitted certificate is not valid. Furthermore, the source of drug substance mentioned in the dossier was M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City instead of M/s Zhejiang Huahai Pharmaceutical Co., Ltd.*
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 59 of DMF of API manufacturer.
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 60-64 of DMF of API manufacturer. Firm has submitted Equivalence study for comparing In-house HPLC assay and related substances analytical method to USP for losartan potassium.
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted that refer to page No. 65-260 page of DMF of API manufacturer. *Firm was asked to provide Analytical method verification studies of the drug substance performed by the drug product manufacturer, however, they didn't provide the same.*
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	Firm has stated that it is responded at serial No. 4 and it is the same query.
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	Submitted.
8.	3.2.P.5.2	• Dissolution test by the finished product has	Firm has submitted that for this product they follow dissolution test 1. According

		mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	to official monograph, test 1 should be performed on UV method. *Dissolution test 1in the official monograph has mentioned both the UV and HPLC method.*
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Already justifies at point No. 08. Firm has submitted proforma invoice and DHL slip only. *However, no clearance certificate attested by DRAP is submitted by the firm for procurement of API.* N/A Submitted. Submitted.

Decision: Registration Board deferred the instant case and decided to give last chance to the applicant for submission the following deficiencies;

- **Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.**
- **Specifications of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.**
- **Documents for the procurement of API with approval from DRAP shall be submitted.**

243.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 35347 dated 06-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 40374714087 dated 30-11-2022.

	The proposed proprietary name / brand name	**Losartan 100mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium ……..…100mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain. ATC code: C09CA01
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	A2A 100mg Tablet, M/s Wilsons Pharma, Reg. No. 059309.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different from USP. Clarification shall be submitted.	
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	
8.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

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

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. F.3-3/2018-Addl. Dir. (QA&LT-I)-70 dated 24-11-2022.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. IT/E/API/10/2019 rev. 1 issued by AIFA Italy in the name of M/s Zhejiang Huahai Pharmaceutical Co., Ltd., Chuannan, Diqiao, Linhai, Zhejiang China valid till 13-03-2022. *The submitted certificate is not valid. Furthermore, the source of drug substance mentioned in the dossier was M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., Jiangkou Development Zone, Huangyan, Taizhou City instead of M/s Zhejiang Huahai Pharmaceutical Co., Ltd.*
3.	3.2.S.4.1	• Specifications of the drug substance by the drug product manufacturer shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 59 of DMF of API manufacturer.
4.	3.2.S.4.2	• Analytical procedures of the drug substance by the drug product manufacturer shall be submitted. • Analytical procedures of the drug substance submitted by the drug substance manufacturer are completely different from USP. Clarification shall be submitted.	*Not submitted.* They only stated that kindly refer to page No. 60-64 of DMF of API manufacturer. Firm has submitted Equivalence study for comparing In-house HPLC assay and related substances analytical method to USP for losartan potassium.
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted that refer to page No. 65-260 page of DMF of API manufacturer. *Firm was asked to provide Analytical method verification studies of the drug substance performed by the drug product manufacturer, however, they didn't provide the same.*
6.	3.2.S.4.4	Submitted COA from drug substance manufacturer has mentioned that it complies USP specifications while the analytical procedures are completely different	Firm has stated that it is responded at serial No. 4 and it is the same query.

		from USP. Clarification shall be submitted.	
7.	3.2.S.5	COA/details of the working standard used during the development studies shall be submitted.	Submitted.
8.	3.2.P.5.2	• Dissolution test by the finished product has mentioned UV method while official monograph has mentioned HPLC method. Clarification shall be submitted.	Firm has submitted that for this product they follow dissolution test 1. According to official monograph, test 1 should be performed on UV method. *Dissolution test 1in the official monograph has mentioned both the UV and HPLC method.*
9.	3.2.P.8	• Justification shall be submitted for using UV method for dissolution while official monograph has mentioned HPLC method. • Documents for the procurement of API with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Already justifies at point No. 08. Firm has submitted proforma invoice and DHL slip only. *However, no clearance certificate attested by DRAP is submitted by the firm for procurement of API.* N/A Submitted. Submitted.

Decision: Registration Board deferred the instant case and decided to give last chance to the applicant for submission the following deficiencies;

- **Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.**
- **Specifications of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.**
- **Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.**
- **Documents for the procurement of API with approval from DRAP shall be submitted.**

244.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.**

	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 36117 dated 12-12-2022.
	Details of fee submitted	Rs.30,000/- vide slip No. 5200767411 dated 27-10-2022.
	The proposed proprietary name / brand name	**Zolapt 40mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Omeprazole as Omeprazole EC Pellets …40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Omeprazole 20mg & 40mg capsule (delayed release pellets), USFDA Approved.
	For generic drugs (me-too status)	Risek 40mg capsule, M/s Getz pharma Karachi, Reg. No. 022109.
	Proposed Pack size	10’ & 14’s.
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.4	• COA submitted by the drug product manufacturer has mentioned dissolution specifications of NMT 15% in 0.1N HCl while drug substance manufacturer has mentioned NMT 10%. Clarification shall be submitted. • Dissolution specification in buffer has mentioned NMT 75% while drug substance manufacturer has mentioned NLT 75%. Clarification shall be submitted.	
5.	3.2.P.2.2	• Details of the comparator product against which PE studies are performed shall be submitted. • Calculation and values of F_2 shall be submitted for each medium.	
6.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	

7.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the Firm:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 27/2023-DRAP (AD-22564512857) dated 08-03-2023 issued on the basis of inspection conducted on 01-03-2023.
2.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	• COA submitted by the drug product manufacturer has mentioned dissolution specifications of NMT 15% in 0.1N HCl while drug substance manufacturer has mentioned NMT 10%. Clarification shall be submitted. • Dissolution specification in buffer has mentioned NMT 75% while drug substance manufacturer has mentioned NLT 75%. Clarification shall be submitted.	Firm has submitted that it was due to typographic mistake. They submitted revised COA with correct specifications with submission of 7500/- fee vide slip No. 3659115539 dated 05-08-2024. Corrected specifications provided.
5.	3.2.P.2.2	• Details of the comparator product against which PE studies are performed shall be submitted. • Calculation and values of F_2 shall be submitted for each medium.	Risek 40mg, Mfg. date 03-2021, B. No. 818C20 manufactured by Getz Pharma. Submitted.
6.	3.2.P.5.2	USP has mentioned gradient method with different composition at different time interval while the submitted analytical procedure has mentioned isocratic method with fixed composition of mobile phase. Clarification shall be submitted.	Firm has submitted that used gradient method while the mistake of isocratic was due to typo error. They further provided revised method as per USP.
7.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	N/A. Submitted.

		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
Decision: Approved.			
245.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hansel Pharmaceuticals (Pvt.) Ltd., Plot No. 2 Pharma City, 30-Km, Multan Road, Lahore.**	
	Name, address of Manufacturing site.	M/s Hansel Pharmaceuticals (Pvt.) Ltd, Plot No. 2 Pharma City, 30-Km, Multan Road, Lahore.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 10.10.2019 based on inspection conducted on 15-05-2019.	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-9/2001-Lic (Vol-II) dated 03-10-2019 wherein Liquid Injectable (Hormone) (Reallocated from first floor to ground floor).	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 8912 dated 07-04-2022.	
	Details of fee submitted	PKR 30,000/- vide slip No. 1530144872 Dated 01-02-2022.	
	The proposed proprietary name / brand name	**Hydroxy Injection 1ml.**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Hydroxyprogesterone Caproate ……. 250mg	
	Pharmacotherapeutic Group of (API)	Progestogen (G03D), Pregnen (4) derivatives (G03DA), Pregnadien derivatives (G03DB).	
	Pharmaceutical form of applied drug	Injection.	
	Reference to Finished product specifications	USP Specifications.	
	Proposed Pack size	All pack sizes approved by PRC/MOH/SRO.	
	Proposed unit price	As per SRO.	
	The status in reference regulatory authorities	Delalutin, Hydroxyprogesterone Caproate, 250mg/ml, USFDA approved. **Federal Register Determination That Product Was Not Discontinued Or Withdrawn For Safety Or Effectiveness Reasons**	
	For generic drugs (me-too status)	Hygest Injection, Shaigan Pharmaceutical, Reg. No. 094205.	
	Name and address of API manufacturer.	Zhejiang Xianju Yangguang Bio Products Co. Ltd., **Address:** Dongyi Road, Modern Industrial Zone, Xianju County, Zhejiang Province, China.	

		Firm has submitted copy of License No. Zhe 20190003 issued by Zhejiang Food and Drug Administration in the name of M/s Zhejiang Xianju County Sunshine Biological Products Co., Ltd., valid till 25-03-2024.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. 5260-201201, mfg. date 07-12-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batches: (17-200305001, 17-200305002 & 17-200305003)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product **Proluton Depot.** Medipharm (Pvt.) Ltd., 108-Kotlakhpat Industrial Estate Lahore. Licencee of Bayer Pharma AG, Germany. Limited
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Zhejiang Xianju Yangguang Bioproducts Co., Ltd.** **Address:** Dongyi Road, Modern Industrial Zone, Xianju Country Zhejiang, China
API Lot No.	5260-201201
Description of Pack (Container closure system)	1 Ampoule of 1mL per unit pack.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	H-411	H-412	H-413
Batch Size	2000 Ampoules	2000 Ampoules	2000 Ampoules
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	17-05-2021	18-05-2021	19-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Products dossier on CTD format of firm has been already approved thus no inspection conducted regarding stability studies of the applied product. Firm has submitted the Audit trail reports and Temperature, Humidity record of Data logger of stability chamber for both Accelerated and Real time studies.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate & DML of API Supplier. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 04-03-2021 specifying 25.0Kg of Hydroxyprogesterone Caproate. The invoice is cleared by AD (I&E) DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1	1.5.9	"Please provide evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board in its 275th meeting for further processing of your case as the submitted reference product is withdrawn by USFDA on April, 06, 2023"	

Decision of 331st meeting of Registration Board:
Deferred for submission of evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting.

Reply submitted by the firm:
Firm has submitted "Proluton Depot 250mg ampoule" manufactured by Bayer as reference approved in Austria.
The same is also verified from the official website of Austria.
Firm has also submitted valid copy of DML w.e.f. 24-06-2020.

Decision: Approved.

246.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma, 23-Km, Multan Road, Lahore.**

	Name, address of Manufacturing site.	M/s Venus Pharma, 23-Km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate No. 353/2019-DRAP (AD-1915187-536) dated 28-11-2019 issued on the basis of inspection conducted on 05-09-2019.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales.
	Dy. No. and date of submission	Form-5F Dy. No. 27750 dated 30-09-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 655622716 dated 31-05-2022.
	The proposed proprietary name / brand name	**Valron Emulgel 2%.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100gm contains; Diclofenac Diethyl ammonium salt 2.32.gm eq. to Diclofenac sodium ……. 2gm.
	Pharmaceutical form of applied drug	Topical gel.
	Pharmacotherapeutic Group of (API)	NSAID.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 x 1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Voltarol 12 hours Emulgel 2.32%, MHRA approved.
	For generic drugs (me-too status)	Voltral Emulgel 2%, GSK OTC (Pvt.) Ltd., Reg. No. 089372.
	Name and address of API manufacturer.	M/s Srikem Laboratories (Pvt.) Ltd., Plot No. 17/24, M.I.D.C. Taloja- 410 208, Navi, Mumbai, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch

		analyses (185008003, mfg. date 06-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions and batches: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 06 months Batches: (195008001, 205008002 & 175008002).
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Brand i.e. Voltral Emulgel 2%, GSK OTC (Pvt.) Ltd., by performing quality tests (Disintegration, Identification, Average weight and Assay).
	Analytical method validation/verification of product	Method validation studies have been submitted including: Accuracy, precision, linearity and specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Srikem Laboratories (Pvt.) Ltd., Plot No. 17/24, M.I.D.C. Taloja- 410 208, Navi, Mumbai, India.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Printed and sealed Alu-Alu tubes having plastic cap further packed in board unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09 months Accelerated: 06 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	19	20	
Batch Size	500 Tubes	500 Tubes	
Manufacturing Date	09-2021	09-2021	
Date of Initiation	11-09-2021	11-09-2021	
No. of Batches	02		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section No.	Observation	Response by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted as the provided one is w.e.f. 25-12-2015. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has once again submitted the same DML w.e.f. 25-12-2015. *Valid DML is required.* Copy of GMP certificate No. 04/2024-DRAP(AD-46168323) dated 02-01-2024 issued on the basis of inspection conducted on 22-08-2023 & 14-09-2023.
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Above mentioned GMP certificate has mentioned cream/ointment section.
3.	1.5.2	This section has mentioned that each 100gm contain Diclofenac Diethyl ammonium salt eq. to 2.32.gm of Diclofenac sodium. Clarification shall be submitted.	Firm has submitted that their product composition is 2% and factor is adjusted according to molecular weight of Diclofenac diethyl ammonium salt. *Firm was asked that they have written Diclofenac Diethyl ammonium salt eq. to 2.32.gm of Diclofenac sodium which is incorrect and 2.32% in label claim. However, they didn't answer the same.*
4.	3.2.S.4.1	Specification of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
5.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	*Not submitted.*
6.	3.2.S.4.3	Verification of analytical procedures of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.5	Details/COA of the working standard used shall be submitted.	Firm has submitted copy of COA of working standard for diclofenac sodium.

			However, COA is from M/s Henen Dongtai Pharm Co., Ltd.
8.	3.2.S.7.3	Accelerated stability studies for the three same batches for which real time stability studies are submitted shall be provided. OR Real time and accelerated stability data for the same batches as per zone Iva shall be submitted.	Firm has once again submitted the same stability data. *Real time and accelerated stability batches are not the same.*
9.	3.2.P.5.1	Justification shall be submitted for not including content uniformity, pH and microbial studies in the specifications of the drug product.	Firm has submitted that content uniformity is applied on single/metered dose containers according to general monographs of topical semi solid preparation in B.P. Firm further submitted that both pH & microbial studies are not included in that monograph.
10.	3.2.P.5.3	Analytical method verification protocol along with analytical method verification studies performed on the finished product shall be submitted.	Submitted.
11.	3.2.P.5.4	Justification shall be submitted for developing only two trial batches.	Firm has submitted that as per guidance document of Form 5F; (a) At least 2 batches having the following minimum batch size considering the scientific reliability • OSDs: 5000 Units • Oral Liquid/Suspension: 2000 • Injectable: 2000 • Aerosol and any other specialized preparations: 500 (b) At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life. *From the above statement of the guidelines, 02 batches with 500 units are for Aerosol and any other specialized preparations while as per point "b" At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life shall be manufactured. However, firm has manufactured only two trial batches with 500 units.*
12.	3.2.P.8	• Justification shall be submitted for not performing content uniformity test and pH and microbial test in stability studies.	Firm has submitted that content uniformity is applied on single/metered dose containers according to general monographs of topical semi solid preparation in B.P.

		• Stability data sheets as per decision of Registration Board with inclusion of API lot number shall be submitted. • Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API used in the development studies with approval from DRAP (in case of import) shall be submitted. • • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Firm further submitted that both pH & microbial studies are not included in that monograph. *Not submitted.* *Firm has also submitted raw data sheets wherein the final concentration used by the FPP is 0.02mg/ml while BP monograph has mentioned 0.05/ml.* Firm has submitted copy of GMP certificate No. 6077473 dated 07-09-2017 issued by Food & Drugs Administration Maharashtra State, India in the name of M/s Srikem Laboratories (Pvt.) Ltd., valid till 06-09-2018. *Valid copy of GMP certificate is required.* Firm has submitted copy of invoice No. E-1819136 dated 20-10-2018 mentioning 25 kg of diclofenac diethyl amine BP, B. No. 185008003, mfg. date 06-2018 attested by Assistant Director, DRAP, Lahore dated 26-10-2018. Not applicable.

Decision of 335th meeting of Registration Board: Deferred for following;

- Valid copy of DML of the applicant shall be submitted.
- Revision of label with submission of full fee as per reference product.
- Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.
- Real time and accelerated stability data of the drug substance for the same batches as per zone Iva shall be submitted.
- Justification shall be submitted for using final concentration of 0.02mg/ml in the submitted raw data sheets while BP monograph has mentioned 0.05/ml.
- Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.

Reply by the firm:

S. No.	Observation	Reply submitted by the firm
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000300 w.e.f. 25-12-2020.
2.	Revision of label with submission of full fee as per reference product.	Firm has submitted fee of 30,000/- vide slip No. 8336119978 dated 30-07-2024.
3.	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
4.	Real time and accelerated stability data of the drug substance for the same batches as per zone Iva shall be submitted.	Submitted.
5.	Justification shall be submitted for using final concentration of 0.02mg/ml in the	Firm has submitted that USP Chapter 621 explain about the chromatography where it allows some variation according to your

	submitted raw data sheets while BP monograph has mentioned 0.05/ml	system, where it states system suitability is compulsory and system suitability is integral part of chromatography, and validation/verification is necessary if you make variation. So we use this concentration from 0.05mg/ml to 0.02mg/ml according to our system. They further stated that we also performed verification studies. They further stated that BP general chapter of chromatography also allow variation according to your system but make sure the system suitability and verification or revalidation of method.
6.	Approval of API/ DML/GMP certificate (valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Submitted.

Decision: Approved.

247.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio-Next Pharmaceuticals, Plot No. 50, Street No. S-10, RCCI, Rawat.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Bio-Next Pharmaceuticals:** Copy of GMP certificate No. F. 3-82/2022-Addl. Dir. (QA & LT-I)-15 dated 15-02-2022 issued on the basis of inspection conducted on 17-12-2021 is submitted. **M/s Bio-Labs (Pvt.) Ltd.,** Not submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012 mentioning ampoule (general) section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29091; dated 13-10-2022.
	Details of fee submitted	PKR 75,000/-: vide slip No. 039600756354 dated 26-09-2022.
	The proposed proprietary name / brand name	**Rotamine 30mg Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine …….. 30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule

	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1ml x 5's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. **Manufacturing site address:** M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. KTM180021, Mfg. date 15-08-18) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{O} \pm 2^{O}$ C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2^{O} C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.		
API Lot No.		KTM180021.		
Description of Pack (Container closure system)		Multi-colour unit carton having ALU/PVC tray containing 5 Glass ampoules filled with almost colorless to slight yellow sterile solution.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		A-745	A-737	A-703
Batch Size		30,000 Ampoules	30,000 Ampoules	30,000 Ampoules
Manufacturing Date		10-2019	10-2019	10-2019
Date of Initiation		26-10-2019	26-10-2019	26-10-2019
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. Drugs (3) Pb. 2021/3124 dated 25-06-2021 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 25-06-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. SCL/2019-20/087 dated 25-07-2019 mentioning 15kg of ketorolac Tromethamine USP with B. No. KTM180021 attested by Assistant Director I&E, DRAP, Islamabad dated 02-08-2019.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response
1.	1.4.3	Valid copy of GMP certificate of the contract acceptor shall be submitted.	
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	
6.	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	
8.	3.2.P.8	• Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted chromatograms for the stability data reflects 20µl injection volume. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

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

Reply submitted by the firm:

Sr. No.	Section Number	Observations	Firm's Response
1.	1.4.3	Valid copy of GMP certificate of the contract acceptor shall be submitted.	Copy of GMP certificate No. F.3-19/2019-Addl. Dir. (QA & LT-I)-77 dated 28-12-2023 issued on the basis of inspection conducted on 09-10-2023 is submitted by the firm
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (3) Pb. 2023/3217 dated 14-09-2023 for M/s. Saurav Chemicals Limited, Bhagwanpura,

			Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 13-09-2025. *However, date on the GMP certificate is overwritten.*
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references without submission of applicable fee.
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	Firm has submitted that USP has not specify the run time for the drug substance but mention the retention time of ketorolac is about 08 to 12 minutes so in the submitted chromatograms the peak of ketorolac has the RT as per USP monograph.
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	Firm has submitted that they have used same ingredients except ethanol according to well establish study on use of ethanol in injections describe that containing organic vehicles such as ethanol have a certain degree of toxicity , which can easily cause irritation upon injection, thereby due avoid any adverse/harmful effect we replace them with citric acid.
6.	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	Firm has submitted that the preparation of ketorolac is done by membrane filtration followed by terminal sterilization. *However, in the initially submitted dossier, there was no terminal sterilization of the said preparation. When they were asked for Justification of not performing terminal sterilization they now stated that they are performing terminal sterilization.*
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	Firm has submitted that as per product label claim30mg/ml, the concentration could be 0.048mg/ml which is nominally 0.05mg/ml. however, analysis was performed with manual injector with fixed loop of 20µl instead of 100µl hence the higher concentration of 0.06mg/ml was preferred.
8.	3.2.P.8	• Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted	Firm has submitted that at time they have performed analysis with the Shimadzu isocratic manual injector and it has fixed loop of 20µl and we didn't used 100µl.

		chromatograms for the stability data reflects 20µl injection volume. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.

Decision: Registration Board deferred the instant case and decided to give last chance to the applicant for submission of for following deficiencies;

- **Clarification regarding the overwriting the date on submitted GMP certificate of the drug substance.**
- **Submission of valid GMP certificate of the drug substance manufacturer issued by relevant / concerned regulatory authority.**
- **Submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Scientific justification for difference in the qualitative composition of the applied formulation and innovator product.**
- **Justification for performing terminal sterilization as in the initially submitted application has not mentioned any terminal sterilization.**

248.	Name, address of Applicant / Marketing Authorization Holder	**M/s Onyx Pharmaceuticals, 30-A, Industrial Estate, Mansehra.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Onyx Pharmaceuticals:** Not submitted. **M/s Bio-Labs (Pvt.) Ltd.,** Not submitted.
	Evidence of approval of manufacturing facility	Copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012 mentioning ampoule (general) section is submitted by the firm.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1731; dated 18-01-2023.
	Details of fee submitted	PKR 75,000/-: vide slip No. 0288763521 dated 15-11-2022.
	The proposed proprietary name / brand name	**Ketonex 30mg Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Ketorolac Tromethamine …….. 30mg
	Pharmacotherapeutic Group of (API)	NSAID
	Pharmaceutical form of applied drug	Clear colorless liquid filled in glass ampoule

	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1ml x 5's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Tekac 30mg/ml Injection, Sami Pharmaceuticals, Reg. No. 092855.
	Name and address of API manufacturer.	M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. **Manufacturing site address:** M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (B. No. KTM180021, Mfg. date 15-08-18) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 ^{O} ± 2 ^{O} C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2 ^{O} C / 65% ± 5% RH for 60 months. (Batch No. KTM06130016, KTM06130017 & KTM06130018)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, pharmaceutical development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence against the product Toradol Ampoule 30mg, B. No. C2436, Mfg. date 01, 2020 by Barrett Hodgson by performing quality tests (Description, Identification, pH, Assay, Sterility, Bacterial endotoxin.)		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s. Saurav Chemicals Limited 370 Industrial Area, Phase II Panchkula, Haryana, 134109 – India. Manufacturing site address: M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India.		
API Lot No.		KTM180021.		
Description of Pack (Container closure system)		Multi-colour unit carton having ALU/PVC tray containing 5 Glass ampoules filled with almost colorless to slight yellow sterile solution.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		A-745	A-737	A-703
Batch Size		30,000 Ampoules	30,000 Ampoules	30,000 Ampoules
Manufacturing Date		10-2019	10-2019	10-2019
Date of Initiation		26-10-2019	26-10-2019	26-10-2019
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. Drugs (3) Pb. 2021/3124 dated 25-06-2021 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 25-06-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. SCL/2019-20/087 dated 25-07-2019 mentioning 15kg of ketorolac Tromethamine USP with B. No. KTM180021 attested by Assistant Director I&E, DRAP, Islamabad dated 02-08-2019.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr. No.	Section Number	Observations	Firm's Response by the firm
1.	1.4.3	• Valid copy of GMP certificate of the contract acceptor shall be submitted. • Valid copy of GMP certificate/last inspection report and DML of the applicant shall be submitted as submitted DML is from 15-06-2011.	
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	
6.	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	
8.	3.2.P.8	• Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted chromatograms for the stability data reflects 20µl injection volume. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply submitted by the firm:

Sr. No.	Section Number	Observations	Firm's Response by the firm
1.	1.4.3	• Valid copy of GMP certificate of the contract acceptor shall be submitted.	Copy of GMP certificate No. F.3-19/2019-Addl. Dir. (QA & LT-I)-77 dated 28-12-2023 issued on the basis of

		• Valid copy of GMP certificate/last inspection report and DML of the applicant shall be submitted as submitted DML is from 15-06-2011.	inspection conducted on 09-10-2023 is submitted by the firm. *No response is submitted by the firm against this point.*
2.	1.6.5	Valid GMP certificate of API manufacturer issued by regulatory body of country shall be submitted.	Firm has submitted copy of GMP certificate No. Drugs (3) Pb. 2023/3217 dated 14-09-2023 for M/s. Saurav Chemicals Limited, Bhagwanpura, Derabassi – Barwala Road, Mohali District Punjab India issued by Food & Drugs Administration, Punjab is submitted by the firm. GMP certificate is valid till 13-09-2025. *However, date on the GMP certificate is overwritten.*
3.	2.3	Table for literature references has mentioned USP for drug substance. Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references without submission of applicable fee.
4.	3.2.S.4.3	Analytical method validation studies performed by the drug substance manufacturer for assay test on HPLC has mentioned run time of 40 minutes. While the submitted chromatograms by the drug product manufacturer for method verification has run time of 12.5 minutes only. Justification shall be submitted.	Firm has submitted that USP has not specify the run time for the drug substance but mention the retention time of ketorolac is about 08 to 12 minutes so in the submitted chromatograms the peak of ketorolac has the RT as per USP monograph.
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Innovator has used Ethanol while the applied formulation has no ethanol. Applied formulation has used Citric acid anhydrous as preservative while the innovator has no citric acid. Justification shall be submitted.	Firm has submitted that they have used same ingredients except ethanol according to well establish study on use of ethanol in injections describe that containing organic vehicles such as ethanol have a certain degree of toxicity , which can easily cause irritation upon injection, thereby due avoid any adverse/harmful effect we replace them with citric acid.
6.	3.2. P.2.3	Justification of not performing terminal sterilization of the drug product shall be submitted.	Firm has submitted that the preparation of ketorolac is done by membrane filtration followed by terminal sterilization. *However, in the initially submitted dossier, there was no terminal sterilization of the said preparation. When they were asked for Justification of not performing terminal sterilization they now stated that they are performing terminal sterilization.*
7.	3.2.P.5.2	Analytical procedures submitted by the firm has mentioned 0.06mg/ml ketorolac Tromethamine concentration for both standard and sample preparation. While USP has mentioned 0.05mg/ml ketorolac	Firm has submitted that as per product label claim30mg/ml, the concentration could be 0.048mg/ml which is nominally 0.05mg/ml. however, analysis was performed with manual injector with

		Tromethamine concentration for both standard and sample preparation. Justification shall be submitted.	fixed loop of 20µl instead of 100µl hence the higher concentration of 0.06mg/ml was preferred.
8.	3.2.P.8	• Analytical procedures submitted by the finished product manufacturer as well as USP has mentioned injection volume of 100µl while the submitted chromatograms for the stability data reflects 20µl injection volume. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that at time they have performed analysis with the Shimadzu isocratic manual injector and it has fixed loop of 20µl and we didn't used 100µl. Submitted.

Decision: Registration Board deferred the instant case and decided to give last chance to the applicant for submission of for following deficiencies;

- **Clarification regarding the overwriting the date on submitted GMP certificate of the drug substance.**
- **Submission of valid GMP certificate of the drug substance manufacturer issued by relevant / concerned regulatory authority.**
- **Submission of 7500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Scientific justification for difference in the qualitative composition of the applied formulation and innovator product.**
- **Justification for performing terminal sterilization as in the initially submitted application has not mentioned any terminal sterilization.**

249.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 45/2021-DRAP (K) dated 29-09-2021 on the basis of inspection conducted on 27-09-2021 is submitted.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9835, dated 18/04/2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 13582877112 dated: 03/02/2022.
	The proposed proprietary name / brand name	Cerucil Sterile Ear Drops.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin as HCl ……3mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic.
	Pharmaceutical form of applied drug	Otic drops.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	10ml.
	Proposed unit price	Ear drops 10ml RS; 118.66.
	The status in reference regulatory authorities	Could not be confirmed.
	For generic drugs (me-too status)	Cipotic Ear Drops, Barrett Hodgson, Reg. No. 032485.
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (DK15-2111042a, Mfg. date 11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 0701192, 0701193 & 0701194.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence studies of their product against Cipotec by performing identification, pH, fill volume and drug release. However, drug release has mentioned limit of 75% - 133% and no details of the comparator product are submitted.

	Analytical method validation/verification of product	Not submitted.	
STABILITY STUDY DATA			
Manufacturer of API	Shangyu Jingxin Pharmaceutical Co., Ltd., No. 31 Weisan Road, Hangzhou Bay Shangyu Economic and technological development area, Shangyu, Zhejiang Province, China.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Plastic bottle with cap and nozzle packed in carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months. Accelerated: 06 months.		
Frequency	Real Time: 0,3,6, 9, 12, 18 & 24 (Months) Accelerated: 0, 03 & 06 (Months).		
Batch No.	TB-101	TB-102	TB-103
Batch Size			
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation			
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted.	

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	

3.	1.5.4	In some sections 5ml pack size is mentioned while in some 10 ml is mentioned. Clarification and exact pack size shall be mentioned.	
4.	1.5.6	This section has mentioned USP specifications. However, official monograph for ciprofloxacin HCl is not available in USP. Clarification shall be submitted.	
5.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities as approved by Registration Board in its 275th meeting shall be submitted.	
6.	1.6.5	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	
7.	2.3	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	
8.	3.2.S.2 & 3.2.S.3	Detailed information of these sections shall be submitted.	
9.	3.2.S.4.1	Specifications of the drug substance from both drug substance and drug product manufacturer shall be submitted.	
10.	3.2.S.4.2	Analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted.	
11.	3.2.S.4.3	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.	
12.	3.2.S.4.4	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug substance manufacturer as it has mentioned mfg. date of 04-11-2021 while trial batches are manufactured in May, 2019.	
13.	3.2.S.5	Details and COA of the working standard used shall be submitted.	
14.	3.2.S.7	Justification shall be submitted for not including most of the test in the stability of the drug substance.	
15.	3.2.P.2.2	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	
16.	3.2.P.5.1	• Reference to the finished product specification shall be submitted. • Specifications has mentioned Assay limit of 90-110% while BP monograph for Ciprofloxacin Ear drops has mentioned 95-110%. Clarification shall be submitted.	

		• Specifications has mentioned pH limit of 3.5 to 5.5 while BP monograph for Ciprofloxacin Ear drops has mentioned 4 to 5. Clarification shall be submitted	
17.	3.2.P.5.2	Justification shall be submitted for the analytical procedures as they are completely different from the official monograph of BP.	
18.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.	
19.	3.2.P.5.6	Justification of specifications has mentioned Manufacturer specifications while section 1.5.6 has mentioned USP specification. Official monograph for ciprofloxacin Ear drops is available in BP. Justification shall be submitted.	
20.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted for using UV method for the analysis of the assay test in stability studies. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

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

Reply submitted by the firm:

Sr. No.	Reason for deferment.	Reply by the firm
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000488 with renewal date from 05-05-2021.
2.	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Firm has submitted copy of letter No. F. 2-4/98-Lic(Pt-I) dated 07-06-2022 mentioning Eye/ear drops.
3.	In some sections 5ml pack size is mentioned while in some 10 ml is mentioned. Clarification and exact pack size shall be mentioned.	Firm has submitted that by typing mistake 10ml is printed instead of 5ml. the actual pack size of 5ml is corrected.
4.	This section has mentioned USP specifications. However, official monograph for ciprofloxacin HCl is not available in USP. Clarification shall be submitted.	***No clarification is submitted by the firm. However, they submitted Ciprofloxacin Ear drops monograph from BP.*** ***Firm has also submitted new information wherein they have changed their***

		specifications from USP to BP without submission of any fee.
5.	Evidence of approval of applied formulation in reference regulatory authorities as approved by Registration Board in its 275th meeting shall be submitted.	Firm has submitted Ciloquin 3mg/ml ear drops as evidence of RRA. Ciloquin 3mg/ml ear drops approved by TGA Australia.
6.	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	Firm has submitted copy of GMP certificate No. SY 31052018 dated 25-05-2016 issued by CFDA valid till 05-24-2021. ***Validity is expired.***
7.	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	***Firm has submitted table for literature references with incorrect information of the drug product.*** ***Not submitted.***
8.	Detailed information of these sections shall be submitted.	Submitted.
9.	Specifications of the drug substance from both drug substance and drug product manufacturer shall be submitted.	Submitted.
10.	Analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted.	Submitted.
11.	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.	Submitted.
12.	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug substance manufacturer as it has mentioned mfg. date of 04-11-2021 while trial batches are manufactured in May, 2019.	Firm has submitted COA of the drug substance however, no details are submitted regarding batch number, Mfg. date and Exp. date etc. *Submitted. However, in the submitted analytical record concentration of the test solution and concentration of the reference solution are completely different from each other's.* Firm has submitted that ciprofloxacin HCl is used in the manufacturing of product "Ophth Cipro" by the drug product manufacturer. During compilation of the dossier file mistakenly the assistant had enclosed copy of new consignment of the material instead of the old one.
13.	Details and COA of the working standard used shall be submitted.	*Submitted.*

14.	Justification shall be submitted for not including most of the test in the stability of the drug substance.	Firm has submitted new stability data sheets for the drug substance from drug substance manufacturer.
15.	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	Firm has submitted pharmaceutical equivalence studies of their applied formulation against the Ciloquin 3mg/ml ear drops, batch No. FDT258, manufacturing date of 02-2019 manufactured by M/s Novartis pharma Australia by performing identification, fill volume, pH, assay and sterility. *However, no pictorial evidence is submitted by the firm for innovator product.* *Firm has also submitted purchase invoice for the Ciloquin Ear drops from Time Medico Karachi.* *However, in the available data of registered products, there is no registration for the same product.*
16.	• Reference to the finished product specification shall be submitted. • • Specifications has mentioned Assay limit of 90-110% while BP monograph for Ciprofloxacin Ear drops has mentioned 95-110%. Clarification shall be submitted. • Specifications has mentioned pH limit of 3.5 to 5.5 while BP monograph for Ciprofloxacin Ear drops has mentioned 4 to 5. Clarification shall be submitted	Firm has submitted that specifications of the product have been updated according to BP monograph. ***No justification is submitted by the firm.*** Firm has submitted that pH limit of the product has been updated as per BP monograph in the dossier that is 4 – 5.
17.	Justification shall be submitted for the analytical procedures as they are completely different from the official monograph of BP.	Firm has submitted that specifications of the product have been updated according to BP monograph. *However, in the initially submitted dossier all the submitted data was as per previous specifications and analytical procedures.*
18.	Analytical method verification studies of the finished product along with analytical record shall be submitted.	Submitted.
19.	Justification of specifications has mentioned Manufacturer specifications while section 1.5.6 has mentioned USP specification. Official monograph for ciprofloxacin Ear drops is available in BP. Justification shall be submitted.	Firm has submitted that specifications of the product have been updated according to BP monograph.
20.	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the	Firm has submitted new stability data sheets with batch size of 1 liter and API lot No. DK0701192. *However, the batch analysis provided in 3.2.S.4.4 has batch No. DK15-2111042a, Mfg. date 11-2021 and is changed from the submitted one.* Firm has submitted that concentration of standard and sample solution has been

	final concentration of both standard and sample preparation are completely different. • Justification shall be submitted for using UV method for the analysis of the assay test in stability studies. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	updated. Standard and sample final concentration in the old testing method was same but it was different from the recent monograph. Firm has submitted that they have performed stability assay test on both techniques UV and HPLC. By mistake the record of HPLC testing could not be attached. We are sending you data on HPLC. Firm has submitted that as per stability guidelines of ICH Q1 A (R2), if a product is packed in a semipermeable container, the stability condition should be 35% ± 5% RH. ***Not submitted.*** Firm has submitted copy of GMP certificate No. SY 31052018 dated 25-05-2016 issued by CFDA valid till 05-24-2021. ***Validity is expired.*** ***Not submitted.*** ***Not submitted.*** Submitted.

Decision: Deferred for following:

- Firm will submit full fee of 30,000/- for pre-approval changes/corrections in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.
- Copies of executed BMR's shall be submitted.
- Justification shall be submitted regarding the newly submitted analytical record for the drug substance wherein the concentration of the test solution and concentration of the reference solution are completely different from each other's.
- Pictorial evidence of the innovator product with visible details of batch number, manufacturing date, expiry date etc. shall be submitted.
- Justification shall be submitted regarding registration status of the reference product against which Pharmaceutical equivalence studies have bene performed.
- Justification shall be submitted regarding the previously submitted analytical record wherein the analytical procedures were completely different from the official monograph of BP.
- Justification shall be submitted regarding the API lot number in the stability data sheet as it is changed from the *batch analysis provided in 3.2.S.4.4. i.e. DK15-2111042a, Mfg. date 11-2021.*
- Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
- Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Reply submitted by the firm:

S. No.	Observation	Reply by the firm
1.	Firm will submit full fee of 30,000/- for pre-approval changes/corrections in registration application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Not submitted.
2.	Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.	Submitted with fee of 7500/- vide slip No. 914179842424 dated 09-01-2024.
3.	Copies of executed BMR's shall be submitted.	Submitted.
4.	Justification shall be submitted regarding the newly submitted analytical record for the drug substance wherein the concentration of the test solution and concentration of the reference solution are completely different from each other's.	No justification is submitted by the firm.
5.	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date, expiry date etc. shall be submitted.	Not submitted.
6.	Justification shall be submitted regarding registration status of the reference product against which Pharmaceutical equivalence studies have bene performed.	Firm has submitted that PE studies are performed against the product Ciloquine 3mg/ml drops. The mentioned product has registration from Australian Board of registration. *Firm was asked to provide pictorial evidence, however, they failed to show the same.*
7.	Justification shall be submitted regarding the previously submitted analytical record wherein the analytical procedures were completely different from the official monograph of BP.	Firm has submitted that they are submitting BP monograph of the product as reference of the product specifications. By mistake the specification of ciprofloxacin HCl ophthalmic solution as per USP specifications were mentioned in the testing method. *Firm was asked some other question, however, they didn't respond to the original query.*
8.	Justification shall be submitted regarding the API lot number in the stability data sheet as it is changed from the *batch analysis provided in 3.2.S.4.4. i.e. DK15-2111042a, Mfg. date 11-2021.*	Firm has submitted new COA and stability data sheets. *However, the newly submitted COA has different number than the previously mentioned COA and is also different from the COA submitted in 3.2.S.4.4.*
9.	Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Firm has submitted copy of GMP certificate No. SY31052018 issued dated 25-05-2016 valid till 24-05-2021. *GMP certificate is not valid.*
10.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of invoice No. ZJ10032019-S dated 20-03-2019 mentioning 50kgs of Ciprofloxacin HCl attested by Assistant Director, DRAP, Karachi dated 28-03-2019.

		However, initially the same document was submitted by the firm without attestation from DRAP.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted.

Decision: Registration Board decided to give a last chasnce to submit the reply of shortcomings. The Board further decided to request the QA&LT, Division for detailed evaluation of the firm and also evaluate the product development, clearance documents of the firm.

250.	Name, address of Applicant / Marketing Authorization Holder	**M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Ophth Pharma (Pvt.) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 45/2021-DRAP (K) dated 29-09-2021 on the basis of inspection conducted on 27-09-2021 is submitted.
	Evidence of approval of manufacturing facility	Not submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8513, dated 01/04/2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 94389054 dated: 03/02/2022.
	The proposed proprietary name / brand name	Sulfadene Cream 1% w/w.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Silver sulfadiazine……10mg
	Pharmacotherapeutic Group of (API)	Sulfonamides. (D06BA)
	Pharmaceutical form of applied drug	Topical cream.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	15gm.
	Proposed unit price	Rs. 150/15gm Aluminum tube.
	The status in reference regulatory authorities	Silvadene 1% (Silver Sulfadiazine) cream, USFDA approved.
	For generic drugs (me-too status)	Quench 1% cream, Ferozsons laboratory, Reg. No. 013090.
	Name and address of API manufacturer.	Srikem Laboratories (Pvt.) Limited, Taloja, Navi Mumbai Plot No. 17/24, 17/22, 17/23, 17/13 M.I.D.C Taloj-410 208, Taluka Panvel. Dist. Raigad (Maharashtra) India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted details of the drug substance including its nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (214001015, Mfg. date 08-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 194001001, 194001002 & 194001003.
	Module-III (Drug Product):	Firm has submitted details of the drug product including its description, composition, pharmaceutical development, manufacture, batch formula, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence studies of their product against Dermazin by performing identification, pH, fill volume and drug release. However, drug release has mentioned limit of 75% - 133% and no details of the comparator product are submitted.
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA	
Manufacturer of API	Srikem Laboratories (Pvt.) Limited, Taloja, Navi Mumbai Plot No. 17/24, 17/22, 17/23, 17/13 M.I.D.C Taloj-410 208, Taluka Panvel. Dist. Raigad (Maharashtra) India..
API Lot No.	Not mentioned.
Description of Pack (Container closure system)	Sulfadene cream 1% w/w will be supplied in Aluminum tube packed in unit carton with leaflet.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months. Accelerated: 06 months.
Frequency	Real Time: 0,3,6, 9, 12, 18 & 24 (Months) Accelerated: 0, 03 & 06 (Months).

Batch No.	TB 101	TB 102	TB 103
Batch Size			
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Remarks of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	
3.	1.6.5	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	
4.	2.3	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	
5.	3.2.S.2 & 3.2.S.3	Detailed information of these sections shall be submitted.	
6.	3.2.S.4.1	• Specifications of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph has mentioned limits for Nitrate while the specifications provided by the drug product manufacturer has no limits for nitrate. Clarification shall be submitted.	
7.	3.2.S.4.2	Analytical procedures for the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	

8.	3.2.S.4.3	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.	
9.	3.2.S.4.4	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted. • Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug product manufacturer as it has mentioned test date of 12-1-2018.	
10.	3.2.P.2.2	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	
11.	3.2.P.5.2	• Wavelength is not mentioned in the chromatographic condition of the assay test in analytical procedure. • Calculation formula used for assay test in the analytical procedures shall be submitted.	
12.	3.2.P.5.3	Analytical method verification studies of the finished product along with analytical record shall be submitted.	
13.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted regarding the submitted chromatograms as no information is available on them neither any wavelength is mentioned on them. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	

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

Reply submitted by the firm:

Sr. No.	Reason for deferment.	Reply by the firm

1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000488 with renewal date from 05-05-2021.
2.	Evidence of approval of manufacturing facility/section approval from licensing authority shall be submitted.	Firm has submitted copy of letter No. F. 2-4/98-Lic(Pt-I) dated 07-06-2022 mentioning Sterile eye ointment/Topical cream (General).
3.	Detailed information of section 1.6.5 shall be submitted with name of the drug substance manufacturer, GMP certificate vendor qualification etc.	Submitted.
4.	• Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted. • Copies of executed BMR's shall be submitted.	Firm has submitted revised table for literature references. ***However, information is not corrected in the table. Furthermore, no fee is submitted by the firm.*** Submitted.
5.	Detailed information of these sections shall be submitted.	Submitted.
6.	• Specifications of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph has mentioned limits for Nitrate while the specifications provided by the drug product manufacturer has no limits for nitrate. Clarification shall be submitted.	Submitted. Firm has submitted that drug substance manufacturer has revised specifications as per USP. Therefore, it is requested to go through the CTD application process, may kindly be approval in our favor at the earliest convenience. ***No clarification is submitted by the firm regarding nitrate limits.***
7.	Analytical procedures for the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	Firm has submitted analytical procedures from both the drug substance manufacturer and drug product manufacturer. *However, the analytical procedures from drug product manufacturer is different from both the USP monograph and drug substance manufacturer as the assay method used by the USP monograph and drug substance manufacturer is by HPLC while the assay method provided by the drug product manufacturer is by titration.*
8.	• Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted. • Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.	Firm has submitted updated analytical method verification studies for the drug product. *Analytical method verification studies for drug substance not provided.* *No clarification is submitted by the firm against this point.*
9.	• COA of the drug substance from drug product manufacturer with complete details i.e. batch number, manufacturing date, Expiry date etc. shall be submitted.	Firm has submitted COA of the drug substance with batch number 214001015, mfg. date August 2018 and retest date of July 2023. ***Not submitted.***

	• Analytical record of the drug substance shall be submitted. • Clarification shall be submitted for the COA of the drug substance provided by the drug product manufacturer as it has mentioned test date of 12-1-2018.	Firm has submitted that date on the COA of the drug substance had been printed wrong.
10.	• Pharmaceutical equivalence of the applied formulation with reference product with all the tests included in the official monograph shall be submitted. • Details of the product including name of manufacturer, manufacturing date, expiry date etc. against which PE is performed shall be submitted.	Firm has submitted new studies of pharmaceutical equivalence against Quench cream, batch No. 15-08-2018 manufactured by Ferozsons Laboratories Limited by performing quality tests of identification, pH, weight fill comparison and drug release.
11.	• Wavelength is not mentioned in the chromatographic condition of the assay test in analytical procedure. • Calculation formula used for assay test in the analytical procedures shall be submitted.	Firm has submitted new analytical procedures in line with USP monograph.
12.	Analytical method verification studies of the finished product along with analytical record shall be submitted.	Submitted.
13.	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of batch size, date of initiation, API lot number shall be submitted. • Justify the standard preparation and sample preparation with respect to the submitted analytical procedure as the final concentration of both standard and sample preparation are completely different. • Justification shall be submitted regarding the submitted chromatograms as no information is available on them neither any wavelength is mentioned on them. • Stability data sheets has 35% RH in real time stability. Clarification shall be submitted. • • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory	Firm has submitted new stability data sheets wherein they have mentioned 1kg of batch size and 214001015 as API lot number. Firm has submitted that preparation of standard and sample solution has been revised to an easy format for clear and easy understanding. *However, no justification is submitted. In the initially submitted data both the standard solution and sample solution were completely different from each other.* Firm has submitted that in old version of HPLC software system this information was not added in chromatograms. As per regulatory requirements, the software has been updated. The stability data after upgradation is reprinted for regulatory convenience. Firm has submitted that stability of the product had been conducted at 65% ± 5% RH. By mistake the results of the stability were compiled on the stability sheets of eye drops. ***Not submitted.*** Firm has submitted copy of GMP certificate No. 6107596 dated 01-07-2022 issued by Food & Drug Administration Maharashtra State India valid till 30-06-2023. ***GMP certificate is not valid.*** ***Not submitted.***

	authority of country of origin shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	***Not submitted.*** Submitted.

Decision OF 333rd meeting of Registration Board: Deferred for following:

- Firm will submit full fee of 30,000/- for submission of different data at different times.
- Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.
- Justification shall be submitted regarding the analytical procedures as the assay method used by the USP monograph and drug substance manufacturer is by HPLC while the assay method provided by the drug product manufacturer is by titration.
- Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted.
- Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug product manufacturer as that of the drug substance manufacturer.
- Analytical record of the drug substance shall be submitted.
- Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
- Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Reply submitted by the firm:

S. No.	**Observation**	**Reply submitted by the firm**
1.	Firm will submit full fee of 30,000/- for submission of different data at different times.	Not submitted.
2.	Table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.	Submitted with fee of 7500/- vide slip No. 3786025038 dated 08-01-2024.
3.	Justification shall be submitted regarding the analytical procedures as the assay method used by the USP monograph and drug substance manufacturer is by HPLC while the assay method provided by the drug product manufacturer is by titration.	No justification is submitted by the firm. They only submitted USP monograph and the analytical procedures by FPP.
4.	Analytical method verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
5.	Clarification shall be submitted regarding the exact results of the analytical method verification studies submitted by the drug	No clarification is submitted by the firm against this point.

	product manufacturer as that of the drug substance manufacturer.	
6.	Analytical record of the drug substance shall be submitted.	Not submitted.
7.	Approval of API/ DML/GMP certificate (Valid) of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Not submitted. Firm has stated that they had ordered the drug substance as sample for R&D. the supplier had provided GMP certificate that was valid at the time of sample shipment. We will collect the new GMP of the drug substance manufacturer when we commercially order the purchase order of the drug substance after the registration of the drug product.
8.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted	Firm has submitted copy of invoice No. SS-281-2018 dated 28-12-2018 attested by assistant Director, DRAP, Karachi dated 03-01-2019
9.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted.

Decision: Registration Board decided to reject the instant application.
The Board after observing the casual behaviour of the firm further decided to refer the case to QA&LT, Division of detailed evaluation of the firm and also evaluate the product development, clearance documents of the firm.

Case 03: Registration applications Imported (Human) drugs deferred cases on Form 5F

251.	Name, address of Applicant / Importer	**M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi.**
	Details of Drug Sale License of importer	DSL No. DHODSK(Drugs)/-809. Status: Drug License by way of whole sale. Address: M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi. Valid up to 08-12-2027.
	Name and address of marketing authorization holder (abroad)	M/s Zydus Healthcare Limited. CTS No. 460/6, I.B. Patel Road, Village Pahadi, Goregaon East, Mumbai-400063, India.
	Name, address of manufacturer(s)	M/s SP Accure Labs Pvt. Ltd., Plot No. 12, Biotech Park, Phase II, Lalgadi Malakpet (V) Shamirpet (M), Medchal – Malkajgiri (Dist.), Telangana (State), India.
	Name of exporting country	India.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) • Colored copy of CoPP (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country. However, as per COPP certificate the product license holder is M/s SPAL Pvt. Ltd., India.

		• Copy of GMP certificate No. 82237/TS/2022 dated 03-03-2022 issued by Drugs Control Administration, Telangana in the name of M/s SPAL Private Limited valid till 02-03-2023 is submitted.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of sole distribution letter between M/s Wellociti Healthcare (Pvt.) Ltd., Office No. 209, 2nd Floor, Thair Plaza, Near City Court, Karachi and M/s Zydus Healthcare Limited, located at Zydus corporate park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandinagar Highway, Ahmad Abad, India. Document has mentioned that M/s Zydus Healthcare Limited, is MAH. However, CoPP has mentioned M/s SPAL Pvt. Ltd., India as MAH for the product. Agreement has mentioned that M/s Wellociti upon registration of products in Pakistan shall be the sole authorized importer for the products (14) in Pakistan. Firm has also submitted copy of contract manufacturing agreement between M/s Zydus Healthcare Limited and M/s SP Accure Labs Pvt. Ltd., wherein M/s Zydus Healthcare Limited is engaged in sale marketing and distribution of wide range of pharmaceutical products in various countries. While M/s SP Accure Labs Pvt. Ltd., is engaged in manufacturing, sales and distribution of pharmaceutical products in India.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 23761: dated 21-11-2023.
	Details of fee submitted	PKR 150,000/-: vide slip No. 7551511337 dated 07-08-2023.
	The proposed proprietary name / brand name	**Cisplat 50.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml vial contains: Cisplatin …… 50mg.
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion.
	Pharmacotherapeutic Group of (API)	Other Antineoplastic Agents, Platinum compound.

	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 vials in a carton along with pack insert.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Cisplatin 50mg/vial, USFDA approved.
	For generic drugs (me-too status)	Cipintu concentrated solution for infusion, Himmel pharma, Reg. No. 099486.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacturer, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Sun pharmaceutical Industries Limited, A-7/A-8, M.I.D.C., Industrial Area, Ahmednagar – Maharashtra, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/NKD/72512/2018/11/24746 dated 30-08-2018 issued by Food & Drugs Administration M.S. Bandra - Mumbai valid till 29-08-2021 is submitted.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 72 months' real time stability data at 25°± 2°C / 60% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015). • 06 month accelerated stability data 40°C ± 2°C / 75% RH ± 5% RH of 03 batches (AH-3-08013, AH-3-08014 & AH-3-08015).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established against product i.e. Cisplatin NeoCorp 1mg/ml, Lot No. JG5128 MAH Hexal AG Industries by performing the following tests; Description, Identification, pH, Assay & Related substances.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	10ml amber 20mm collar vials (flat bottoms) with 20mm 4432/50 gray fluorotec B2 coating westarrs serum stopper and sealed with 20mm easy to open C/L Alu. Seals with matt finish plastic purple.
	Stability study data of drug product, shelf life and storage conditions	• 36-month real time stability data at 30°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)). • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (CISI00118C (I), CISI00118C (U) & CISI00218C (I)).

Evaluation by PEC:

Sr. No.	**Section**	Observations	Reply by the firm.
1.	•	• Notarized agreement shall be submitted. • Address of the marketing authorization holder mentioned in 1.4 and that mentioned in sole distribution agreement are different. Clarification shall be submitted.	
2.		Valid, notarized and legalized copy of GMP certificate of the manufacturer shall be submitted.	
3.	•	• Notarized and legalized copy of CoPP certificate shall be submitted. • Submitted CoPP has mentioned M/s SPAL Pvt. Ltd., India as product license holder while the agreement of the M/s Wellociti is with M/s Zydus Healthcare Limited. Clarification shall be submitted.	
4.	1.4.1	Section 1.4.1 has mentioned domestic and export sales while the sole distribution agreement has mentioned in Pakistan only. Clarification shall be submitted.	
5.	3.2.S.4.2	BP monograph has mentioned injection volume of 20µl while the specifications submitted by both the drug substance and drug product manufacturer has mentioned 10µl. clarification shall be submitted.	
6.	3.2.P.1	Qualitative composition of the applied formulation is different from innovator with respect to mannitol. Clarification shall be submitted.	
7.	3.2.P.2.2	Justification shall be submitted for not performing uniformity of content, sterility and bacterial endotoxin test in PE studies.	

Decision of 333rd meeting of registration Board: Deferred for submission of reply to above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observations	Reply by the firm.

1.	• Notarized agreement shall be submitted. • Address of the marketing authorization holder mentioned in 1.4 and that mentioned in sole distribution agreement are different. Clarification shall be submitted.	Firm has once again submitted coloured copy of agency agreement. Firm has submitted that SPAL is manufacturer, as per India FDA rule this is third party manufacturing product so license holder is SPAL. They further submitted that they also shared a letter for relationship between Zydus and SPAL. *As per submitted CoPP certificate (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country. However, as per COPP certificate the product license holder is M/s SPAL Pvt. Ltd., India.*
2.	Valid, notarized and legalized copy of GMP certificate of the manufacturer shall be submitted.	Coloured copy of GMP certificate No. 109200/TS/2023 dated 28-03-2023 issued by Drugs Control Administration, Telangana in the name of M/s SPAL Private Limited valid till 26-03-2024 is submitted. *GMP certificate is submitted is coloured copy*.
3.	• Notarized and legalized copy of CoPP certificate shall be submitted. • Submitted CoPP has mentioned M/s SPAL Pvt. Ltd., India as product license holder while the agreement of the M/s Wellociti is with M/s Zydus Healthcare Limited. Clarification shall be submitted.	*Not submitted.* Firm has submitted that SPAL is manufacturer, as per India FDA rule this is third party manufacturing product so license holder is SPAL. They further submitted that they also shared a letter for relationship between Zydus and SPAL.
4.	Section 1.4.1 has mentioned domestic and export sales while the sole distribution agreement has mentioned in Pakistan only. Clarification shall be submitted.	Firm has submitted that agreement between Zydus and Wellociti is for Pakistan sale only. SPAL is contract manufacturer of Zydus for domestic as well as export. *Section 1.4.1 from the applicant had mentioned domestic and export sales while agency agreement was for Pakistan only.*
5.	BP monograph has mentioned injection volume of 20µl while the specifications submitted by both the drug substance and drug product manufacturer has mentioned 10µl. clarification shall be submitted.	Firm has submitted that 20µl injection volume was mentioned for related substances and for assay it was mentioned as 10µl. they also submitted BP monograph for the same.
6.	Qualitative composition of the applied formulation is different from innovator with respect to mannitol. Clarification shall be submitted.	Firm has submitted that SPAL has chosen Neocorp as reference product which does not contain mannitol in its composition. SPAl product is similar to Neocorp which is the innovator. So, the composition of the applied formulation which was applied in module 3.2.P.1 does not contain mannitol. They also submitted pictures of Neocorp product. However, the language is other than English that could not be read.

7.	Justification shall be submitted for not performing uniformity of content, sterility and bacterial endotoxin test in PE studies.	Firm has submitted that PE studies only contains the information regarding the test vs RLD qualitative information. Therefore, uniformity of content, sterility and bacterial endotoxin test will not be reflected in the PE studies.

Decision of 336th meeting of Registration Board: Deferred for following;

- Notarized agreement shall be submitted.
- Valid, Notarized and legalized copy of CoPP certificate shall be submitted.

Reply submitted by the firm:

- Firm has submitted two documents regarding the agreement wherein M/s Zydus Healthcare Limited has stated that they will supply the products manufactured by M/s SP Accure Labs Pvt. Ltd., to M/s Wellociti Health Care Pvt. Ltd. The document is notarized from India.
- Second document has also mentioned products with agreement between M/s Zydus Healthcare Limited, India and M/s Wellociti Health Care Pvt. Ltd., Pakistan. This document is also Notarized from Government of India.
- Firm has also submitted copy of contract manufacturing agreement between M/s Zydus Healthcare Limited and M/s SP Accure Labs Pvt. Ltd., wherein M/s Zydus Healthcare Limited is engaged in sale marketing and distribution of wide range of pharmaceutical products in various countries.

While M/s SP Accure Labs Pvt. Ltd., is engaged in manufacturing, sales and distribution of pharmaceutical products in India. However, this document is not notarized.

- Firm has also submitted GMP certificate No. 143233/TS/2024 dated 25-04-2024 valid till 24-04-2025.
- Firm has submitted CoPP (certificate No. 3474593/TS/2022 dated 21-10-2022 issued by Drugs Control Administration Telangana for cisplatin concentrate for solution for infusion BP 50mg/50ml valid till 24-08-2025 is submitted. The document also confirms that the applied product strength is actually on the market in exporting country. However, CoPP certificate is only notarized from Government of India.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

- **Firm will submit notarized contract manufacturing agreement between M/s Zydus Healthcare Limited and M/s SP Accure Labs Pvt. Ltd.**

Case No. IV: Capacity assessment:

Name of Firm	M/S Welmark Pharmaceuticals
Physical Address:	Plot No.122 Block B phase v industrial estate hattar pakistan
Drug Manufacturing license No.	000614 Valid till 11-04-2022
Contact	info@welmarkpharma.com 0992617660
Date of inspection:	17th June, 2021
Purpose of inspection:	Assessment And Confirmation Of Manufacturing Capacity
Names of inspectors	1. Mr.Faisal Shehzad, Additional Director, DRAP Peshawar. 2. Mr.Atiq Ul Bari, FID DRAP Peshawar.
Names of firm's representatives:	1. Ashfaq ur Rahman (Production Manager) 2. Hamid shah (Quality Control Manager) 3. Mr.Waheed Anjum (Quality Assurance Incharge)

I. BRIEF ABOUT FIRM:

Ms. Welmark Pharmaceuticals situated at Plot No.122 Block B phase v industrial estate Hattar Pakistan. Was visited and inspected as per instructions contained in referred DRAP letter for the assessment of and confirmation of manufacturing surplus capacity in the following manufacturing sections:

1. Liquid Injection (General)
2. Dry Powder Injectable (General)
3. Dry Powder Injectable (Cephalosporin)

The firm was inspected in detail as per scope and relevant manufacturing; packaging and quality control records etc. for the last year were reviewed in detail and concluded accordingly. Manufacturing record/data was evaluated from January 2020 to December 2020 for the said purpose.

REGISTERED PRODUCTS		**Annexure**
Total registered products:	**349**	**A**
Registered products in aforementioned sections	**97**	**B**
Existing contract manufactured products in aforementioned sections	**36**	**C**
Registered products (Export) in aforementioned sections	**14**	

The details of Capacity calculations are as under:

Liquid Injection (General)	
Step wise capacity of General Liquid Ampoule Injection manufacturing	Capacity
Semi Auto Ampoule Washing:	
● **Per single shift** of 7 working hours (Load per Day)	**56,000 amps**
● **Per month** (23 working Days) with single shift of 7 working hours	**1,288,000 amps**
Depyrogenation Capacity (Dryer) :	
● **Per single shift** of 7 working hours (2Load per Day)	**60,000 amps**
● **Per month** (23 working Days) with single shift of 7 hours	**1,380,000 amps**
Ampoule Filling:	
● **Per single shift** of 7 working hours (Load per Day)	**52,500 amps**
● **Per month** (23 working Days) with single shift of 7hours	**1,207,500 amps**
Auto Clave:	
● **Per single shift** of 7 working hours (2Load per Day)	**50,000 amps**
● **Per month** (23 working Days) with single shift of 7 hours	**1,150,000 amps**
Packing Capacity:	
● **Per single shift** of 7 working hours (13 workers)	**28,000 amps**
● **Per month** (23working Days) with single shift of 7 hours	**644,000 amps**
Note: Limiting step in this process is Packing process for calculation Utilized Capacity	

Quarter Wise capacity utilized in General Liquid Injection Section

Quarter	**Actual Production (Amps)**	**Capacity (Amps)**	**Capacity utilized in %**
1st – 2020	721,500	1,932,000	37.34%
2nd – 2020	552,000	1,932,000	28.57%
3rd – 2020	1,272,600	1,932,000	65.86%
4th – 2020	910,500	1,932,000	47.12%
Total	3,456,600	7,728,000	.....
Average per Quarter	864,150	1,932,000	44.72%
Manufacturing Capacity Utilized (Average) =			***44.72%***
Manufacturing Capacity Available (Average) =			***55.28%***

SECTION WISE CAPACITY CALCULATION	
Dry Powder Injectable (Cephalosporin)	
Step wise capacity of General Dry Powder Injection manufacturing	Capacity
Rotary vial Washing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 working hours	**322,000 Vials**
Depyrogenation Capacity (Dryer):	
• **Per single shift** of 7 working hours (2Load per Day)	**28,000 Vials**
• **Per month** (23 working Days) with single shift of 8 hours	**644,000 Vials**
Dry Powder Filling Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**322,000 Vials**
Vial Sealing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,400 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**331,200 Vials**
Packing Capacity:	
• **Per single shift** of 7 working hours (with 13 Workers)	**25,900 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**595,700 Vials**
Note: Limiting step in this process is Filling process for calculation Utilized Capacity	

Quarter Wise capacity utilized in Cephalosporin Powder Injectable Section

Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in %**
1st – 2020	141,350	966,000	14.632%
2nd – 2020	23,761	966,000	2.50%
3rd – 2020	171,319	966,000	17.7%
4th – 2020	187,676	966,000	19.43%
Total	524,106	3,864,000	54.262%
Average per Quarter	131,026	966,000	13.563%
Manufacturing Capacity Utilized (Average) =			***13.563%***
Manufacturing Capacity Available (Average) =			***86.427%***

SECTION WISE CAPACITY CALCULATION

Dry Powder Injectable (General)

Step wise capacity of General Infusion Injectable manufacturing	Capacity
Rotary vial Washing Machine:	

• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (26 working Days) with single shift of 8 working hours	**322,000 Vials**
Depyrogenation Capacity (Dryer):	
• **Per single shift** of 7 working hours (2Load per Day)	**28,000 Vials**
• **Per month** (23working Days) with single shift of 7 hours	**644,000 Vials**
Dry Powder Filling Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,000 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**322,000 Vials**
Vial Sealing Machine:	
• **Per single shift** of 7 working hours (Load per Day)	**14,400 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**331,200 Vials**
Packing Capacity:	
• **Per single shift** of 7 working hours (with 13 Workers)	**25,900 Vials**
• **Per month** (23 working Days) with single shift of 7 hours	**595,700 Vials**

Note: Limiting step in this process is Filling process for calculation Utilized Capacity

Quarter Wise capacity utilized in General Powder Injectable Section			
Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in %**
1st – 2020	56,991	966,000	5.90%
2nd – 2020	57,848	966,000	5.98%
3rd – 2020	92,319	966,000	9.60%
4th – 2020	80,926	966,000	8.37%
Total	288,084	3,864,000	29.85%
Average per Quarter	72,021	234,000	7.462%

Manufacturing Capacity Utilized (Average) = 7.462%
Manufacturing Capacity Available (Average) = *92.538%*

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details							
S. #	**Equipment**	**Qty.**	**Capacity per day (tests)**	**Capacity per month (tests)**	**Max: utilization / month (tests)**	**Capacity utilization (%age)**	**Capacity available %age)**
1.	HPLC	2	4	92	69	74.5	25.5
2.	FTIR	1	20	460	29	6.15	93.85
3.	Spectrophotometer (Hitachi U-2800)	1	10	230	27	11.39	88.61
4.	Sterility Testing	Lab	4	92	13	14.17	85.83
5.	Moisture Analyser	1	50	1150	350	30.43	69.56
6.	Total Organic carbon Analyser	1	30	690	300	43.47	56.52
7.	Karl Fischer	1	30	690	129	18.69	81.30
8.	pH meter	1	50	1150	130	11.30	88.7

9.	Conductivity Meter	1	50	1150	380	33.04	66.96
10.	Weighing balance	1	50	1150	510	44.34	55.65
11.	Liquid particle Counter	1	29	667	380	57	43
12.	Hot incubator	1	50	1150	350	30.34	69.56
13.	Cool incubator	1	50	1150	350	30.34	69.56
14.	Convection Oven	1	50	1150	610	53.04	46.95
15.	Autoclave	1	10	230	125	54.34	45.65
16.	Weighing balance	1	50	1150	510	44.34	55.65

CAPACITY OF STERILE DRY POWDER INJECTION (GENERAL)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
14	0	0	8	5

CAPACITY OF STERILE INJECTABLE LIQUID AMPOULE (GENERAL)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
41	0	5	9	7

CAPACITY OF DRY POWDER INJECTABLE (CEPHALOSPORIN)

Welmark Pharmaceuticals Registration	Welmark Pharmaceuticals Export Registration	Welmark Pharmaceuticals Pending Applications	Contract Products Registrations	Contract products Pending Applications
42	0	0	21	3

CONCLUSION:

Production and QC capacity utilized and available is summarized below:

Section name	**Manufacturer total registrations**	**Pending application for registration**	**Contract product registration**	**Contract products pending application**	**Manufacturing capacity utilized (average)**	**Manufacturing capacity available (average)**
Sterile Injectable Liquid Ampoule (General)	41	05	09	07	44.72%	55.28%
Sterile Dry Powder Injectable (General)	14	0	08	05	7.462%	92.538%
Sterile Dry Powder Injectable (Cephalosporin)	42	0	21	03	13.563%	86.427%

QC Department

S. No	**Equipment**	**Capacity Available (%)**
1.	HPLC	25.5
2.	FTIR	93.85
3.	Spectrophotometer (Hitachi U-2800)	88.61
4.	Sterility Testing	85.83
5.	Moisture Analyser	69.56

6.	Total Organic carbon Analyser	56.52
7.	Karl Fischer	81.30
8.	pH meter	88.7
9.	Conductivity Meter	66.96
10.	Weighing balance	55.65
11.	Liquid particle Counter	43
12.	Hot incubator	69.56
13.	Cool incubator	69.56
14.	Convection Oven	46.95
15.	Autoclave	45.65
16.	Weighing balance	55.65

Based on the people met, documents reviewed and observations made during the detailed inspection, M/S Welmark Pharmaceuticals situated at Plot No.122 Block B phase v industrial estate hattar pakistan, has **ample surplus capacity** in the manufacturing and quality control laboratory for the purpose of manufacturing on contract basis as summarized above.

SIGNATURES OF INSPECTORS

FIRM'S REPRESENTATIVES	**INSPECTOR**
Mr. Ashfaq ur Rahman (Production Manager)	**Mr. Faisal Shehzad,** Additional Director, DRAP Peshawar.
Mr. Hamid Shah (Quality Control Manager)	**Mr. Atiq Ul Bari** FID DRAP, Peshawar.
Mr. Waheed Anjum (Quality Assurance In-Charge)	

Decision of 321st meeting of Registration Board:

Registration Board deliberated upon the above presented capacity assessment report of M/s Welmark Pharmaceuticals and referred the case back to the panel for confirmation of following from the firm:

a) No. of registered products of M/s Welmark Pharmaceuticals being analyzed on HPLC.
b) No. of registered products of M/s Welmark Pharmaceuticals having pharmacopoeial monographs but are being tested on in-house methods.

Moreover, keeping in view already registered products and present testing capacity, the Board directed M/s Welmark Pharmaceuticals to add 02 more HPLC systems in their Quality Control laboratory.

Registration Board deferred following cases of contract manufacturing from M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan till compliance of above cited points.

As per decision of the registration Board, Chairman registration Board vide letter No. F.15-1/2022-PEC dated 15-08-2023 has assigned Additional Director, DRAP, Peshawar to nominate an officer for confirmation of above points including addition of 02 more HPLCs.

In response to the above said letter, Additional Director (QALT), Islamabad vide No. F.167. Add. Dir. (QALT) dated 30-07-2024 forwarded the report and conveyed that the undersigned inspected M/s Wellmark Pharmaceuticals, plot No. 122, phase 5, Block B, Industrials Estate, Hatter on 11-07-2024.

The establishment has now 4 HPLCs with addition of 2 HPLCs ***and are functional and tests / analysis are*** *being* ***performed as evident from log books*** *(Annexure-A). Moreover, the establishment is conducting test / analysis as per Official Compendium testing procedures for majority of their products except for few for which testing methods are not in Official Compendium and they have the innovator / in-house method (Annexure-B).*

Annex A:

Total number of products	140
Number of products tested by Pharmacopoeial method	107
Number of products tested by Innovator's specifications	33
Number of products tested by In-House specifications	0

Accordingly following cases are placed before the Board for consideration;

252.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan

		By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Anmol 40mg Injection
	Composition	Each Vial Contains: Omeprazole sodium (Lyophilized powder) …..…40mg
	Diary No. Date of R& I & fee	Dy. No. 40718: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm has applied for Omeprazole as sodium (as per master formula). The firm revised Omeprazole to Omeprazole sodium in the label claim. • The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for submission of fee for revision of formulation and capacity assessment of m/s welmark.
	Evaluation by PEC	• The firm submitted the capacity assessment report as presented above. • The firm did not submit the fee for revision of formulation.
	Decision of 312th Meeting: deferred for the following: • latest GMP inspection report of m/s Roryan pharmaceuticals conducted in the last three years. • latest GMP inspection report of m/s Welmark pharmaceuticals conducted in the last three years. • capacity assessment of M/s Welmark pharmaceuticals on the prescribed proforma. • submission of fee for revision of salt form. **submission by the firm:** • Copy of GMP certificate of m/s Roryan pharmaceuticals Pvt. ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • Copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021. • The firm has submitted full fee Rs. 75,000/- for revision of formulation from omeprazole sodium 40mg to omeprazole as sodium 40mg vide challan number 29997310489 dated 04/07/2022. **Label claim:** **Each Vial Contains:** **Omeprazole as sodium ……40mg** **(Lyophilized powder)**	
Decision: Approved with innovator specifications.		
253.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals (Pvt.) Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan

		By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Irosuc 20mg/ml Injection
	Composition	Each injection contains: Iron sucrose ……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 40713: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml ampule x 5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm revised 'iron sucrose' to 'iron (III)-hydroxide-sucrose eq. to elemental iron' without submission of applicable fee. • Adjustment of weight of API as per salt factor is required in master formula. • Proof of international availability of same formulation, same strength and same filled volume in reference regulatory authorities as defined in 275th meeting of the registration board is required. Otherwise, revise the strength in line with the reference product along with submission of applicable fee. • The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for; • Submission of fee for revision of formulation • Adjustment of weight of API in the master formulation • capacity assessment of m/s Welmark
	Evaluation by PEC	• The firm submitted the capacity assessment report as presented above. • The TGA Australia has mentioned iron sucrose as synonym for iron (III)-hydroxide-sucrose. The board may look into the matter of fee. • Adjustment of weight of API as per salt factor is required in master formula.
	Decision of 312th meeting: Deferred for the following • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. • Adjustment of weight of API as per salt factor is required in master formula along with submission of applicable fee. submission by the firm:	

	• copy of GMP certificate of m/s Roryan pharmaceuticals (Pvt.) Ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021. • The firm has submitted full fee Rs. 75,000/- for revision of formulation from Iron Sucrose to Iron (III) hydroxide Sucrose Eq. to elemental Iron 100mg per ampoule (5mL) vide challan number 94055850266 dated 04/07/2022 along with the revised master formula. **Label Claim:** **Each Ampoule (5mL) contains:** **Iron (III) hydroxide sucrose complex Eq. to Elemental Iron …….……100mg**	
Decision: Approved.		
254.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Mospro 80mg/ml Injection
	Composition	Each injection contains: Artemether ……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 40715: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Artemether 80mg/ml solution for injection (1ml). PMDA approved
	Me-too status	Malasan Injection (1ml). Reg. No. 30366
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for capacity assessment of m/s welmark.
	Evaluation by PEC	The firm submitted the capacity assessment report as presented above.
	Decision of 312th meeting: Deferred for the following: • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. submission by the firm: • copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021.	
Decision: Approved with innovator specifications. • **Registration letter will be issued after submission of 7500/- fee for change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		

255.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	ME LOXIT 500mg Injection
	Composition	Each ml contains: Mecobalamin ……..…500mcg
	Diary No. Date of R& I & fee	Dy. No. 40714: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mecobalamin injection 500µg (1ml). PMDA approved
	Me-too status	Balco 500mcg IM/IV Injection (1ml). Reg. No. 81484
	GMP status	**Applicant**: could not be confirmed. **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Pharmaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Pharmaceuticals for contract manufacturing. • Latest GMP inspection report of M/s Roryan Pharmaceuticals is required.
	Previous decision	The Board in its 295th meeting deferred the case for capacity assessment of m/s welmark.
	Evaluation by PEC	The firm submitted the capacity assessment report as presented above.
	Decision of 312th meeting: Deferred for the following: • Latest GMP inspection report of M/s Roryan Pharmaceuticals conducted in the last three years. • Latest GMP inspection report of M/s Welmark Pharmaceuticals conducted in the last three years. • Capacity assessment of M/s Welmark Pharmaceuticals on the prescribed proforma. submission by the firm: • Copy of GMP certificate of m/s Roryan pharmaceuticals pvt ltd. no. f.11-52/2022-drap-71 dated 17th June 2022 issued on the basis of inspection conducted on 13/01/2022. • Copy of GMP certificate no. f.11-96/2021-drap-97 dated 23/11/2021 issued on the basis of inspection conducted on 11/11/2021.	
Decision: Approved.		

Agenda of Ms. Saima Hussain

256.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Dynatis Pakistan (Pvt.) Ltd., Plot no. 710, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s. Dynatis Pakistan (Pvt.) Ltd., Plot no. 710, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6025 :03-03-2023
	Details of fee submitted	PKR 30,000/- : vide slip no. 628159695 dated 23-02-2023
	The proposed proprietary name / brand name	Eslicarbazepine 400mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….400mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit requisite fee for application of new molecule, since Me-Too of applied formulation is not been registered yet.	
2.	**3.2.S.4.2**	Assay procedure given by drug substance manufacturer is different from the assay method specified by you in section 3.2.S.4.2, justify for not adopting the same assay method as recommended by drug substance manufacturer.
3.	**3.2.P.2.2.1**	Submit cumulative data sheets of comparative dissolution profile in all three recommended media ,since you have only submitted the raw data sheets and chromatograms.
4.	**3.2.P.5.2**	Justify for keeping the 2 time point sampling for dissolution of 200mg strength, since the innovator product recommends single point acceptance criteria for 200mg tablet of eslicarbazepine.

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

257.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Dynatis Pakistan (Pvt.) Ltd., Plot no. 710, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s. Dynatis Pakistan (Pvt.) Ltd., Plot no. 710, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6024: 03-03-2023
	Details of fee submitted	PKR 30,000/- : vide slip no. 85169557 dated 28-02-2023
	The proposed proprietary name / brand name	Eslicarbazepine 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Eslicarbazepine Acetate….200mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic, Carboxamide Derivatives
	Reference to Finished product specifications	Innovator's specification

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (APTIOM TABLET, 200mg,400mg,600mg,800mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit requisite fee for application of new molecule, since Me-Too of applied formulation is not been registered yet.	
2.	**3.2.S.4.2**	Assay procedure given by drug substance manufacturer is different from the assay method specified by you in section 3.2.S.4.2, justify for not adopting the same assay method as recommended by drug substance manufacturer.
3.	**3.2.P.2.2.1**	Submit cumulative data sheets of comparative dissolution profile in all three recommended media ,since you have only submitted the raw data sheets and chromatograms.
4.	**3.2.P.5.2**	Justify for keeping the 2 time point sampling for dissolution of 200mg strength, since the innovator product recommends single point acceptance criteria for 200mg tablet of eslicarbazepine.

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

258.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12906: 25-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no. 2932484787 dated 28-07-2022
	The proposed proprietary name / brand name	Predbon T ophthalmic Suspension Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Loteprednol Etabonate ….5 mg (0.5%)** **Tobramycin…. 3 mg (0.3%)**
	Pharmacotherapeutic Group of (API)	Corticosteriods/Aminoglycoside Antibiotics
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Lotetab Eye Drops of M/s. Helix Pharma Pvt. Ltd. (Reg.no.092853)

Evaluation by PEC-XV:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1	Justify for not using the sterile Loteprednol Etabonate drug substance, since it is used in the	Firm replied that Sterility tests confirm that ophthalmic suspension is sterile. We have performed the sterility test in our product and

		manufacturing of ophthalmic suspension.	stability documents verify product sterility (Attached as Annex-1). Further the execution of the filling was carries out under Laminar Flow and the finished product was subjected to terminal sterilization through Pak Electron Beam (pvt) Ltd. Reference documents are attached as Annex-I. However, the clarification is needed regarding the procedure of terminal sterilization adopted for the ophthalmic solution, since the submitted manufacturing procedure and Batch manufacturing record did not reflect any such step in the manufacturing of applied product.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.	Submitted
3.	3.2.S.7	Submit complete real time stability data of drug substance till claimed re-test date, since you have only submitted the data of 18 months.	Submitted
4.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
5.	3.2.P.8.1	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in LDPE (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers. Further, neither you have performed the water loss study of applied product while performing the stability study as recommended by ICH guidelines for drug product packaged in semi-permeable membrane, justify how you have complied the ICH standard of performing stability study of drug product packed in semi-permeable containers.	Firm replied that "In accordance with ICH Guidelines we adopted alternative approach to conduct stability studies at higher humidity levels. This allowed us to access the product stability under more rigorous condition that is 30°C ± 2°C/65% ±5% RH and 40°C ± 2°C/75% ±5% RH IICH Guideline QIA (R2) is attached. Furthermore, we determined water loss at the reference relative humidity through calculated measurements attached.

Decision: Deferred for clarification regarding the procedure adopted for terminal sterilization of drug product along with the approval letter from DRAP for outsourcing the terminal sterilization procedure from the third party i.e. *Pak Electron Beam (pvt) Ltd.*

259.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II Industrial Area, Hattar**
	Name, address of Manufacturing site.	**M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II Industrial Area, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10974 : 03-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.35675800229 dated 09-03-2023
	The proposed proprietary name / brand name	Artham 40/240mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Artemether….40mg** **Lumefantrine……240mg**
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	International Pharmacopeia specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO recommended formulation as uncoated tablet
	For generic drugs (me-too status)	Artemef Fort Tablet 40/240mg of M/s Panacea Pharmaceuticals Rawat, Islamabad 056334

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	**3.2.S.7**	Provide reference which confirm the storage condition of drug substance Artemether at refrigerated temperature, since you have submit the stability data performed at refrigerated conditions.
4.	**3.2.P.2.2.1**	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results.
5.	**3.2.P.5.1**	Provide reference of adopted acceptance criteria of dissolution testing. Further, clarify the release pattern of Artemether, since the sampling time point mentioned in the acceptance limit revealed that the artemether is released for prolonged period of time, how the sustained release behavior was shown without using any polymer for extended release.
6.	**3.2.P.5.3**	• Justify for not performing the verification studies on the assay method same as recommended in international pharmacopeia. • According to the international pharmacopeia the peak for artemether is eluted at a retention time of approximately 19 minutes, and that for lumefantrine at a retention time of approximately 34 minutes, while the verification report submitted by you revealed that artemether is eluted at a retention time of approximately 3.18 minutes, and that for lumefantrine at a retention time of approximately 7 minutes, clarify regarding the observed disparity in the retention time of both active substances.
7.	**3.2.P.6**	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	**3.2.P.8.2**	• Justify for not including the identification test while performing the stability of drug product. • Justify for keeping the run time of only 10minutes while performing the assay of drug product via HPLC when the international pharmacopeia recommends that, "*set the UV spectrophotometer detector at 210nm for the first 28 minutes*

		and then switch to about 380 nm for the elution of Lumefantrine which is eluted at a retention time of approximately 34 minute". • Further, clarify for not performing the assay in accordance with the procedure recommended by International Pharmacopeia in the monograph of **Artemether and lumefantrine tablets.**
9.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.

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

260.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II Industrial Area, Hattar**
	Name, address of Manufacturing site.	**M/s. Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II Industrial Area, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11793 : 15-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.97118333389 dated 09-03-2023
	The proposed proprietary name / brand name	Artham 40/240mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Artemether….80mg** **Lumefantrine……480mg**
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	International Pharmacopeia specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO recommended formulation as uncoated tablet
	For generic drugs (me-too status)	MALA DS Tablet 80mg/480mg of M/s. Werrick Pharmaceuticals (Reg.no. 082053)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.1-3.2.S.4.2**	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	**3.2.S.4.3**	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	**3.2.S.7**	Provide reference which confirm the storage condition of drug substance Artemether at refrigerated temperature, since you have submit the stability data performed at refrigerated conditions.
4.	**3.2.P.2.2.1**	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results.
5.	**3.2.P.5.1**	Provide reference of adopted acceptance criteria of dissolution testing. Further, clarify the release pattern of Artemether, since the sampling time point mentioned in the acceptance limit revealed that the artemether is released for prolonged period of time, how the sustained release behavior was shown without using any polymer for extended release.

6.	**3.2.P.5.3**	• Justify for not performing the verification studies on the assay method same as recommended in international pharmacopeia. • According to the international pharmacopeia the peak for artemether is eluted at a retention time of approximately 19 minutes, and that for lumefantrine at a retention time of approximately 34 minutes, while the verification report submitted by you revealed that artemether is eluted at a retention time of approximately 3.18 minutes, and that for lumefantrine at a retention time of approximately 7 minutes, clarify regarding the observed disparity in the retention time of both active substances.
7.	**3.2.P.6**	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	**3.2.P.8.2**	• Justify for not including the identification test while performing the stability of drug product. • Justify for keeping the run time of only 10minutes while performing the assay of drug product via HPLC when the international pharmacopeia recommends that, "*set the UV spectrophotometer detector at 210nm for the first 28 minutes and then switch to about 380 nm for the elution of Lumefantrine which is eluted at a retention time of approximately 34 minute*". • Further, clarify for not performing the assay in accordance with the procedure recommended by International Pharmacopeia in the monograph of **Artemether and lumefantrine tablets.**
9.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.

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

261.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Pharmasol (Pvt.) Ltd. Plot No. 549, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	**M/s.Pharmasol (Pvt.) Ltd. Plot No. 549, Sunder Industrial Estate, Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 16411: dated 27-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.71970862532 dated 03-05-2023
	The proposed proprietary name / brand name	Colistim Injection 4.5MIU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial contains:** **Colistimethate Sodium Powder for reconstitution 4.5MIU (Equivalent to approximate 360mg)**
	Pharmacotherapeutic Group of (API)	Antibiotic (Polymixin Group) ATC code (J01XB01)
	Reference to Finished product specifications	**USP Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Coly-Mycin M 4.5 MIU Injection (USFDA Approved)
	For generic drugs (me-too status)	CBA 150 (Powder for solution for Injection) of M/s. Biocare Pharmaceutica (Reg.no.103783)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings

1.	**1.5.2**	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.
2.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	**3.2.S.4.4**	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.
4.	**3.2.S.7**	Justify for not including test of identification, free colistin test and bacterial endotoxin test while performing the stability study of drug substance.
5.	**3.2.P.1**	• Description of applied 4.5MIU strength is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied 4.5MIU strength is white to slightly yellow fine powder, clarify how the applied product is similar to innovator product/reference product. • Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product. • Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
6.	**3.2.P.5.4**	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.
7.	**3.2.P.8**	• In-use stability studies of opened bottles are required to be submitted along with proposed in-use storage statement and in-use shelf-life. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Justify for not including the test of *Free colistin under Colistimethate Sodium* while performing the stability study of drug product.
8.	**3.2.R.1.1**	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.

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

262.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s.Pharmasol (Pvt.) Ltd. Plot No. 549, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	**M/s.Pharmasol (Pvt.) Ltd. Plot No. 549, Sunder Industrial Estate, Lahore**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12910 : dated 25-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.71970862532 dated 28-04-2023
	The proposed proprietary name / brand name	Colistim Injection 3MIU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Vial Contains:** **Colistimethate Sodium Powder for Reconstitution Eq. to Approximately 240mg…3 MIU**
	Pharmacotherapeutic Group of (API)	Antibiotic (Polymixin Group) ATC code (J01XB01)

	Reference to Finished product specifications	**USP Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colistimethate Sodium 3 million I.U. Powder for Solution for Injection. (MHRA Approved)
	For generic drugs (me-too status)	Nogotex injection 3MIU of M/s Nabiqasim Industries Reg# 110207

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.
2.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	**3.2.S.4.4**	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.
4.	**3.2.S.7**	Justify for not including test of identification, free colistin test and bacterial endotoxin test while performing the stability study of drug substance.
5.	**3.2.P.1**	• Description of applied 4.5MIU strength is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied 4.5MIU strength is white to slightly yellow fine powder, clarify how the applied product is similar to innovator product/reference product. • Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product. • Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
6.	**3.2.P.5.4**	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.
7.	**3.2.P.8**	• In-use stability studies of opened bottles are required to be submitted along with proposed in-use storage statement and in-use shelf-life. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Justify for not including the test of *Free colistin under Colistimethate Sodium* while performing the stability study of drug product.
8.	**3.2.R.1.1**	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.

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

263.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15393 : dated 19-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.79936521138 dated 20-03-2023
	The proposed proprietary name / brand name	Prefen 267mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Film coated tablet contains: Pirfenidone……267mg**
	Pharmacotherapeutic Group of (API)	Pyridones Immunosuppressant
	Reference to Finished product specifications	**Manufacturer's Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 267mg film-coated tablets (USFDA approved)
	For generic drugs (me-too status)	Pirfedow 267mg tablet of M/s Martin Dow Limited. Registration No.107754

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.2**	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm submitted the detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
2.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the same verification report for both drug substance and drug products.
3.	**3.2.P.2.2.1**	Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.	Firm submitted the summarised table of F2 calculation without submitting the complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product in all three physiological media
4.	**3.2.P.5.2**	Submit complete and detailed analytical procedure used for analysis of drug product.	Submitted
5.	**3.2.P.5.3**	• Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product. • Justify for submitting same analytical method verification report for drug substance and drug product.	Without any clarification firm submitted the verification report which was the same report firm submitted in section 3.2.S.4.3 as a verification report for drug substance.
6.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Deferred for submission of following shortcomings:

- **Submit analytical method verification report of drug substance performed by drug product manufacturer.**
- **Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.**
- **Justify for submitting same analytical method verification report for drug substance and drug product.**
- **Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.**

264.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15394 : dated 19-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.60051552014 dated 20-03-2023
	The proposed proprietary name / brand name	Prefen 801mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Film coated tablet contains:** **Pirfenidone……801mg**
	Pharmacotherapeutic Group of (API)	Pyridones Immunosuppressant
	Reference to Finished product specifications	**Manufacturer's Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 801mg film-coated tablets (USFDA approved)
	For generic drugs (me-too status)	Mac-Fenid 801mg tablet of M/s Macter International Limited. Registration No. 105300

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.2**	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm submitted the detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
2.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the same verification report for both drug substance and drug products.
3.	**3.2.P.2.2.1**	Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.	Firm submitted the summarised table of F2 calculation without submitting the complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product in all three physiological media

4.	**3.2.P.5.2**	Submit complete and detailed analytical procedure used for analysis of drug product.	Submitted
5.	**3.2.P.5.3**	• Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product. • Justify for submitting same analytical method verification report for drug substance and drug product.	Without any clarification firm submitted the verification report which was the same report firm submitted in section 3.2.S.4.3 as a verification report for drug substance.
6.	**3.2.R.1.1**	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Deferred for submission of following shortcomings:

- **Submit analytical method verification report of drug substance performed by drug product manufacturer.**
- **Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.**
- **Justify for submitting same analytical method verification report for drug substance and drug product.**
- **Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.**

265.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Saffron Pharmaceuticals (Pvt.) Limited 19-km, Sheikhupura Road, Faislabad**
	Name, address of Manufacturing site.	**M/s. Saffron Pharmaceuticals (Pvt.) Limited 19-km, Sheikhupura Road, Faislabad**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10833 : dated 02-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.355926665049 dated 15-03-2023
	The proposed proprietary name / brand name	Lignocaine 1% Injection (3.5ml) IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Lidocaine Hydrochloride….10mg**
	Pharmacotherapeutic Group of (API)	Local Anesthetic
	Reference to Finished product specifications	**USP Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lidocaine HCl 1% w/v Solution for Injection (MHRA Approved) 2ml,5ml,10ml,20ml

	For generic drugs (me-too status)	Anacaine 1% Injection of M/s. Akson (Reg.no. 052412) 2ml

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.8-15.9	Submit evidence of international approved reference of applied volume i.e. 3.5ml, since the submitted international reference and Me-Too evidence both are available in the volume size of 2ml,5ml,10ml or 20ml.
2.	3.2.S.4.1	• Submit specification of drug substance used for analysis by the drug product manufacturer. • Justify for not using sterile API for the manufacturing of injectable drug product, since the specification did not mention the test of sterility and Bacterial Endotoxin Test.
3.	3.2.S.4.2	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
4.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
5.	3.2.P.1	Justify the formulation without any excipient as submitted in section 3.2.P.1 of module 3

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

266.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura**
	Name, address of Manufacturing site.	**M/s. Bajwa Pharmaceuticals (Pvt.) Ltd., 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11789 : dated 15-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.98430327031 dated 26-12-2023
	The proposed proprietary name / brand name	**Phenytoin Sodium Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml ampoule contains:** **Phenytoin Sodium….250mg**
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	**USP Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Phenytoin Sodium 50mg/ml)
	For generic drugs (me-too status)	Epigran 250mg/5ml IV/IM of M/s. Atco (Reg.no. 047189)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1	Submit specification of drug substance used for analysis by the drug product manufacturer with the clarification that which pharmacopeia has been followed for analysis of drug substance by finished product manufacturer.
2.	3.2.S.4.2	• Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer, since the submitted analytical procedure neither

		included the test of free phenytoin, water content test and appearance of solution test as recommended in the specification of drug substance by drug substance manufacturer. • Justify for using different assay method for analysis of drug substance by drug product manufacturer from that recommended by drug substance manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.1	Justify the formulation without any pH adjuster, since the innovator/reference product used sodium hydroxide for pH adjustment.
5.	3.2.P.2.2.1	Justify for not including all the quality test as per specification of drug product in the pharmaceutical equivalence study of drug product.
6.	3.2.P.3.3	Description of Manufacturing procedure given in the requisite section reflect that the drug product neither undergone any terminal sterilization process nor the manufacturing has been done under aseptic condition, justify for not taking any sterilization measure while the manufacturing of applied formulation from the non-sterile drug substance.
7.	3.2.P.5.1	Justify for not including the test of identification, Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* in the specification of drug product.
8.	3.2.P.5.4	Justify for not including the bacterial endotoxin test, sterility test, test of Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* while performing the batch analysis of drug product, since these test are recommended by the USP Monograph of "**Phenytoin Sodium Injection".**
9.	3.2.P.8	Justify for not including the bacterial endotoxin test, test of Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* while performing the stability study of drug product, since these test are recommended by the USP Monograph of "**Phenytoin Sodium Injection".**

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

267.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10769 : dated 28-04-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.85181845 dated 07-02-2023
	The proposed proprietary name / brand name	**L-Carta 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml vial contains:** **Levocarnitine…..1000mg**
	Pharmacotherapeutic Group of (API)	Metabolic/Endocrine Quaternary Amines
	Reference to Finished product specifications	**USP Specification**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	MHRA Approved (Carnitor® 1 g Solution for Injection)
	For generic drugs (me-too status)	Kefei Injection of M/s. R.G. Pharmaceuticals Pvt. Ltd. Karachi (Reg.no.059054)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1	Submit specification of drug substance used for analysis by the drug product manufacturer with the clarification that which pharmacopeia has been followed for analysis of drug substance by finished product manufacturer.
2.	3.2.S.4.2	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.5.2	Submit detailed analytical procedure used for the analysis of drug product, since you have submitted the copy of Pharmacopeial monograph.
5.	3.2.P.5.3	Submit the detailed of concentrations used in the different parameters of verification studies of drug product, since you have only submitted the results of chromatograms.
6.	3.2.P.5.1	Justify for not including the test of identification, Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* in the specification of drug product.
7.	3.2.P.5.4	Justify for not including the test of Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* while performing the batch analysis of drug product, since these test are recommended by the USP Monograph of "**Levocarnitine Injection".**
8.	3.2.P.8	Justify for not including the test of Particulate matter in injection and other test required under the head of *Injections and Implanted Drug Products* while performing the stability study of drug product, since these test are recommended by the USP Monograph of "**Levocarnitine Injection".**
9.	3.2.P.8.3	○ Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. ○ Documents for the procurement of API with approval from DRAP (in case of import).

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

Previously Deferred of Form 5-F (Local Manufacturing):

268.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3315 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.5069866666 dated 09-01-2023
	The proposed proprietary name / brand name	Neprival 24mg/26mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….24mg Valsartan…..26mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 24/26mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 093098)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.
5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.
6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.
9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision of 336th meeting of Registration Board:

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard	Firm claimed that it was a typographical mistake, now they are submitting the corrected version of Form 5-F.
2.	Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay.	Firm submitted the amended specification of drug substance in accordance with the specification of drug substance manufacturer.
3.	Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.	Firm submitted the response of drug substance manufacturer i.e. The pH was established according to batches testing result.
4.	• Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard. • Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.	Firm replied that "Performing the validation study on the assay method is the same as that specified in section 3.2. S.4.2. The assay test method in section 3.2.S.4.2 and 3.2.S.4.3.2 is the same. There is a little difference between them, including that addition of the system suitability requirement and optimization of the procedure for the item assay in section 3.2. S.4.3.2. It has no effect on the product testing."
5.	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.	Firm submitted the revised analysis report in which result of enantiomeric purity test is included along with the results of other test.
6.	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.	Firm replied that "The retest date for API is proposed to 48 months. 48 months stability data for the batches 57317080101-03 under the condition of 25±2°C and 60±5%RH has been included in page 364-366/366 of DMF (Sacubitril Valsartan 2019022C OP A02), please check. No stability data under the condition of 30±2°C and 60±5%RH (Zone IVA) is available so far. 36 months stability data for the batches 57319010802-04 under the condition of 30±2°C and 75±5%RH (Zone IV-B) is attached as Annex 1, please check.
7.	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.	Firm submitted a revised pharmaceutical equivalence report including the results of all the test specified in the specification of drug product.
8.	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.	Firm submitted the revised method and acceptance criteria of dissolution test which is in accordance with innovator product.

9.	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.4 regarding Assay Validation report: 1. Analytical Method Validation was performed and submitted for Assay test was for strength Sacubitril / valsartan 24/26 mg with considering the fact that final sample concentration of assay sample for all strengths are approximately same i.e. Sacubitril / valsartan 24/26 mg mg/ml) Sacubitril / valsartan 49 / 51 mg mg/ml) Sacubitril / valsartan 97 / 103 mg mg/ml) Sacubitril (0.038 mg/ml) Valsartan (0.041 - Sacubitril (0.038 mg/ml) Valsartan (0.041 Sacubitril (0.039 mg/ml) Valsartan (0.041 However, due to difference in weight per tablet, additionally we have performed and being submitted Analytical Method Validation for strengths Sacubitril / valsartan 49/ 51 mg and Sacubitril / valsartan 97/103 mg as both strengths are dose proportional and same AMV can be applied to both these strengths. Attachment: Analytical Method Validation Sacubitril / valsartan (49/51 mg & 97/103 mg)"
10.	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.5 regarding average weight of tablet in batch analysis report of drug product: Although the weight of uncoated tablet as per the composition given in section 3.2.P.1 is 205.0 mg / tablet, however, average weight of coated tablet mentioned in batch analysis report of drug product Sacubitril / valsartan 24/26 mg is 204.9 mg/tablet which is slightly on lower side in comparison with uncoated tablet but within tolerance limits as covered in drug product specifications i.e. 201.56-222.78 mg/tab. Same is followed for other two strengths as well i.e. Sacubitril / Valsartan tablet 49/51 mg and Sacubitril / Valsartan tablet 97/103 mg.
11.	Submit updated stability of drug product, since you have submitted stability data of only three months.	Firm submitted the stability data of drug product till 6th month.
12.	Submit detailed calculation of dispensed weight of active per tablet.	Submitted

Decision: Deferred for providing the reference adopted for setting acceptance limit of weight variation of coated tablet along with scientific justification of getting the obtained weight of coated tablet on the lower side comparing the theoretical weight of uncoated tablet.

269.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3316 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.243624158 dated 13-01-2023
	The proposed proprietary name / brand name	Neprival 49mg/51mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….49mg Valsartan…..51mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 49/51mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 093083)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.
5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.
6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.

9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard	Firm claimed that it was a typographical mistake, now they are submitting the corrected version of Form 5-F.
2.	Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay.	Firm submitted the amended specification of drug substance in accordance with the specification of drug substance manufacturer.
3.	Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.	Firm submitted the response of drug substance manufacturer i.e. The pH was established according to batches testing result.
4.	• Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard. • Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.	Firm replied that "Performing the validation study on the assay method is the same as that specified in section 3.2. S.4.2. The assay test method in section 3.2.S.4.2 and 3.2.S.4.3.2 is the same. There is a little difference between them, including that addition of the system suitability requirement and optimization of the procedure for the item assay in section 3.2. S.4.3.2. It has no effect on the product testing."
5.	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.	Firm submitted the revised analysis report in which result of enantiomeric purity test is included along with the results of other test.
6.	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.	Firm replied that "The retest date for API is proposed to 48 months. 48 months stability data for the batches 57317080101-03 under the condition of 25±2°C and 60±5%RH has been included in page 364-366/366 of DMF (Sacubitril Valsartan 2019022C OP A02), please check. No stability data under the condition of 30±2°C and 60±5%RH (Zone IVA) is available so far. 36 months stability

		data for the batches 57319010802-04 under the condition of 30±2°C and 75±5%RH (Zone IV-B) is attached as Annex 1, please check.
7.	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.	Firm submitted a revised pharmaceutical equivalence report including the results of all the test specified in the specification of drug product.
8.	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.	Firm submitted the revised method and acceptance criteria of dissolution test which is in accordance with innovator product.
9.	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.4 regarding Assay Validation report: 1. Analytical Method Validation was performed and submitted for Assay test was for strength Sacubitril / valsartan 24/26 mg with considering the fact that final sample concentration of assay sample for all strengths are approximately same i.e. Sacubitril / valsartan 24/26 mg mg/ml) Sacubitril / valsartan 49 / 51 mg mg/ml) Sacubitril / valsartan 97 / 103 mg mg/ml) Sacubitril (0.038 mg/ml) Valsartan (0.041 - Sacubitril (0.038 mg/ml) Valsartan (0.041 Sacubitril (0.039 mg/ml) Valsartan (0.041 However, due to difference in weight per tablet, additionally we have performed and being submitted Analytical Method Validation for strengths Sacubitril / valsartan 49/ 51 mg and Sacubitril / valsartan 97/103 mg as both strengths are dose proportional and same AMV can be applied to both these strengths. Attachment: Analytical Method Validation Sacubitril / valsartan (49/51 mg & 97/103 mg)"
10.	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.5 regarding average weight of tablet in batch analysis report of drug product: Although the weight of uncoated tablet as per the composition given in section 3.2.P.1 is 205.0 mg / tablet, however, average weight of coated tablet mentioned in batch analysis report of drug product Sacubitril / valsartan 24/26 mg is 204.9 mg/tablet which is slightly on lower side in comparison with uncoated tablet but within tolerance limits as covered in drug product specifications i.e. 201.56-222.78 mg/tab. Same is followed for other two strengths as well i.e. Sacubitril / Valsartan tablet 49/51 mg and Sacubitril / Valsartan tablet 97/103 mg.

11.	Submit updated stability of drug product, since you have submitted stability data of only three months.	Firm submitted the stability data of drug product till 6th month.
12.	Submit detailed calculation of dispensed weight of active per tablet.	Submitted

Decision: Deferred for providing the reference adopted for setting acceptance limit of weight variation of coated tablet along with scientific justification of getting the obtained weight of coated tablet on the lower side comparing the theoretical weight of uncoated tablet.

270.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	**M/s. Martin Dow Marker Limited 07-Jail Road, Quetta.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3317 dated : 06-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.50178601519 dated 13-01-2023
	The proposed proprietary name / brand name	Neprival 97mg/103mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Sacubitril….97mg Valsartan…..103mg
	Pharmacotherapeutic Group of (API)	Angiotensin II Receptor Antagonist
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Entresto Tablet 24mg/26mg, 49mg/51mg, 97mg/103mg)
	For generic drugs (me-too status)	Valsatril Tablets 97/103mg Tablet Sami Pharmaceuticals (Pvt.) Ltd. (Reg.no. 103096)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.2**	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard
2.	**3.2.S.4.1**	• Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay. • Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.
3.	**3.2.S.4.2**	Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard.
4.	**3.2.S.4.3**	Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.

5.	**3.2.S.4.4**	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.
6.	**3.2.S.7**	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.
7.	**3.2.P.2.2.1**	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.
8.	**3.2.P.5.2**	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.
9.	**3.2.P.5.4**	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.
10.	**3.2.P.5.5**	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.
11.	**3.2.P.8**	Submit updated stability of drug product, since you have submitted stability data of only three months.
12.	**3.2.R.1.1**	Submit detailed calculation of dispensed weight of active per tablet.

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings**.**

Response of the firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Innovator label claim is "*Each film-coated tablet contains 24.3 mg sacubitril and 25.7 mg valsartan (as sacubitril valsartan sodium salt complex)",* while the label claim mentioned by you is "*Each film-coated tablet contains 24mg sacubitril and 26mg valsartan",* same difference is observed in other 2 stregnths,so clarification is required in this regard	Firm claimed that it was a typographical mistake, now they are submitting the corrected version of Form 5-F.
2.	Justify for adopting different specification of drug substance by drug product manufacturer from that recommended by the drug substance specifically with reference to acceptance limit of water content and assay.	Firm submitted the amended specification of drug substance in accordance with the specification of drug substance manufacturer.
3.	Further, please provide the reference of acceptance criteria of pH , since the test of pH is not included in the specification of drug substance manufacturer.	Firm submitted the response of drug substance manufacturer i.e. The pH was established according to batches testing result.
4.	• Justify for not following the same procedure for analysis of enantiomer of valsartan and sacubitril as specified by the drug substance manufacturer. Similarly, adopted assay procedure of drug substance by drug product manufacturer is also not in accordance with the assay method of drug substance manufacturer, clarification is required in this regard. • Justify for performing the validation studies on assay method different from that specified in section 3.2.S.4.2.	Firm replied that "Performing the validation study on the assay method is the same as that specified in section 3.2. S.4.2. The assay test method in section 3.2.S.4.2 and 3.2.S.4.3.2 is the same. There is a little difference between them, including that addition of the system suitability requirement and optimization of the procedure for the item assay in section 3.2. S.4.3.2. It has no effect on the product testing."

5.	Justify for not performing the enantiomeric purity test by the drug product manufacturer while analysis of drug substance, as evident from the batch analysis report.	Firm submitted the revised analysis report in which result of enantiomeric purity test is included along with the results of other test.
6.	Stability data of 12 months has been submitted by the drug substance manufacturer, while the innovator literature revealed that the proposed re-test period of 36 months is suggested for innovator product, in this regard clarify for submitting the stability data of only 12 months.	Firm replied that "The retest date for API is proposed to 48 months. 48 months stability data for the batches 57317080101-03 under the condition of 25±2°C and 60±5%RH has been included in page 364-366/366 of DMF (Sacubitril Valsartan 2019022C OP A02), please check. No stability data under the condition of 30±2°C and 60±5%RH (Zone IVA) is available so far. 36 months stability data for the batches 57319010802-04 under the condition of 30±2°C and 75±5%RH (Zone IV-B) is attached as Annex 1, please check.
7.	Justify for not performing all the quality test while establishing the pharmaceutical equivalence against the innovator product.	Firm submitted a revised pharmaceutical equivalence report including the results of all the test specified in the specification of drug product.
8.	Justify for not adopting the acceptance criteria of dissolution test as recommended by the innovator brand, further dissolution conditions are also not in accordance with innovator product.	Firm submitted the revised method and acceptance criteria of dissolution test which is in accordance with innovator product.
9.	Justify for submitting the same assay validation report for all strength despite the fact that all strength has different weight per tablet, which is crucial for sample preparation.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.4 regarding Assay Validation report: 1. Analytical Method Validation was performed and submitted for Assay test was for strength Sacubitril / valsartan 24/26 mg with considering the fact that final sample concentration of assay sample for all strengths are approximately same i.e. Sacubitril / valsartan 24/26 mg mg/ml) Sacubitril / valsartan 49 / 51 mg mg/ml) Sacubitril / valsartan 97 / 103 mg mg/ml) Sacubitril (0.038 mg/ml) Valsartan (0.041 - Sacubitril (0.038 mg/ml) Valsartan (0.041 Sacubitril (0.039 mg/ml) Valsartan (0.041 However, due to difference in weight per tablet, additionally we have performed and being submitted Analytical Method Validation for strengths Sacubitril / valsartan 49/ 51 mg and Sacubitril / valsartan 97/103 mg as both strengths are dose proportional and same AMV can be applied to both these strengths. Attachment: Analytical Method Validation Sacubitril / valsartan (49/51 mg & 97/103 mg)"
10.	Justify the obtained weight of tablet i.e. 204.91mg, as mentioned in the batch analysis report of drug product, when the weight of uncoated tablet as per the composition table given in section 3.2.P.1 is 205.0mg per tablet. Same clarity is required in other two strengths.	Firm replied that "This is with reference to the query letter received regarding the product Sacubitril / Valsartan tablet range, please find below response for point 3.2.P.5.5 regarding average weight of tablet in batch analysis report of drug product: Although the weight of uncoated tablet as per the composition given in section

		3.2.P.1 is 205.0 mg / tablet, however, average weight of coated tablet mentioned in batch analysis report of drug product Sacubitril / valsartan 24/26 mg is 204.9 mg/tablet which is slightly on lower side in comparison with uncoated tablet but within tolerance limits as covered in drug product specifications i.e. 201.56-222.78 mg/tab. Same is followed for other two strengths as well i.e. Sacubitril / Valsartan tablet 49/51 mg and Sacubitril / Valsartan tablet 97/103 mg.
11.	Submit updated stability of drug product, since you have submitted stability data of only three months.	Firm submitted the stability data of drug product till 6th month.
12.	Submit detailed calculation of dispensed weight of active per tablet.	Submitted

Decision: Deferred for providing the reference adopted for setting acceptance limit of weight variation of coated tablet along with scientific justification of getting the obtained weight of coated tablet on the lower side comparing the theoretical weight of uncoated tablet.

271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.474 dated : 05-01-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.31737402255 dated 03-01-2023
	The proposed proprietary name / brand name	Cmyate 2MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 2MIU eq. to colistimethate Sodium….160mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (1MIU & 2MIU)
	For generic drugs (me-too status)	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration letter of cmyate IMIU Injection is as attached). However,

	sodium instead of Colistimethate base activity as recommended by USP.	the Assay results were calculated as Colistine base activity as defined in USP. But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during manufacturing, since, the drug substance is used in the preparation of injectable dosage form.	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is sensitive to heat so heat sterilization of the product is not suitable."
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays,* specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range".* then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin"

		The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity. However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
7.	• Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA). • Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
8.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm replied that "Comparative study was performed with the following product: Product name: Colistim Injection By M/s Biopharmaceutica".
9.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
10.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"
11.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.

12.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.
13.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Not submitted the reply of this query.
14.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
15.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".
16.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
17.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.
- Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.
- Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".
- Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for

changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.

- Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.
- How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".
- Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.
- Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.

Response of the Firm:

Sr.no.	Decision of 336th meeting of RB	Response of the Firm
1.	Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.	Firm submitted the revised label claim as per USP i.e. as follows: Each vial contains: Colistimethate Sodium eq. to 68mg Colistin base activity.
2.	Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.	Firm replied that " initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP.
3.	Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".	Firm submitted the revised pharmaceutical equivalence report in which the result of free colistin test is included in the report.
4.	Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.	Firm replied that "initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP. The analysis was performed as per USP specification with the same base layer as well as bacterial layer and the median concentration of 1 µg/mL in accordance with USP".
5.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the	Firm submitted the verification study report. Verification report of each strength is submitted. The concentration details are also provided. Initial concentration of every strength is different from the other strength, however the final concentration of all the strength is same i.e. 1 µg/mL in accordance with USP.

	concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	
6.	Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.	Firm submitted the COA of Mueller-Hinton Agar which confirm the composition of this medium.
7.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm submitted the calculation regarding the dispensed weight of colistimethate sodium per vial.

Decision: Approved.

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

272.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.1554 dated : 17-01-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.0564003397 dated 12-01-2023
	The proposed proprietary name / brand name	Cmyate 3MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 3MIU eq. to colistimethate Sodium….240mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (1MIU & 2MIU)
	For generic drugs (me-too status)	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration letter of cmyate IMIU Injection is as attached). However, the Assay results were calculated as Colistine base activity as defined in USP.

		But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during manufacturing, since, the drug substance is used in the preparation of injectable dosage form.	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is sensitive to heat so heat sterilization of the product is not suitable."
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays*, specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range".* then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin" The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity.

		However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
7.	• Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA). • Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
8.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm replied that "Comparative study was performed with the following product: Product name: Colistim Injection By M/s Biopharmaceutica".
9.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
10.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"
11.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.
12.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.
13.	• Please provide detailed report of verification studies including the	Not submitted the reply of this query.

	sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	
14.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
15.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".
16.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
17.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision of 336th meeting of Registration Board:

Deferred for the submission of following:

- Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.
- Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.
- Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".
- Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.
- Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.
- How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of

Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".

- Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.
- Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.

Response of the Firm

Sr.no.	Decision of 336th meeting of RB	Response of the Firm
1.	Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.	Firm submitted the revised label claim as per USP i.e. as follows: Each vial contains: Colistimethate Sodium eq. to 102mg Colistin base activity.
2.	Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.	Firm replied that " initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP.
3.	Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".	Firm submitted the revised pharmaceutical equivalence report in which the result of free colistin test is included in the report.
4.	Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.	Firm replied that "initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP. The analysis was performed as per USP specification with the same base layer as well as bacterial layer and the median concentration of 1 µg/mL in accordance with USP".
5.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Firm submitted the verification study report. Verification report of each strength is submitted. The concentration details are also provided. Initial concentration of every strength is different from the other strength, however the final concentration of all the strength is same i.e. 11 µg/mL in accordance with USP.
6.	Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.	Firm submitted the COA of Mueller-Hinton Agar which confirm the composition of this medium.

7.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm submitted the calculation regarding the dispensed weight of colistimethate sodium per vial.

Decision: Approved.

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

273.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Name, address of Manufacturing site.	**M/s. Aulton Pharmaceuticals, Plot No. 84/1,Block-A Phase V Industrial Estate, Hattar**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.3223 dated : 03-02-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.7878225619 dated 01-02-2023
	The proposed proprietary name / brand name	Cmyate 4.5 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium 4.5MIU eq. to colistimethate Sodium….360mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial polymyxin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Coly-Mycin® M Parenteral 150 mg colistin base activity **USFDA** Approved
	For generic drugs (me-too status)	Colistim 4.5MIU by Biocare Pharmaceutica,

Evaluation by PEC (XV):

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.	The label claim given by the DRAP for cmyate IMIU Injection, was followed for the abovementioned strengths for the harmonization of all the strengths of (registration letter of cmyate IMIU Injection is as attached). However, the Assay results were calculated as Colistine base activity as defined in USP. But the firm has declared the label claim with reference to the quantity of colistimethate sodium instead of colistimethate base activity.
2.	Manufacturing procedure of drug substance did not include the step of sterilization neither the document revealed regarding the manufacturing under aseptic condition, clarify the sterilization procedure adopted during	Firm replied that "As defined in the manufacturing procedure the of sterilization of API is assured by sequential "Ultra filtration and Nano filtration technology". Since the API is

	manufacturing, since, the drug substance is used in the preparation of injectable dosage form.	sensitive to heat so heat sterilization of the product is not suitable."
3.	Assay method specified in section 3.2.S.4.2 is not in accordance with the USP general chapter *<81> antibiotics—microbial assays*, specifically with reference to concentration of standard and sample solution and the calculation of sample potency determination, clarification is required in this regard.	The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, > however product specific adjustments in the procedure are allowed by the USP (Ref: General Notice 6.30). Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. 1, Moreover the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable. However as per General chapter of USP *"It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range".* then firm has to provide reasons to change the conc of solutions and the limits of adjustment which is considered while adjusting the conc. as per General notices of USP. Further, provide complete calculation of petency dertermination as per the USP general chapter <81>.
4.	Justify for performing verification studies on assay method different from that recommended by USP general chapter *<81> antibiotics—microbial assays.*	Firm replied that, "In The USP general chapter <81> provides the general guidelines for the microbiological assay of substances, however product specific adjustments in the procedure are allowed by the USP. Therefore, API manufacturer has adopted USP Chapter <81> for the procedure and dilution and concentrations are adjusted in accordance with the product requirement. Moreover, the standard analytical procedure is validated as per USP and ICH guidelines. So the procedure used by API manufacturer is justifiable". Please justify the adjusted concentration of solutions in the light of allowable limits of USP.
5.	Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "The CoA is in accordance with USP and the limit defined by the USP is as follows: "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg". From the above label claim it is evident that the potency is defined in terms of colistin base activity.
6.	Description of applied product is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied product is white to slightly yellow powder, clarify how the applied product is similar to innovator product/reference product.	Applied formulation is available in lyophilized powder form in the reference product approved in Health Canada.

7.	Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.	Firm replied that "The limit defined by the USP is in the monograph "Colistimethate for Injection" is"Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin" The limit given the CoA of finished product by drug product manufacturer is "90% to 120%" which is the limit of colistin base activity. However, the label claim specified by the drug product manufacturer needs to be amended in accordance with the colistin base activity as per USP.
8.	Justify dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
9.	Provide the calculation which rationalize the adopted filled weight quantity of colistimethate sodium per vial i.e. 360mg of colistimethate sodium.	Firm replied that the dispensed weight is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) of Powder for solution for injection". But the firm has not submitted the calculation of dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).
10.	Submit the detail of manufacturer, brand name and Registration no. in case of local manufacturer of reference/comparator product against which pharmaceutical equivalence has been established.	Firm submitted the details.
11.	Justify for not performing content uniformity test and test of *Free colistin under Colistimethate Sodium while performing the pharmaceutical equivalence against the comparator product.*	Firm replied that "The uniformity of dosage is performed at each stability interval. Therefore, in equivalence study content uniformity was not performed. Moreover, the "free colistin test is given by USP in "raw material monograph. For finished product the USP do not defines the free colistin test". However, the "*Free colistin test"* is included in the USP monograph of finished drug product, further, the pharmaceutical equivalence study should include all the test of specification of drug product.
12.	Justify for not including the test of *Free colistin under Colistimethate Sodium* in the specification of drug product.	Firm replied that "The "free colistin test is given by USP in "raw material monograph and this test were performed for the raw material by the Aulton Pharmaceutical for finished product the USP do not defines the free colistin test". However, the test of free colistin is included in the USP monograph of drug product " Colistimethate for Injection"

13.	Justify for adopting the microbial assay procedure which is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics Microbial Assays <81>", particularly the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis is in accordance with the said USP chapter.	Firm replied that "The USP general chapter <81> provides the general Assay guidelines for the microbiological assay of substances, rdance The procedure adopted was same as USP, however the dilution was prepared as defined by the assay of API manufacturer. Moreover, the standard analytical and procedure is validated as per USP and ICH guidelines. So, the procedure used by API manufacturer is nation, justifiable. Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions.
14.	Further, clarify the culture medium in which seed layer has been prepared.	Firm replied that "for seed layering USP <81> defined "Medium 1" was used. However for further validation specie specific medium "SB Medium" was also used.
15.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strength is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Not submitted the reply of this query.
16.	Submitted batch analysis report does not clarify the potency whether in terms of CBA or IU of CMS.	Firm replied that "In CoA the limits are given according to USP ie: "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin".
17.	Clarify on which batches you have performed in-use stability studies in the year 2021, because the trail batches on which stability study has been performed were manufactured in 01-2022.	Firm replied that it was a typographic mistake , in-use stability was performed on the same stability batches.
18.	Description of product mentioned in the stability data sheets specify that the product is crystalline powder, while the general properties given in the documents of drug substance manufacturer revealed that the ready to fill material is amorphous in nature.	Firm replied that "As the powder is ready to fill material, so the specification of finished product given by Aulton report Pharmaceuticals are "White to slightly yellow powder filled in glass vials', which is in accordance with USP and API manufacturer specification".

19.	Provide the COA of Mueller-Hinton Agar with the facts that the composition of the media in in accordance with Media 9 i.e. the recommended media for colistimethate as per USP.	Firm submitted the documents which did not mentioned the composition of Mueller-Hinton Agar.
20.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm replied that "The weight/vial is calculated in accordance with the innovator's product "COLOMYCIN 2 million International Units (IU) Powder for solution for injection". But the query is relevant to submission of calculation of dispensed weight of colistimethate sodium per vial.

Decision of 336th meeting of Registration Board:
Deferred for the submission of following:

- Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.
- Description of applied product is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied product is white to slightly yellow powder, clarify how the applied product is similar to innovator product/reference product.
- Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.
- Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".
- Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.
- Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations.
- How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".
- Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.
- Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.

Response of the Firm:

Sr.no.	Decision of 336th meeting of RB	Response of the Firm
1.	Revised label claim in terms of Colistimethate base activity as recommended by USP since the firm claimed USP specifications for finished drug product.	Firm submitted the revised label claim as per USP i.e. as follows: Each vial contains: Colistimethate Sodium eq. to 153mg Colistin base activity.
2.	Description of applied product is different from the innovator product, since the innovator product is white to slightly yellow lyophilized cake and the applied product is white to slightly yellow powder, clarify how the applied product is similar to innovator product/reference product.	Firm has not submitted the reply of this query.

3.	Justify the adjusted concentration of both standard and sample solution of drug substance in the light of allowable limits of USP.	Firm replied that " initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP.
4.	Submit pharmaceutical equivalence report including the test of content uniformity and free colistin test, since both of these test is the part of USP Monograph of "Colistimethate for injection".	Firm submitted the revised pharmaceutical equivalence report in which the result of free colistin test is included in the report.
5.	Firm has not complied the requirements mentioned in the USP General Chapter <81> particularly, the volume of base layer is different, volume of bacterial layer is not same neither the standard dilutions preparation and assay calculation/analysis. Further the firm submitted the raw data sheets of potency calculation of drug product, which shows that the median concentration of 5.20 is prepared for analysis while the USP recommends 1 µg/mL. Firm has to submit the adjustment limit which is considered for changing the concentration of solutions along with clarification regarding the said changes in the assay procedure of drug product.	Firm replied that "initially the concentrations were selected as per specification of API manufacturer, however we are hereby submitting the results of analysis as per USP specification using the same concentration as mentioned in the USP. The analysis was performed as per USP specification with the same base layer as well as bacterial layer and the median concentration of 1 µg/mL in accordance with USP".
6.	• Please provide detailed report of verification studies including the sample and standard solution preparation method and complete potency calculations. • How can the verification report of all three applied strengths is same despite the initial reconstituted solution of each strength has different concentration, which ultimately change the required quantity of Buffer B.6 to achieve the concentration recommended in the general chapter "Antibiotics Microbial Assays <81>".	Firm submitted the verification study report. Verification report of each strength is submitted. The concentration details are also provided. Initial concentration of every strength is different from the other strength, however the final concentration of all the strength is same i.e. 1µg/mL in accordance with USP.
7.	Provide the COA or other document of Mueller-Hinton Agar which confirm the composition of this medium.	Firm submitted the COA of Mueller-Hinton Agar which confirm the composition of this medium.
8.	Provide calculation detail of dispensed weight of colistimethate sodium per vial. Since the submitted BMR did not contain the same information.	Firm submitted the calculation regarding the dispensed weight of colistimethate sodium per vial.

Decision: Approved.

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

274.	Name, address of Applicant / Marketing Authorization Holder	M/s Surge Laboratories Private Limited 10th KM, Faisalabad Road, Bikhi District Sheikhupura,

		Pakistan.
	Name, address of Manufacturing site.	M/s Surge Laboratories Private Limited 10th KM, Faisalabad Road, Bikhi District Sheikhupura, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20435 dated 27/07/2021
	Details of fee submitted	PKR 20,000/-: dated 05/05/2021
	The proposed proprietary name / brand name	Hemarest 500mg/5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Tranexamic Acid BP … 500mg (BP Specifications)
	Pharmaceutical form of applied drug	Clear, Colorless liquid free from foreign particles.
	Pharmacotherapeutic Group of (API)	Antihaemorrhagics, Antifibrinolytics.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	5ml x 5's 5ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azeptil Injection 500mg/5ml by M/s Medochemie Ltd., MHRA Approved.
	For generic drugs (me-too status)	Tranmax Injection by M/s Nabiqasim Industries (Pvt). Ltd., Reg. No. 057745
	GMP status of the Finished product manufacturer	New license granted on 19/12/2015 General Liquid Injectables (Including blow fill seal area) & Cephalosporin Dry Powder Injectables section approved.
	Name and address of API manufacturer.	Changzhou Yinsheng Pharmaceuticals Co. (Pvt). Ltd. Weitang, Chemical zone, Xinbei District, Changzhou, Jiangsu Province - 213033 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tranexamic Acid is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 12 months. Batches: (100301, 100303, 100302)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Transamin Injection 250mg/5ml by Hilton Pharma by performing quality tests (Description, pH, Assay, Bacterial Endotoxins and Sterility).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity, Limit of Detection, Limit of Quantitation, Ruggedness & Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Changzhou Yinsheng Pharmaceuticals Co. (Pvt). Ltd. Weitang, Chemical zone, Xinbei District, Changzhou, Jiangsu Province - 213033 China		
API Lot No.	20141213		
Description of Pack (Container closure system)	5ml Break Ring Clear Glass Ampoule (USP Type I) as 5ml x 5's 5ml x 10's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI-001V	TRI-002W	TRI-003W
Batch Size	1500 Ampoules	1500 Ampoules	1500 Ampoules
Manufacturing Date	02-2015	08-2016	09-2016
Date of Initiation	02-2015	08-2016	09-2016
No. of Batches	03		

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20170680 issued by China Food And Drug Administration valid till 20/06/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 2014DW145-DRAP dated 08.01.2015 is submitted for Tranexamic Acid.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2. S.4.3**	**Validation of analytical procedures** Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.
2.	**3.2. P.5.1**	**Validation of analytical procedures:** You have submitted the validation studies of assay method of transic injection by spectrophotometer while according to the BP monograph of tranexamic acid injection assay has been performed via potentiometric titration, clarification is required in this regard.
3.	**3.2. P.8**	**Stability** • As per the submitted stability data, stability studies of all three batches has been initiated in the year 2015 and 2016 despite that firm has submitted only 6 months' data of real time stability study for all three batches. Submit the remaining real time stability data of all three batches. • Submitted raw data sheets reflect that the assay of drug product has been performed via UV spectrophotometer while according to BP, assay of the drug product has been performed by potentiometric titration. Justify, how your product complies BP specification. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.
5.	**2.3. R.1.1**	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
6.	**Amendment in QOS (Module 2) for above points.**	

Decision of 322nd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:
Firm replied that they have manufactured new batches of applied product and conduct development studies/stability studies according to BP monograph. Development studies / stability data of new batches till date indicates that product tested as per BP monograph of Tranexamic Acid Injection. However, the stability study of new batches was submitted without requisite fee. New stability batches were developed using the API from same source but the procurement date was different from the previous stability batches, accordingly commercial invoice duly attested from DRAP officer has been submitted by the firm.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Submitted
2.	You have submitted the validation studies of assay method of transic injection by spectrophotometer while according to the BP monograph of tranexamic acid injection assay has been performed via potentiometric titration, clarification is required in this regard.	Firm has submitted new dossier with stability study data complying BP monograph of Tranexamic Acid Injection. They have submitted verification studies of applied product in compliance of BP monograph.
3.	• As per the submitted stability data, stability studies of all three batches has been initiated in the year 2015 and 2016 despite that firm has submitted only 6 months' data of real time stability study for all three batches. Submit the remaining real time stability data of all three batches. • Submitted raw data sheets reflect that the assay of drug product has been performed via UV spectrophotometer while according to BP, assay of the drug product has been performed by potentiometric titration. Justify, how your product complies BP specification. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm submitted new stability data in compliance of BP specification.
4.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	BMR of new stability batches are submitted by the firm.

Decision: Approved. Applicant shall submit full registration fee for submitting new development data and stability data of new batches , prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.

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

275.	Name, address of Applicant / Marketing Authorization Holder	M/s Surge Laboratories Private Limited 10th KM, Faisalabad Road, Bikhi District Sheikhupura, Pakistan.
	Name, address of Manufacturing site.	M/s Surge Laboratories Private Limited 10th KM, Faisalabad Road, Bikhi District Sheikhupura, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20435 dated 27/07/2021
	Details of fee submitted	PKR 30,000/-: dated 17/07/2021 slip no.743946345307
	The proposed proprietary name / brand name	Hemarest 250mg/5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Tranexamic Acid BP … 250mg (BP Specifications)
	Pharmaceutical form of applied drug	Clear, Colorless liquid free from foreign particles.
	Pharmacotherapeutic Group of (API)	Antihaemorrhagics, Antifibrinolytics.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	5ml x 5's 5ml x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Azeptil Injection 250mg/5ml by M/s Medochemie Ltd., MHRA Approved.
	For generic drugs (me-too status)	Tranmax Injection by M/s Nabiqasim Industries (Pvt). Ltd., Reg. No. 057745
	GMP status of the Finished product manufacturer	License granted on 19/12/2015 General Liquid Injectables (Including blow fill seal area) & Cephalosporin Dry Powder Injectables section approved.
	Name and address of API manufacturer.	Changzhou Yinsheng Pharmaceuticals Co. (Pvt). Ltd.Weitang, Chemical zone, Xinbei District, Changzhou, Jiangsu Province - 213033 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tranexamic Acid is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance		
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 12 months. Batches: (100301, 100303, 100302)		
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Transamin Injection 250mg/5ml by Hilton Pharma by performing quality tests (Description, pH, Assay, Bacterial Endotoxins and Sterility).		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, Limit of Detection, Limit of Quantitation, Ruggedness & Robustness.		
STABILITY STUDY DATA				
Manufacturer of API		Changzhou Yinsheng Pharmaceuticals Co. (Pvt). Ltd. Weitang, Chemical zone, Xinbei District, Changzhou, Jiangsu Province - 213033 China		
API Lot No.		20141213		
Description of Pack (Container closure system)		5ml Break Ring Clear Glass Ampoule (USP Type I) as 5ml x 5’s 5ml x 10’s		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TRI-001W	TRI-002W	TRI-003W
Batch Size		1500 Ampoules	1500 Ampoules	1500 Ampoules
Manufacturing Date		02-2015	08-2016	09-2016
Date of Initiation		02-2015	08-2016	09-2016
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20170680 issued by China Food and Drug Administration valid till 20/06/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 2014DW145-DRAP dated 08.01.2015 is submitted for Tranexamic Acid.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of the Evaluator:

Sr.no.	Section no.	Observations	Firm's response
1.	3.2. S.4.3	Provide analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer.	Firm submitted the analytical method verification studies of drug substance performed by drug product manufacturer.
2.	3.2. P.2	Justification is required regarding the use of NaOH and HCl for pH adjustment as the innovator/reference product has not been used any excipient for pH adjustment.	Firm has submitted that no any excipient "NaOH or HCl" is used to set the pH in Hemarest 250mg/5ml injection as its pH is auto set at target i.e. 7.3 and stays within the pH range mentioned in BP (6.5-8.0). However, both the excipients are mentioned in BMR because they can be used to set pH to the target point if pH fluctuates.
3.	3.2. P.2.2.1	Justify the process of terminal sterilization via autoclave at 121°C for 15minutes with reference to degradation occurred in the accelerated stability studies conducted at 40°C as claimed in pharmaceutical development section. If the degradation of product start at 40°C then how the product will bear the temperature of 121°C during terminal sterilization.	Firm has replied that Hemarest 250mg/5ml is stable at 121°C for 15minutes and testing report of finished product is also submitted that shows the impurities/degradable substances (after sterilization at 121°C for 15 min) are within the specified limits. However, the degradation at 40°C and 75% Relative humidity is the result of long-term impact of temperature and humidity i.e. 6 months.
4.	3.2. P.2.2.1	Justify the degradation of your product during accelerated stability studies because as per the innovator /reference product, the drug product remains stable during the accelerated stability studies conducted at 40 ° C, relative humidity 75%, 6 months and no overage has been used in their formulation.	Firm has submitted the reply that we have worked over the formulation of this product to make it more effective and stable and based on the various trials we have added 2.0% overage. The overage used is for covering the loss during different steps of manufacturing process therefore the quantity of API i.e. Tranexamic Acid is 270.3mg/5.3ml. Furthermore, the reason behind filling behind filling of 5.3ml volume of solution in injection instead of exact 5ml is to obtain the extractable

			volume of 5ml according to label claim and is in accordance of USP 43 recommendation for excess volume.
5.	3.2. P.5.1	You have submitted the validation studies of assay method of transic injection by spectrophotometer while according to the BP monograph of tranexamic acid injection assay has been performed via potentiometric titration, clarification is required in this regard.	Firm has stated that Hemarest injection (Tranexamic acid) 250mg/5ml is BP specification product. For our finished product we have developed the alternative method on UV spectrophotometer as alternative method after parallel equivalency testing because the availability of raw data in the form of spectra is better than titration method. After development of method successful analytical method validation was performed in accordance with the requirement of ICH Q2(R1) and united states pharmacopoeia <1225>. BP allows to adapt the alternative method if equivalent accuracy with pharmacopoeial method is evident under clause "Test and Assays "of BP General chapter "General Notices" which states that "The analyst is not precluded from employing alternative methods, including methods of micro-analysis, in-any assay or test if it is known that the method used will gave a result of equivalent accuracy. Limit detection and quantitation limit parameters are not performed according to the ICH guidelines and pharmacopeial recommended chapters.
6.	3.2. P.8.3	As per the submitted stability data, stability studies of all three batches has been initiated in the year 2015 and 2016 despite that firm has submitted only 6 months data of real time stability study for all three batches. Submit the remaining real time stability data of all three batches.	Firm has submitted the stability data till the claimed shelf life.
7.	3.2. P.8.3	Submitted raw data sheets reflect that the assay of drug product has been performed via UV spectrophotometer while according to BP, assay of the drug product has been performed by potentiometric titration. Justify, how your product complies BP specification.	BP allows to adapt the alternative method if equivalent accuracy with pharmacopoeial method is evident under clause "Test and Assays "of BP General chapter "General Notices" which states that "The analyst is not precluded from employing alternative methods, including methods of micro-analysis, in-any assay or test if it is known that the method used will gave a result of equivalent accuracy.
8.	2.3. R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Firm has submitted only batch manufacturing order instead of batch manufacturing record. In Batch manufacturing order 0.0.30L of hydrochloric acid and 0.0.30L of sodium hydroxide dispensed for pH adjustment.
Decision of 316th meeting of Registration Board: Deferred for scientific justification of applying alternative method from that recommended by BP monograph of "Tranexamic acid injection", for the drug product Assay test during stability studies.			
Response of the Firm:			

Firm replied that they have manufactured new batches of applied product and conduct development studies/stability studies according to BP monograph. Development studies / stability data of new batches till date indicates that product tested as per BP monograph of Tranexamic Acid Injection. However, the stability study of new batches was submitted without requisite fee. New stability batches were developed using the API from same source but the procurement date was different from the previous stability batches, accordingly commercial invoice duly attested from DRAP officer has been submitted by the firm**.**		
Decision: Approved. Applicant shall submit full registration fee for submitting new development data and stability data of new batches, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
276.	Name, address of Applicant / Marketing Authorization Holder	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of DML issue dated 13-09-2021.
	Evidence of approval of manufacturing facility	Firm submitted copy of issuance of DML Letter dated 17-09-2021 with the list of approved section including tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. V5A-8QN-U986 Application no. 1074 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 256673461543 dated 18-12-2023
	The proposed proprietary name / brand name	**SITAQAD 50mg/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hydrochloride …… 1000mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin …….50mg
	Pharmacotherapeutic Group of (API)	For the treatment of Diabetes mellitus Type II/Hypoglycemic Agents/Blood sugar lowering agents
	Pharmaceutical form of applied drug	Film-coated tablets
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA (emc) Janumet tablets

	For generic drugs (me-too status)	TreviaMet 50mg/1000mg of M/s. Getz Pharma Pakistan (PVT) Ltd of Reg.no. 055444.
	Name and address of API manufacturer.	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (sitagliptin phosphate) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Firm has submitted stability study data of 3 batches of drug substance (Metformin Hydrochloride) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Sitaglu Met 50mg+1000mg Tablets of M/s.Hilton Pharma (PVT.) Ltd. Further, submitted comparative dissolution against the same above mentioned comparator product in all three medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		Metformin Hydrochloride:

	M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	L-D05-CP11422001 MEF/12031196		
Description of Pack (Container closure system)	A white color oblong shape, film coated tablet, Score on one side in Alu-Alu Blister packs in unit carton with leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR040	TTR041	TTR042
Batch Size	600 tablets	600 tablets	600 tablets
Manufacturing Date	04/2023.	04/2023.	04/2023.
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate of both API manufacturers.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Reply
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and analytical procedure used for analysis of both drug substances by drug product manufacturer.	Firm submitted the specification and analytical procedure of both drug substance.
2.	3.2.S.4.1	Justify for using in-house complied drug substance (sitagliptin phosphate) for the manufacturing of drug product when the official monograph of sitagliptin phosphate is available in the USP.	Firm replied that This is a mistake from the procurement department though the parameters are similar to USP still we undertake that for commercial product manufacturing we will use USP monograph API.
3.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by the drug product manufacturer.	Firm submitted the same validation/verification report of drug substance as submitted for drug product.

4.	3.2.S.4.4	Submit batch analysis report of both drug substance by drug product manufacturer.	Submitted
5.	3.2.S.7	Stability data of sitagliptin phosphate specified that the drug substance complied USP specification while the other sections of drug substance part claimed that the in-house complied sitagliptin phosphate has been used in the manufacturing of drug product.	Firm replied that "The accelerated stability study of sitagliptin phosphate specified that the drug substance complied USP is in API manufacturer DMF, we have communicated the matter to the API manufacturer to address the subject, and we will communicate to the DRAP as will received their reply".
6.	3.2.P.5.1	Specify the acceptance criteria of dissolution test in term of Q value, since the BP monograph of applied product recommends the acceptance limit of dissolution test in terms of Q value.	Firm replied that "The acceptance criteria of dissolution test in term of Q value are 80% in the BP monograph of applied product". Dissolution acceptance limit need to be changed in accordance with BP monograph.
7.	3.2.P.5.2	Justify for not adopting the same assay procedure as recommended by the BP monograph of Metformin and Sitagliptin Tablets, since the submitted method is different from the procedure given in official monograph of BP.	Firm replied that "The method adopted in the assay was that for dissolution of tablet due to isocratic mode and give good results for both drug substances. We undertake to use gradient method in future for the assay of combination tablets" Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
8.	3.2.P.5.3	Assay procedure verified is not in accordance with BP Monograph ,justify how the applied product complied BP specification.	Firm replied that "Sir please consider it valid. The same BP dissolution method in isocratic mode was used for the method verification of both substances and is well within the range of acceptance criteria". Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
9.	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted Form-6 of both drug substance.
10	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision of 335th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.
- Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.
- Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections.
- Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.

- Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.
- Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"

Response of the Firm:

Sr.no.	Decision of 335th meeting of Reg. Board	Response of the Firm
1.	Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.	Firm submitted the requisite fee PKR 7500/- of pre-registration variation via fee challan no.0050198276.
2.	Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.	Submitted
3.	Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections	Firm replied that The specification of Sitagliptin phosphate monohydrate is established on the basis of ICH guidelines and corresponding USP chapters.
4.	Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.	Firm revised the acceptance limit of dissolution test in accordance with BP monograph.
5.	Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.	Firm revised the assay method in accordance with BP and accordingly submit the performance report of next time point of long term stability studies.
6.	Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"	Submitted

Decision: Approved.

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

277.	Name, address of Applicant / Marketing Authorization Holder	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Name, address of Manufacturing site.	M/s. Qadir Pharmaceuticals Address: Veerum Fateh Garh Sahuwala road, Sialkot-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of DML issue dated 13-09-2021.

	Evidence of approval of manufacturing facility	Firm submitted copy of issuance of DML Letter dated 17-09-2021 with the list of approved section including tablet general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. 82V-HAH-4GEN Application no. 1044 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 914933883933 dated 18-12-2023
	The proposed proprietary name / brand name	**SITAQAD 50mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Metformin Hydrochloride……500mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin …….50mg
	Pharmacotherapeutic Group of (API)	For the treatment of Diabetes mellitus Type II/Hypoglycemic Agents/Blood sugar lowering agents
	Pharmaceutical form of applied drug	Film-coated tablets
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA (emc) Janumet tablets
	For generic drugs (me-too status)	TreviaMet 50mg/500mg of M/s. Getz Pharma Pakistan (PVT) Ltd of Reg.no. 055443.
	Name and address of API manufacturer.	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (sitagliptin phosphate) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Firm has submitted stability study data of 3 batches of drug substance (Metformin Hydrochloride) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Sitaglu Met 50/500mg of Hilton Pharma (PVT) Ltd. Further, submitted comparative dissolution against the same above mentioned comparator product in all three medias.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Metformin Hydrochloride: M/s. AARTI DRUGS LTD MANUFACTURING FACILITY Plot No. G– 60, M.I.D.C. Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA. Sitagliptin Phosphate Monohydrate: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	L-D05-CP11422001 MEF/12031196		
Description of Pack (Container closure system)	A white color oblong shape, film coated tablet, Score on one side in Alu-Alu Blister packs in unit carton with leaflet		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTR037	TTR038	TTR039
Batch Size	600 tablets	600 tablets	600 tablets
Manufacturing Date	04/2023.	04/2023.	04/2023.
No. of Batches	03		

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate of both API manufacturers.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings	Reply
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and analytical procedure used for analysis of both drug substances by drug product manufacturer.	Firm submitted the specification and analytical procedure of both drug substance.
2.	3.2.S.4.1	Justify for using in-house complied drug substance (sitagliptin phosphate) for the manufacturing of drug product when the official monograph of sitagliptin phosphate is available in the USP.	Firm replied that This is a mistake from the procurement department though the parameters are similar to USP still we undertake that for commercial product manufacturing we will use USP monograph API.
3.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by the drug product manufacturer.	Firm submitted the same validation/verification report of drug substance as submitted for drug product.
4.	3.2.S.4.4	Submit batch analysis report of both drug substance by drug product manufacturer.	Submitted
5.	3.2.S.7	Stability data of sitagliptin phosphate specified that the drug substance complied USP specification while the other sections of drug substance part claimed that the in-house complied sitagliptin phosphate has been used in the manufacturing of drug product.	Firm replied that "The accelerated stability study of sitagliptin phosphate specified that the drug substance complied USP is in API manufacturer DMF, we have communicated the matter to the API manufacturer to address the subject, and we will communicate to the DRAP as will received their reply".
6.	3.2.P.5.1	Specify the acceptance criteria of dissolution test in term of Q value, since the BP monograph of applied product recommends the acceptance limit of dissolution test in terms of Q value.	Firm replied that "The acceptance criteria of dissolution test in term of Q value are 80% in the BP monograph of applied product". Dissolution acceptance limit need to be changed in accordance with BP monograph.
7.	3.2.P.5.2	Justify for not adopting the same assay procedure as recommended by the BP monograph of Metformin and Sitagliptin Tablets, since the submitted method is different from the procedure given in official monograph of BP.	Firm replied that "The method adopted in the assay was that for dissolution of tablet due to isocratic mode and give good results for both drug substances. We undertake to use gradient method in future for the assay of combination tablets" Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
8.	3.2.P.5.3	Assay procedure verified is not in accordance with BP Monograph ,justify how the applied product complied BP specification.	Firm replied that "Sir please consider it valid. The same BP dissolution method in isocratic mode was used for the method verification of both substances and is well within the range of acceptance criteria".

			Firm has not adopted BP specification for the applied product, since the assay procedure acquired by the firm is not in accordance with BP monograph.
9.	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted Form-6 of both drug substance.
10	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision of 335th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.
- Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.
- Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections.
- Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.
- Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.
- Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"

Response of the Firm:

Sr.no.	Decision of 335th meeting of Reg. Board	Response of the Firm
1.	Submit PKR 7500/- pre-registration variation fee for revision of specification, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023.	Firm submitted the requisite fee PKR 7500/- of pre-registration variation via fee challan no.2910214155.
2.	Submit analytical method verification report of both drug substances performed by the drug product manufacturer, since in the reply you have submitted the same verification report as submitted for drug product.	Submitted
3.	Clarify the ambiguity related to the specification of drug substance, since the documents supplied by the drug substance manufacturer shows disparity in the specification claim of drug substance in their various sections	Firm replied that The specification of Sitagliptin phosphate monohydrate is established on the basis of ICH guidelines and corresponding USP chapters.
4.	Revise the dissolution acceptance limit in accordance to the BP Monograph of applied product.	Firm revised the acceptance limit of dissolution test in accordance with BP monograph.

5.	Revise the assay procedure of applied product in accordance with the BP Monograph of "Metformin and Sitagliptin Tablet" and accordingly submit the performance report of next time point of long term stability studies.	Firm revised the assay method in accordance with BP and accordingly submit the performance report of next time point of long term stability studies.
6.	Submit analytical verification report of drug product, which is performed in accordance with the "Metformin and Sitagliptin Tablet"	Submitted

Decision: Approved.

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

278.	Name, address of Applicant / Marketing Authorization Holder	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Name, address of Manufacturing site.	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of GMP certification no. 12/2022-DRAP(AD-89400934157) dated 10-02-2022.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section letter in which eye/ear/nose drop section granted to firm dated 20-01-2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. JWU-5TM-A2E8 Application no. 732 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 2174454153 dated 05-09-2023
	The proposed proprietary name / brand name	**Lutica Nasal Spray 0.05% w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	50mcg/spray of Fluticasone Propionate
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Pharmaceutical form of applied drug	Nasal Spray
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA, FLONASE ALLERGY RELIEF FLUTICASONE PROPIONATE 0.05MG/SPRAY (Each 100-mg spray delivers 50 mcg of fluticasone propionate).

	For generic drugs (me-too status)	Ticovate Nasal Spray (Each spray contains Fluticasone Propionate 50mcg) of M/s. Saffron Pharmaceuticals Pakistan (Pvt.) Ltd. (Reg.no. 060353)
	Name and address of API manufacturer.	M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol,Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product Ticovate Nasal Spray (Each spray contains Fluticasone Propionate 50mcg) of M/s. Saffron Pharmaceuticals Pakistan (Pvt.) Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.
STABILITY STUDY DATA		
Manufacturer of API		M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA
API Lot No.		FTP/922001
Description of Pack (Container closure system)		Almost color hazy suspension, filled in a plastic bottle fitted with a meter dose atomizing pump packed in unit carton along with leaflet.
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period		Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	83 Bottles	83 Bottles	83 Bottles
Manufacturing Date	11/2022	11/2022	11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted copy of GMP Certificate of API manufacturer (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Gujarat, India is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Further, according to section 3.2.S.2.1 drug substance manufacturer is M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, clarify the disparities observed regarding the drug substance manufacturer.	Firm has not submitted the reply of this query.
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm has not submitted the specification and analytical procedure of drug substance by drug product manufacturer.
3.	Mobile phase ratio used by drug product manufacturer during verification studies of assay method was different from the mobile phase ratio recommended by USP monograph of fluticasone propionate, justification is required in this regard.	Firm replied that "*As per general Monograph of BP, change in mobile phase allowed and our Mobile phase is within the limit"* However, the firm has submitted only the statement without any calculations with reference to the allowable adjustment limit of mobile phase.
4.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm has not submitted the reply of this query.

5.	Justify for not performing all the quality test in accordance with BP monograph of fluticasone propionate nasal spray while establishing the pharmaceutical equivalence against the comparator product..	Firm has not submitted the reply of this query.
6.	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of fluticasone propionate nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm has not submitted the reply of this query.
7.	Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of fluticasone propionate nasal spray as evident from the submitted procedure in the relevant section.	Firm replied that "*As per general Monograph of BP, change in mobile phase allowed and our Mobile phase is within the limit"* However, the firm has submitted only the statement without any calculations with reference to the allowable adjustment limit of mobile phase.
8.	Please specify the details of spray configuration/no. of actuation with reference to the filled volume.	Firm replied that 120 Spray = 14ml+0.2ml.
9.	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm has not submitted the reply of this query.
10	Justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product.	Firm has not submitted the reply of this query.
11	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has submitted procurement document of API without attested by AD (I&E) DRAP
12	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision of 335th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Section 1.6.5(a) specify that M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Gujarat, India is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Further, according to section 3.2.S.2.1 drug substance manufacturer is M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, clarify the disparities observed regarding the drug substance manufacturer.
- Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.
- Justify the change in mobile phase ratio while performing the assay of drug substance drug product in the light of allowable adjustment limit of mobile phase as mentioned in the general chapters of USP.
- Justify for not performing all the quality test in accordance with BP monograph of fluticasone propionate nasal spray while establishing the pharmaceutical equivalence against the comparator product.

- Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of fluticasone propionate nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.
- Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.
- Justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product.

Response of the Firm:

Sr.no.	Decision of 335th meeting of Registration Board	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Shankus Pharmaceuticals, Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Gujarat, India is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Further, according to section 3.2.S.2.1 drug substance manufacturer is M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, clarify the disparities observed regarding the drug substance manufacturer.	In their reply firm submitted the GMP certificate of M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, without any clarification.
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Submitted
3.	Justify the change in mobile phase ratio while performing the assay of drug substance drug product in the light of allowable adjustment limit of mobile phase as mentioned in the general chapters of USP.	Submitted the reply in the light of allowable adjustment limit of mobile phase as mentioned in the general chapters of USP.
4.	Justify for not performing all the quality test in accordance with BP monograph of fluticasone propionate nasal spray while establishing the pharmaceutical equivalence against the comparator product.	Firm replied that the test for uniformity of delivered mass is for the solution whereas the product Medison Nasal Spray is suspension.
5.	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of fluticasone propionate nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm submitted the revised specification of drug product in which they include test of uniformity of delivered dose and test of number of deliveries per container along with all other parameters. Further, firm clarify that the test of the assay is the stated amount of actuation from the valve.
6.	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm submitted the water loss study as recommended in ICH guidelines as an alternative approach of performing stability study for drug product packaged in plastic containers.
7.	Justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product.	Firm claimed that they performed all the quality test while performing the stability of drug product, however the stability data did not include the test of uniformity of delivered dose and test of number of deliveries per container as recommended by BP.

Decision: Deferred for submitting revised pharmaceutical equivalence report in accordance with the revised specification of drug product. Further, justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product,

since the stability data did not include the test of uniformity of delivered dose and test of number of deliveries per container.		
279.	Name, address of Applicant / Marketing Authorization Holder	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Name, address of Manufacturing site.	M/s. Shrooq Pharmaceuticals (Pvt.) LTD. 21-km Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted copy of GMP certification no. 12/2022-DRAP(AD-89400934157) dated 10-02-2022.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section letter in which eye/ear/nose drop section granted to firm dated 20-01-2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Tracking ID no. A9Z-QNA-BS5Q Application no. 604 dated 02-02-2024
	Details of fee submitted	Rs.30,000/- vide slip no. 45995881099 dated 05-09-2023
	The proposed proprietary name / brand name	Medison Nasal Spray 0.05% w/w
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	50mcg/spray of Mometasone Furoate
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Pharmaceutical form of applied drug	Nasal Spray
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA, NASONEX 24HR ALLERGY MOMETASONE FUROATE 0.05MG/SPRAY
	For generic drugs (me-too status)	MMS Nasal Spray 0.05% w/w (Each spray contains Mometasone Furoate 50mcg) of Remington Pharmaceuticals Industries (Pvt.) Ltd. (Reg.no. 076820)
	Name and address of API manufacturer.	M/s. SWATI SPENTOSE PRIVATE LIMITED A1/2111, Phase III, G.I.D.C, Vapi, Gujarat – 396 195, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the comparator product MMS Nasal Spray 0.05% w/w of Remington Pharmaceuticals (Pvt.) Ltd. Lahore.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA		
API Lot No.	FTP/922001		
Description of Pack (Container closure system)	Almost color hazy suspension, filled in a plastic bottle fitted with a meter dose atomizing pump packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	83 Bottles	83 Bottles	83 Bottles
Manufacturing Date	11/2022	11/2022	11/2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted copy of GMP Certificate of API manufacturer (M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of commercial invoice without attested from DRAP.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b).Clarify for submitting the GMP certificate of M/s. FLAX Laboratories instead of M/s. Sawati Spentose Pvt. Ltd.	Firm has not submitted the reply of this query.
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm has not submitted the specification and analytical procedure of drug substance by drug product manufacturer.
3.	Justify for performing verification studies on assay method different from the assay procedure recommended by the USP monograph of Mometasone Furoate.	Firm replied that "Method is as per BP not USP". However the drug substance manufacturer complied USP specification for drug substance as per the submitted documents in the relevant section.
4.	Justify for not including the test of optical rotation while quality analysis of drug substance by drug product manufacturer.	Firm submitted the revised quality analysis report of drug substance in which test of optical rotation is included.
5.	Submit the amended label claim specifying the delivered volume containing the quantity of mometasone Furoate	Firm replied "*Each spray = 0.1ml Mometasone Furoate= 50mcg".* However, the label claim of innovator product is "*Each actuation of the pump delivers a metered spray containing 100 mcg or 100 microliter of aqueous suspension of mometasone furoate monohydrate equivalent to 50 mcg (0.05% w/w) mometasone furoate calculated on the anhydrous basis."*
6.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm has not submitted the reply of this query.
7.	Submit the analysis report/COA of excipients glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.	Firm has not submitted the reply of this query.
8.	Justify for not performing all the quality test in accordance with BP monograph of Mometasone Furoate aqueous nasal spray while establishing the	Firm has not submitted the reply of this query.

	pharmaceutical equivalence against the comparator product.	
9.	Provide the reference of label claim mentioned in the pharmaceutical equivalence table	Firm has not submitted the reply of this query.
10	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of Mometasone Furoate aqueous nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm has not submitted the reply of this query.
11	Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray as evident from the submitted procedure in the relevant section.	Firm has not submitted the reply of this query.
12	Please specify the details of spray configuration/no. of actuation with reference to the filled volume.	
13	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm has not submitted the reply of this query.
14	Justify for not including all the quality test recommended by the BP monograph of Mometasone Furoate aqueous nasal spray while performing the stability of drug product.	Firm has not submitted the reply of this query.
15	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has submitted procurement document of API without attested by AD (I&E) DRAP.
16	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted BMR reflects that 14ml filled in each bottle Label claim *Each spray contains: Mometasone Furoate…50mcg (Each bottle contains 120 sprays).*

Decision of 335th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Section 1.6.5(a) specify that M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Clarify for submitting the GMP certificate of M/s. FLAX Laboratories instead of M/s. Sawati Spentose Pvt. Ltd.
- Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.
- Justify for adopting the BP specification for USP complied drug substance, since the drug substance manufacturer claimed USP specification for drug substance.

- Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
- Submit the analysis report/COA of excipients glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.
- Justify for not performing all the quality test in accordance with BP monograph of Mometasone Furoate aqueous nasal spray while establishing the pharmaceutical equivalence against the comparator product.
- Provide the reference of label claim mentioned in the pharmaceutical equivalence table.
- Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of Mometasone Furoate aqueous nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.
- Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray as evident from the submitted procedure in the relevant section.
- Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.
- Justify for not including all the quality test recommended by the BP monograph of Mometasone Furoate aqueous nasal spray while performing the stability of drug product.

Response of the Firm:

Sr.no.	Decision of 335th meeting of Registration Board	Response of the Firm
1.	Section 1.6.5(a) specify that M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA is the drug substance manufacturer, while the GMP certificate of M/s. Flax Laboratories (Pvt.) Limited Raigad, India has been submitted in section 1.6.5(b). Clarify for submitting the GMP certificate of M/s. FLAX Laboratories instead of M/s. Sawati Spentose Pvt. Ltd.	In their reply firm submitted the GMP certificate of M/s. Sawati Spentose Pvt. Ltd A-1/2111, Phase III, G.I.D.C, Vapi, Gujarat - 396 195, INDIA, without any clarification.
2.	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.	Submitted
3.	Justify for adopting the BP specification for USP complied drug substance, since the drug substance manufacturer claimed USP specification for drug substance.	Firm replied that as per submitted documents the drug substance manufacturer complies with the USP specification however, we Shrooq Pharmaceuticals being the drug product manufacturer tested the drug substance as per BP Monograph and its upto us which method we want to adopt for testing of drug substance.
4.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
5.	Submit the analysis report/COA of excipients glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-6/2024-QC dated 30th January,2024.	Submitted
6.	Justify for not performing all the quality test in accordance with BP monograph of Mometasone Furoate aqueous nasal spray while establishing the pharmaceutical equivalence against the comparator product.	Firm replied that the test for uniformity of delivered mass is for the solution whereas the product Medison Nasal Spray is suspension.
7.	Provide the reference of label claim mentioned in the pharmaceutical equivalence table.	Firm claimed that they follow label claim of innovator product approved in USFDA.

8.	Justify for not including the test of uniformity of delivered dose, test of number of deliveries per container and leak test as recommended by the BP monograph of Mometasone Furoate aqueous nasal spray. Further, clarify the stated amount of assay test either it is amount actuation from the valve or otherwise.	Firm submitted the revised specification of drug product in which they include test of uniformity of delivered dose and test of number of deliveries per container along with all other parameters. Further, firm clarify that the test of the assay is the stated amount of actuation from the valve.
9.	Justify for not adopting the analytical procedure of drug product in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray as evident from the submitted procedure in the relevant section.	Firm submitted the revised analytical procedure which is in accordance with the BP monograph of Mometasone Furoate aqueous nasal spray
10.	Justify for not performing the stability of drug product at alternate condition recommended in ICH guidelines for drug product packaged in plastic containers.	Firm submitted the water loss study as recommended in ICH guidelines as an alternative approach of performing stability study for drug product packaged in plastic containers.
11.	Justify for not including all the quality test recommended by the BP monograph of Mometasone Furoate aqueous nasal spray while performing the stability of drug product.	Firm claimed that they performed all the quality test while performing the stability of drug product, however the stability data did not include the test of uniformity of delivered dose and test of number of deliveries per container as recommended by BP.

Decision: Deferred for submitting revised pharmaceutical equivalence report in accordance with the revised specification of drug product. Further, justify for not including all the quality test recommended by the BP monograph of fluticasone propionate nasal spray while performing the stability of drug product, since the stability data did not include the test of uniformity of delivered dose and test of number of deliveries per container.

280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Name, address of Manufacturing site.	**M/s. Genix Pharma (Pvt.) Ltd. Plot no.44-45 B, Korangi Creek Road Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.37077 dated : 20-12-2022
	Details of fee submitted	PKR 30,000/- : vide slip no.7626939893 dated 12-12-2022
	The proposed proprietary name / brand name	Haemic Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet contains: Tranexamic Acid……500mg
	Pharmacotherapeutic Group of (API)	AntiFibrinolytic agent, Haemostasis
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Traumax 500mg Tablet of M/s. Siza International (Pvt.) Ltd. (Reg.no.024787)

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2.S.4.3**	Submit analytical method verification report of drug substance performed by drug product manufacturer.
2.	**3.2.P.5.1**	Adapt the acceptance limit of dissolution in term of Q, since the USP monograph specify the limit with Q value i.e. NLT 80% (Q) of the labeled amount of tranexamic acid dissolved.
3.	**3.2.P.5.2**	Justify how USP specification be applied on the strength of 500mg tablet considering the sample preparation procedure of assay recommended in USP monograph of Tranexamic acid tablet in which crushed powder of tablet equivalent to 650mg tranexamic acid is taken for sample preparation.
4.	**3.2.P.5.3**	Rationalize the spiked concentration of active taken while performing the accuracy parameter of verification studies of drug product specifically with reference to the applied strength.

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
2.	Adapt the acceptance limit of dissolution in term of Q, since the USP monograph specify the limit with Q value i.e. NLT 80% (Q) of the labeled amount of tranexamic acid dissolved.	Firm submitted the revised acceptance limit of dissolution in term of Q i.e. NLT 80% (Q) of the labeled amount of tranexamic acid dissolved within 60 minutes.
3.	Justify how USP specification be applied on the strength of 500mg tablet considering the sample preparation procedure of assay recommended in USP monograph of Tranexamic acid tablet in which crushed powder of tablet equivalent to 650mg tranexamic acid is taken for sample preparation.	Firm replied that they have taken 822.12mg of crushed powder of tablet which is eq. to 650mg of Tranexamic Acid (same as USP concentration i.e. 2.6mg/ml) 632.4mg/500mg *650= 822.12mg Note. 632.4mg of tablet weight Eq. 500mg of Tranexamic Acid hence 822.12mg of tablet weight eq. 650mg of Tranexamic Acid.
4.	Rationalize the spiked concentration of active taken while performing the accuracy parameter of verification studies of drug product specifically with reference to the applied strength.	Firm replied that As per USP monograph final concentration of sample is 2.6mg/ml. So, we prepare the accuracy sample in the range of 50%-150%.So, we prepare, 2.6mg/ml for 100% concentration, 1.3mg/ml for 50% concentration, 3.9mg/ml for 150% concentration.

Decision: Approved.Applicant shall submit PKR 7500/- pre-registration variation fee for change in specification of drug product, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.

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

Export Facilitation: Applications was received through letter No.F.1-76/2019-PR-I (EFD)
"M/s Pharmedic Laboratories (Pvt.) Ltd. have achieved benchmark OF USD 1576776.335 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 05 products applications submitted by the firm."

281.	Name, address of Applicant / Marketing Authorization Holder	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Name, address of Manufacturing site.	**Name: Pharmedic Laboratories (Pvt.) Ltd.**

		Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2629 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..2.5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 2.5mg Tablet by M/s Getz Pharma, Reg. No. 061344
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's , 3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	NEB2.5-TR002	NEB2.5-TR003	NEB2.5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

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

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our

			claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria**.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.		
Decision: The Registration Board deferred the application as last chance to submit the reply for the shortcomings already communicated. their submitted responses were still deemed unsatisfactory after evaluation.		
282.	Name, address of Applicant / Marketing Authorization Holder	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Name, address of Manufacturing site.	**Name: Pharmedic Laboratories (Pvt.) Ltd.** **Address: 16km Multan Road, Lahore-Pakistan**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2630 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 5mg Tablet by M/s Getz Pharma, Reg. No. 061345
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NEB5-TR002, NEB5-TR003, NEB5-TR004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB5-TR002	NEB5-TR003	NEB5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020

Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.n	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water conent in the release specification of drug product, since these test are included in the specification of innovator brand. Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than

		80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

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

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not

		the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria**.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision: The Registration Board deferred the application for last chance to submit reply to the communicated shortcomings as their submitted responses were still deemed unsatisfactory after evaluation.

283.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.9330 dated 12/04-2022
	Details of fee submitted	PKR 30,000/-: dated 17/03/2022
	The proposed proprietary name / brand name	Nevol 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..10mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Bynevol 10mg Tablet by Atco Laboratories, Reg. No. 081562
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any Pharmacoepia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bynevol 10mg tablet by Atco Laboratories. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bynevol 10mg tablet by Atco Laboratories..…. in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.
API Lot No.	NBB-19070031M
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's, 3x 10's and 2x 7's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 12 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB10-TR002	NEB10-TR003	NEB10-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA. Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.

		Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

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

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in	Firm submitted the revised analytical procedure of drug along with specification.

		the specification of innovator brand.	
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision of 329th meeting of Registration Board:

Deferred for submission of following shortcomings:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- **Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria**.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- **Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision: The Registration Board deferred the application for last chance to submit the reply to the communicated shortcomings, as their submitted responses were still deemed unsatisfactory after evaluation.

284.	Name, / Marketing Authorization Holder address of Applicant	M/s. Ophth Pharma (Pvt.) Ltd. Plot no. 241, Sector 24, Korangi Industrial Area Karachi.
	Name, address of Manufacturing site.	M/s. Ophth Pharma (Pvt.) Ltd. Plot no. 241, Sector 24, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.30262 dated 05-11-2021
	Details of fee submitted	PKR 30,000/- dated 19/01/2021
	The proposed proprietary name / brand name	Carmeze Eye drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboxymethyl cellulose sodium…10mg
	Pharmaceutical form of applied drug	Clear, colorless to slight yellow viscous solution and packed in unit carton along with leaflet
	Pharmacotherapeutic Group of (API)	Ophthalmic lubricant
	Reference to Finished product specifications	BP
	Proposed Pack size	10ml

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved CELLUVISC® 1% w/v EYE DROPS, SOLUTION (Carmellose Sodium).
	For generic drugs (me-too status)	Optheez drops of M/s. Barrett & Hodgson Pakistan (Pvt.) Ltd. Reg.no.093070
	GMP status of the Finished product manufacturer	GMP certificate issued dated 29th sep,2021 based upon inspection conducted on 27th sep, 2021,valid for 2 years.
	Name and address of API manufacturer.	M/s. Anhui Sunhere Pharmaceutical Excipients Co. Ltd. No.2 Hebin Road, Economic Development Zone,Huainan,Anhui,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of drug substance present BP Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (110403,110404,110405)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the comparator product that is Optheez drops of M/s. Barrett & Hodgson Pakistan (Pvt.) Ltd. Reg.no.093070 performing quality tests (Identification, ,pH, osmolality).
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Anhui Sunhere Pharmaceutical Excipients Co. Ltd. No.2 Hebin Road, Economic Development Zone,Huainan,Anhui,China
API Lot No.	110405
Description of Pack (Container closure system)	Primary Container: 10ml plastic bottle Secondary Container: packed in a printed carton along with a leaflet.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Real Time: 0, 2, 4, 6 ,12,18,24(Months) Accelerated : 0, 3, 6 (Months)		
Batch No.	Tb-101	Tb-102	Tb-103
Batch Size	1 LITRE	1 LITRE	1 LITRE
Manufacturing Date	11-2017	11-2017	11-2017
Date of Initiation	03-11-2017	03-11-2017	03-11-2017
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the letter related to submission of sample of carboxymethyl cellulose sodium to M/s. Ophth Pharma from Rasheedsons for evaluation purpose.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1	Justify the finished product specifications as "USP specifications" since the drug product monograph is only available in BP Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Firm submitted the revised finished product specification from USP specification to BP specification in section 3.2.P.5., however in module 1 section 1.5.6 firm again claimed USP specification for drug product.
2	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer as well as drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Firm only submit the copy of USP monograph of carboxymethyl cellulose sodium. Specification and analytical procedure by drug substance manufacturer has not been submitted by the firm.
3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the	Firm submitted the analytical method verification report without any detail regarding the assay procedure which has been verified and clarity related quantification data of precision and accuracy parameter (either the quantify amount was of carboxymethyl cellulose sodium or only the sodium content)

	testing of drug substance was carried out without performing verification studies.	
4	• Provide details including batch number, expiry date and name of manufacturer of the product along with pharmaceutical equivalence was performed. • Perform all the test which are included in the BP monograph of carmellose sodium ophthalmic drops to establish pharmaceutical equivalence with the reference product.	Firm submitted the pharmaceutical equivalence report performed against the optheez eye drop of M/s. Barrett & Hodgson and only identification and pH and osmolality test has been included in the report. Assay has not performed while the performance of pharmaceutical equivalence.
5	According to the batch analysis report of finished product you have adopted in-house specification for the testing of drug product since the monograph of applied product is present in BP pharmacopeia. Revise the specification of drug product in compliance to BP monograph and accordingly submit the revised analytical procedure and verification report.	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the BP monograph.
6	Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.	Firm submitted the COA of working standard with USP claim, while the claimed specification of finished product is BP.
7	Provide detail about the container closure system and performance report of water loss study	Firm informed that the primary container closure system is plastic bottle and did not submit the report of water loss study.
8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the letter related to submission of sample of carboxymethyl cellulose sodium to M/s. Ophth Pharma from Rasheedsons for evaluation purpose.
9	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	As per the submitted raw data sheets it is evident that firm has not performed the assay testing as recommended by BP monograph with reference to sample and standard conc.
1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Submitted.

Decision of 323rd meeting of Registration Board:

Deferred for the submission of following:

- Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Submit detailed analytical method of the drug substance from the drug product manufacturer as well as drug substance manufacturer in section 3.2.S.4.2.
- Performed verification study on the assay method of drug substance in accordance with USP monograph by drug product manufacturer.
- Pharmaceutical Equivalence report against the innovator/reference product and performed all the quality test as recommended by the BP monograph.

- Analytical method verification report of drug product including specificity, accuracy and precision (repeatability) parameter.
- Submitted COA of working standard is of USP grade, whereas drug product specifications have been claimed as per BP monograph.
- Water loss study of drug product, since the primary container of drug product is LDPE bottles.
- API procurement document including copy of commercial invoice attested by AD (I&E) DRAP.
- Scientific justification for non-compliance of BP monograph while performing the assay testing of drug product during stability studies as evident from submitted raw data sheets.

Response of the Firm:

Sr.no.	Decision of 323rd meeting of Registration Board	Response of the Firm
1.	Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm submitted the fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021
2.	Submit detailed analytical method of the drug substance from the drug product manufacturer as well as drug substance manufacturer in section 3.2.S.4.2.	Submitted
3.	Performed verification study on the assay method of drug substance in accordance with USP monograph by drug product manufacturer.	Submitted
4.	Pharmaceutical Equivalence report against the innovator/reference product and performed all the quality test as recommended by the BP monograph.	Firm submitted the pharmaceutical equivalence report performed against the reference product Celluvis Eye Drop of M/s. Allergan Pharmaceuticals Ireland (Batch no. FDT258).
5.	Analytical method verification report of drug product including specificity, accuracy and precision (repeatability) parameter.	Firm submitted the analytical verification report of drug product.
6.	Submitted COA of working standard is of USP grade, whereas drug product specifications have been claimed as per BP monograph.	Submitted
7.	Water loss study of drug product, since the primary container of drug product is LDPE bottles	Firm submitted the water loss study of drug product. However, firm submitted the water loss study of only trial batch TB-101 while water loss study of remaining two batches is still not submitted.
8.	API procurement document including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submitted the copy of commercial invoice attested by the DRAP officer.
9.	Scientific justification for non-compliance of BP monograph while performing the assay testing of drug product during stability studies as evident from submitted raw data sheets.	Firm replied that they performed the assay in accordance with BP monograph, by mistake the assistant have not attached the file of testing in the CTD file.

Decision: The Registration Board deferred the application for last chance to submit the reply to the communicated shortcomings, as their submitted responses were still deemed unsatisfactory after evaluation.		
285.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021 in which Syrup/Oral Suspension section is specified in the list of approved section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27403 dated 27-09-2022
	Details of fee submitted	Rs. 75,000/- vide slip no. 70273076715 dated 22-09-2022
	The proposed proprietary name / brand name	**Baclast 5mg/5ml Oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Baclofen…….5mg
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (gamma-aminobutyric acid (GABA-ergic) agonist)
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	60ml,100ml,200ml & 300ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA (Baclofen 5 mg/5 mL Oral Solution) Approved in 300ml pack volume.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures

		and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the reference product Baclofen oral solution 5mg/5ml oral solution of M/s. Advanz Pharma (Batch no. E5896)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India		
API Lot No.	BCF/2122007		
Description of Pack (Container closure system)	Clear,colorless solution with raspberry flavour filled in amber glass bottle 30ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-167-01	21SB(B)-168-02	21SB(B)-169-03
Batch Size	75 BOTTLES	75 BOTTLES	75 BOTTLES
Manufacturing Date	10-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.INDBGMP202201594) issued dated 02-March-2022 and valid for 5 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of DRAP attested invoice related to the procurement of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

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

Therapeutic indications:
Baclofen 5 mg/5 mL Oral Solution is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord. Baclofen 5 mg/5 mL Oral Solution is also indicated in adults and children for the relief of spasticity of voluntary muscle arising from e.g. cerebrovascular accidents, cerebral palsy, meningitis, traumatic head injury. Patient selection is important when initiating Baclofen 5 mg/5 mL Oral Solution therapy; it is likely to be of most benefit in patients whose spasticity constitutes a handicap to activities and/or physiotherapy. Treatment should not be commenced until the spastic state has become stabilised.

Posology and method of administration
Before starting treatment with Baclofen 5 mg/5 mL Oral Solution it is prudent to realistically assess the overall extent of clinical improvement that the patient may be expected to achieve. Careful titration of dosage is essential (particularly in the elderly) until the patient is stabilised. If too high a dose is initiated or if the dosage is increased too rapidly side effects may occur. This is particularly relevant if the patient is ambulant in order to minimise muscle weakness in the unaffected limbs or where spasticity is necessary for support. Adults: The following gradually increasing dosage regimen is suggested, but should be adjusted to suit individual patient requirements. 5mg three times a day for three days 10mg three times a day for three days 15mg three times a day for three days 20mg three times a day for three days Satisfactory control of symptoms is usually obtained with doses of up to 60mg daily, but a careful adjustment is often necessary to meet the requirements of each individual patient. The dose may be increased slowly if required, but a maximum daily dose of more than 100mg is not advised unless the patient is in hospital under MHRA PAR; BACLOFEN 5 MG/5 ML ORAL SOLUTION, PL 06464/2354 13 careful medical supervision. Small frequent dosage may prove better in some cases than larger spaced doses. Also some patients benefit from the use of Baclofen 5 mg/5 mL Oral Solution only at night to counteract painful flexor spasm. Similarly, a single dose given approximately 1 hour prior to performance of specific tasks such as washing, dressing, shaving, physiotherapy, will often improve mobility. Once the maximum recommended dose has been reached, if the therapeutic effect is not apparent within 6 weeks a decision whether to continue with Baclofen 5 mg/5 mL Oral Solution should be taken.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide the evidence of reference product approved in reference regulatory agencies in the volume size of 60ml,100ml &200ml.	Firm replied that reference product is available only in 300ml pack size. However for patient compliance and affordability we have requested pack size of 60ml,100ml and 200ml.
2.	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
3.	Drug Substance manufacturer claimed IP specification for the drug substance while you have complied BP specification, clarify for using different specification for	Firm replied that drug substance in Drug Master File Claim both IP & BP.

	the drug substance from that claimed by drug substance manufacturer.	However, the monograph of Baclofen drug substance is not present in IP, Eleventh Edition,2022.
4.	Submit complete real time stability data of drug substance till claimed re-test date, since you have only submitted the data of 18 months.	Submitted
5.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
6.	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm submitted raw material analytical report of Propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol including the COA of vendor of raw material Propylene glycol and sorbitol. However COA of sorbitol from raw material manufacturer did include the impurity testing related to the presence of ethylene glycol and diethylene glycol.
7.	Storage condition specified by the reference product and BP monograph of "Baclofen Oral Solution) is "Baclofen oral solution should be stored below 25°C, while the storage condition mentioned by you is store below 30°C, Justify the storage condition recommended by you for your applied product.	Firm replied that mistakenly it is written as store below 30°C the actual correct storage is store below 25°C. Revised SOP is submitted.
8.	Justify for not adopting the BP specifications for the drug product when the monograph of Baclofen Oral Solution is present in BP.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
9.	Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided".	Firm submitted the in-use stability data of 28 days. Stability study has been performed on 30ml pack size, which is not included in the demanded pack size.

Decision of 335th meeting of Registration Board:

Deferred for revision of analytical procedure of drug product specifically assay method in accordance with BP monograph of "Baclofen Oral Solution" and submit the performance report in accordance with revised analytical method at next time point of long term stability studies.

Response of the Firm:

Firm submitted the revised analytical procedure in compliance of BP monograph of "**Baclofen Oral Solution**" and accordingly submit the performance report of next time point of stability study in accordance with revised assay procedure.

Decision: Approved.

- **Applicant shall submit PKR 7500/- pre-registration variation fee for change in specification of drug product, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

286.	Name, address of Applicant / Marketing Authorization Holder	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s. Genix Pharma (Private) Ltd. 44-45-B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021.
	Evidence of approval of manufacturing facility	Firm submitted GMP certificate no.46/2021-DRAP(K) dated 07th October,2021 in which Syrup/Oral Suspension section is specified in the list of approved section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27403 dated 27-09-2022
	Details of fee submitted	Rs. 75,000/- vide slip no. 70273076715 dated 22-09-2022
	The proposed proprietary name / brand name	**Baclast 10mg/5ml Oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Baclofen…….10mg
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (gamma-aminobutyric acid (GABA-ergic) agonist)
	Pharmaceutical form of applied drug	Oral Solution
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	60ml,100ml,200ml & 300ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA (Baclofen 10mg/5 mL Oral Solution) Approved in 300ml pack volume.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence against the reference product Baclofen oral solution 10mg/5ml oral solution of M/s. Thames Laboratories (Batch no.HFCR0004)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Panchsheel Organics Limited B6-B7,Sector-C,Sanwer Road, Industrial Estate Indore (M.P), India		
API Lot No.	BCF/2122007		
Description of Pack (Container closure system)	Clear,colorless solution with raspberry flavour filled in amber glass bottle 30ml		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21SB(B)-170-01	21SB(B)-171-02	21SB(B)-172-03
Batch Size	75 BOTTLES	75 BOTTLES	75 BOTTLES
Manufacturing Date	10-2021	10-2021	10-2021
No. of Batches	03		

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No.INDBGMP202201594) issued dated 02-March-2022 and valid for 5 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of DRAP attested invoice related to the procurement of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide the evidence of reference product approved in reference regulatory agencies in the volume size of 60ml,100ml &200ml.	Firm replied that reference product is available only in 300ml pack size. However for patient compliance and affordability we have requested pack size of 60ml,100ml and 200ml.
2.	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
3.	Drug Substance manufacturer claimed IP specification for the drug substance while you have complied BP specification, clarify for using different specification for the drug substance from that claimed by drug substance manufacturer.	Firm replied that drug substance in Drug Master File Claim both IP & BP. However, the monograph of Baclofen drug substance is not present in IP, Eleventh Edition,2022.
4.	Submit complete real time stability data of drug substance till claimed re-test date, since you have only submitted the data of 18 months.	Submitted
5.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
6.	Submit the analysis report/COA of excipients propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol, in compliance of notification issued by DRAP vide letter No. F.3-42/2023-QC dated 1st, December,2023.	Firm submitted raw material analytical report of Propylene glycol and sorbitol which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol including the COA of vendor of raw material Propylene glycol and sorbitol. However COA of sorbitol from raw material manufacturer did include the impurity testing related to the presence of ethylene glycol and diethylene glycol.

7.	Storage condition specified by the reference product and BP monograph of "Baclofen Oral Solution) is "Baclofen oral solution should be stored below 25°C, while the storage condition mentioned by you is store below 30°C, Justify the storage condition recommended by you for your applied product.	Firm replied that mistakenly it is written as store below 30°C the actual correct storage is store below 25°C. Revised SOP is submitted.
8.	Justify for not adopting the BP specifications for the drug product when the monograph of Baclofen Oral Solution is present in BP.	Firm replied they have performed the stability studies as per BP method but they skipped to mention BP specification therefore they have revised the specification as per BP. Requisite fee of Rs.7500/- has submitted vide deposit slip no. 69383266679 dated 19-01-2024. However, the analytical procedure of drug product given in section 3.2.P.5.2 specifically assay procedure is different from method recommended by the BP monograph of Baclofen Oral Solution.
9.	Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided".	Firm submitted the in-use stability data of 28 days. Stability study has been performed on 30ml pack size, which is not included in the demanded pack size.

Decision of 335th meeting of Registration Board:

Deferred for revision of analytical procedure of drug product specifically assay method in accordance with BP monograph of "Baclofen Oral Solution" and submit the performance report in accordance with revised analytical method at next time point of long term stability studies.

Response of the Firm:

Firm submitted the revised analytical procedure in compliance of BP monograph of "**Baclofen Oral Solution**" and accordingly submit the performance report of next time point of stability study in accordance with revised assay procedure.

Decision: Approved.

- **Applicant shall submit PKR 7500/- pre-registration variation fee for change in specification of drug product, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Previously Deferred Cases of Form 5-F (Finished Import):

287.	Name, address of Applicant / Importer	M/s. VIZ Remedies Pakistan LLP
	Details of Drug Sale License of importer	License No. 1174 Address: Suit No.26 4th Floor Kehkashan Mall, Tariq Road. Block-2 PECHS Karachi Address of Go down: NA Validity: 13-02-2022 Status: License to sell drugs as distributor Renewal: Firm has submitted for renewal

	Name and address of marketing authorization holder (abroad)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name, address of manufacturer(s)	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted copy of CoPP certificate (No: 20200029) dated 16-06-2020 issued by Shaanxi Provincial Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned. Furthermore, the CoPP was valid till 15-06-2022. Copy of GMP certificate of M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. is submitted which was valid till 22-09-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Exclusive Marketing Agreement between M/s. VIZ Remedies Pakistan LLP and M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. The letter specifies that the manufacturer appoints M/s. VIZ Remedies Pakistan LLP. Is their exclusive agent in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24063 : dated 01-09-2021
	Details of fee submitted	PKR 100,000/-: dated 18-01-2021 (Differential fee of Rs. 50,000/- is to be submitted by the firm)
	The proposed proprietary name / brand name	Tirofiban Hydrochloride Injection 5mg/100ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL contains: Tirofiban Hydrochloride (calculated based on Tirofiban)5mg
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Anti-Platelet
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1x100ml neutral borosilicate glass infusion bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (AGGRASTAT Injection)

	For generic drugs (me-too status)	Not confirmed in the applied volume i.e.100ml
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Xi'an Wanlong Pharmaceutical Co. Ltd. No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of Tirofiban hydrochloride Injection instead of Tirofiban hydrochloride API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence study has been performed against the innovator product AGGRASTAT Injection (Batch no. C856260) which includes quality test (Appearance, pH , Assay, Citric Acid and sodium citrate content, sodium chloride content and related substance test.)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml- neutral borosilicate glass Infusion bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 following batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. B171001,B171002,B171003

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
2.	1.4	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.

3.	3.2.S.7	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.
4.	3.2.P.3	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.
5.	3.2.P.5.1	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.
6.	3.2.P.5.4	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.	Firm replied that they submitted original and legalized CoPP at the time of registration. However due to its expiration, renewed CoPP has been requested to the principal manufacturer.
2.	Submit valid drug sale license of VIZ Remedies Pakistan LLP ,since you have submitted the expired DSL.	Firm submitted the copy of DSL no. 0324 which is valid till 14/03/2028.
3.	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.	Firm submitted the stability data of 36 months of three batches performed at long term conditions.
4.	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.	Firm in their reply submitted a document, which only stated the quality parameters used for the analysis of activated charcoals INSTEAD of providing reference from international standard to rationalize the use of activated charcoal for sterilizing the injectable solution..
5.	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.	Firm clarify that they quantify the quantity of tirofiban by using external standard method, the obtained assay is for tirofiban hydrochloride, then the results will multiply by conversion coefficient (0.8899) to obtain labelled amount of Tirofiban.
6.	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.	Firm replied that the role of sodium chloride in this formulation is as “Osmotic Pressure Modifier”.

Decision of 333rd meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
- Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.

Response of the Firm:

- **Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.**

Firm replied that the valid original and legalized Certificate of Pharmaceutical Product (CoPP) were submitted at the time of submission of registration application.

- **Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.**

Firm submitted guidance document of PMDA, Japan "Guidance on the Manufacture of Sterile Pharmaceutical Products by Aseptic Processing" but the submitted documents did not contain any material relevant to the use of activated charcoal carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin. Further, firm submitted the patent documents of tirofiban hydrochloride as a proof of use of activated carbon instead of tirofiban hydrochloride injection.

Decision of 336th meeting of Registration Board:
Deferred for submission of relevant guidance document of reference agencies which clearly recommends the usage of activated carbon in the manufacturing procedure of sterile preparation for removal of bacterial endotoxin.

Response of the Firm:
Firm replied that the activated carbon is no longer employed in the manufacturing process by the Principal. Therefore, with regard to the manufacturing process, the following documents are enclosed as an evidence:

i. Manufacturing Process
ii. Process Validation
iii. Sterility Report

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility. Registration Board further decided that the panel shall confirm the manufacturing procedure of drug product, since the applicant claimed that the activated carbon has no longer used in the manufacturing procedure of applied injectable by the Manufacturer Abroad.

288.	Name, address of Applicant / Importer	M/s: Sohail Corporation Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan.
	Details of Drug Sale License of importer	License No: 239 Address: Plot no 7, SR-5, Serai Quarters, Techno City Ware house no 42, Karachi-Pakistan. Address of Godown: NA Validity: 18-Nov-2027 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale Renewal: Our license has been renewed and the details written above are for the renewed licenses.
	Name and address of marketing authorization holder (abroad)	M/s.Tianjin King York Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99 Hanjiang Bei Road, Xiangyang, Hubei, P.R. China.
	Name, address of manufacturer(s)	Name of Manufacturer: M/s.Tianjin King York Group Hubei Tianyao Pharmaceuticals Co. Ltd. Address: No.99 Hanjiang Bei Road, Xiangyang, Hubei, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No:20211201 Dated 09-02-2022 issued by Hubei Xiangyang Administration for Market Regulation of the Peoples Republic of China No.41.Chunyuan Road, Xiangyang City, Hubei Province. and validity is for two years.

		Firm has submitted GMP certificate no.HB20190552 of Manufacturer M/s.Tianjin KingYork Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99, HanjiangBei Road, XiangYang City, Hubei Province and the certificate remain valid until; 26-11-2024.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of agent & distributor agreement dated 18th June,2021 between three companies. The letter species that the M/s. Qingdao JidaBarr International Trade Co. Ltd., China is the Exporter, M/s. Sohail Corporation Karachi is the Distributor and M/s. Tianjin KingYork KingDroy International Trading Co. Ltd. a company incorporated in China having its registered Unit 1702, Yangzhao Building, Tianjin Pilot Free Trade Zone, Tianjin China hereby on behalf of Tianjin KingYork Group Hubei Tianyao Pharmaceuticals Co. Ltd. No.99, HanjiangBei Road, XiangYang City, Hubei Province is the Manufacturer. The Manufacturer is engaged in manufacturing and desired to enter into an agreement with the exporter to export these products to the Pakistan Territory.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 27734 dated 20-09-2022
	Details of fee submitted	PKR 150,000/-: vide slip no. 7062718500 dated 23-09-2022.
	The proposed proprietary name / brand name	**Paracetamol Injection 1g/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml solution contains……1g
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	In-house
	Proposed Pack size	1 bottle of 100ml packed in printed unit box with a product leaflet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (Acetaminophen 1g/100ml)
	For generic drugs (me-too status)	Parazyl L Injection of M/s. Searle IV solution Pvt. Ltd., Lahore (Reg.no. 078617)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Anqiu Lu'an Pharmaceuticals Co. Ltd. No.35 Weixu North Road, Aniqu, Shandog, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30°C ± 2°C and 75%+5 RH. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence studies report against the reference product of M/s. Cisen Pharmaceuticals Co. Ltd., China (Paracetamol Injection 1g/100ml), but an incomplete report has been submitted by the firm.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml type I glass bottle made of low borosilicate glass: Butyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 3 batches is for 36 months

Evaluation by PEC:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
2.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
3.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.
4.	3.2.P.2.2.1	Submitted equivalence report did not include the results of applied product of Tianjin KingYork Group Hubei Tianyao Pharmaceutical Co. Ltd. along with quality analysis reports of reference product. Submit the comparison/equivalence report mentioning the quality results of both test and reference product.
5.	3.2.P.5.1	Justify for keeping the pH of drug product between 4.5-6.0 when the innovator recommends pH between 5.0 and 6.3.
6.	3.2.P.5.4	Assay procedure given in section 3.2.P.5.2 is different from the assay method validated in section 3.2.P.5.4, justification is required in this regard.

7.	3.2.P.7	Clarify the disparities observed in the container closure report as the results of few container compatibility test stated that the 2ml type I glass bottle are compatible for the product, further the final conclusion of report claimed that the paracetamol injection 1mg/100ml is stable with the type I glass bottles.

Decision of 335th meeting of Registration Board:

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

Response of the Firm:

S.no.	Section	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.	Firm replied that The specification of Paracetamol used by Tianjin Kingyork Group Hubei Tianyao Pharmaceutical Co., Ltd. is consistent with that provided by the manufacturer (Anqiu Lu'an), and all meet the requirements under BP monograph. Therefore, Tianyao has validated the analytical method, please see the following pages for details.
2.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.	Submitted
3.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted
4.	3.2.P.2.2.1	Submitted equivalence report did not include the results of applied product of Tianjin King York Group Hubei Tianyao Pharmaceutical Co. Ltd. along with quality analysis reports of reference product. Submit the comparison/equivalence report mentioning the quality results of both test and reference product.	Firm replied that We have added the test results of Tianjin King York Group Hubei Tianyao Pharmaceutical Co. Ltd. to the Equivalence Report snd submit the revised equivalence report .
5.	3.2.P.5.1	Justify for keeping the pH of drug product between 4.5-6.0 when the innovator recommends pH between 5.0 and 6.3.	Firm replied that "As described under the monograph for Paracetamol Injection in the Chinese Pharmacopoeia, the pH range is set between 4.5 and 6.5. However, in establishing our product quality standards, we opted for stricter pH control, narrowing the range to 4.5 to 6.0. Through rigorous production and quality testing, we have consistently observed that the pH of our injections falls within a narrower range of approximately 5.5 to 5.9. If necessary, based on future market demands or the need for product quality control, we are fully capable of adjusting the pH range to 5.0 to 6.3, while ensuring that the overall product quality remains compliant with established standards and requirements.
6.	3.2.P.5.4	Assay procedure given in section 3.2.P.5.2 is different from the assay method validated in section 3.2.P.5.4, justification is required in this regard.	Firm replied that We apologize for the inconvenience caused by our oversight, as we inadvertently submitted an outdated version of the assay method validation report for a different strength. Kindly refer to the enclosed corrected version of the assay method validation report.

			We would like to once again apologize for the inconvenience caused by this mistake. and will take necessary measures to ensure the completeness and accuracy of future document submissions.
7.	3.2.P.7	Clarify the disparities observed in the container closure report as the results of few container compatibility test stated that the 2ml type I glass bottle are compatible for the product, further the final conclusion of report claimed that the paracetamol injection 1mg/100ml is stable with the type I glass bottles.	Firm replied that After thorough examination, we regret to find that the Section 3.2.P.7 of the submitted documentation does not contain a specific description of "2ml type I glass." Instead, the relevant section on primary packaging materials only mentions "100ml type II glass bottle." To ensure the completeness and accuracy of the document, we kindly ask your confirmation of this oversight in our submission. We apologize for any inconvenience this may have caused and will take necessary measures to ensure the completeness and accuracy of future document submissions.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

289.	Name, address of Applicant / Marketing Authorization Holder	*Innovegic Pharmaceuticals* *Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad.*
	Detail of Drug Sale License	License No:1605 Address: Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad. Status: License to sell drug as distributor
	Name and address of Marketing authorization holder(abroad)	Aburaihan Pharmaceutical Co. Address: No.1 Hojrebne Oday Ave, Tehran pars, Tehran, I.R.IRAN.
	Name, address of Manufacturer	M/s Aburaihan Pharmaceutical Co.,Iran
	Status of the applicant	☐ Manufacturer ☑ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting Country	Iran
	Detail of certificate attached (COPP, Free sale certificate, GMP certificate)	Firm has submitted COPP Certificate No:665/106835 valid up to 11-03-2024 issued by Islamic Republic of Iran.
	Detail of letter of authorization/sole agency agreement	M/s. Aburaihan Pharmaceutical Co., No. 1, Hojr Ebne Oday Ave., Tehranpars P.O. Box: 16765/1568 Tehran I.R. Iran. duly authorize to M/s. Innovegic Pharmaceuticals, Plot c-19, 2nd Floor, Rawat Industrial Estate, Rawat Islamabad to act as our agent for the registration, sale and marketing of our products stated below in Pakistan: • Fertigest 200mg suppository • Fertigest 400mg suppository
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☑Domestic and Export sales
	Dy. No. and date of submission	Dy. No.9830 dated 18-04-2022
	Details of fee submitted	PKR 150,000/-: dated 21-10-2022
	The proposed proprietary name / brand name	Fertigest 200mg suppository
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pack contains: progesterone…..200mg
	Pharmaceutical form of applied drug	Suppository
	Pharmacotherapeutic Group of (API)	Antimineralocorticoid:Neurosteroid
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5x2's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cyclogest 200mg L.D Collins& Co.Ltd,UK ,MHRA Approved
	For generic drugs (me-too status)	Cyclogest Pessary 200mg by Excel health care
	GMP status of the Finished product manufacturer	GMP certificate of Aburaihan Pharmaceutical Co. was granted by Islamic Republic of Iranvalid upto21-01-2023.
	Name and address of API manufacturer.	M/s. Symbiotic Pharmalab private limited, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies of Drug Substance	Stability study conditions: Real time: 30±2°C / 65% ± 5% RH for 24 months Accelerated: 40±2°C / 75% ± 5% RH for 6 months Batches: (ZPGNC15019, ZPGNC15020, ZPGNC15021)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies of Drug Product	Stability study conditions: Real time: 30±2°C / 65% ± 5% RH for 36 months Accelerated: 40±2°C / 75% ± 5% RH for 6 months

		Batches: (9001,9002, 9003)
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence performed against RMP Cyclogest 200mg,Uk
	Analytical method validation/verification of product	Submitted.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.5**	Provide valid GMP certificate of Manufacturer Abroad, since the submitted GMP certificate was expired in 2021.
2.	**3.2.S.4.1**	Specification of drug substance by drug product manufacturer is different from the specifications specified in the BP monograph, justify for not complying the EP specifications, when the drug substance manufacturer claimed that the material complied EP specification.
3.	**3.2.S.4.2**	Submit detailed analytical procedure of drug substance by drug product manufacturer.
4.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
5.	**3.2.P.2.2.1**	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."
6.	**3.2.P.5.1**	Justify the finished product specifications as "USP specifications" since the drug product monograph is not available in USP Pharmacopoeia. Revise your specifications along with submission of requisite fee
7.	**3.2.P.5.2**	• Justify how product comply the USP monograph of "Progesterone Compounded vaginal insert", when the drug product was neither fall under the definition of Pharmaceutical Compounding as per the general chapter of USP <795> nor the applied drug product comply the packaging and storage condition specified in the said monograph. • Provide detailed procedure of dissolution testing of drug product, since the dissolution is included in the finished product specification.

Decision of 331st meeting of Registration Board:

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide valid GMP certificate of Manufacturer Abroad, since the submitted GMP certificate was expired in 2021.	Firm submitted the GMP certificate of Manufacturer Abroad which issued dated 20/12/2023 and it valid for a period of one year.
2.	Specification of drug substance by drug product manufacturer is different from the specifications specified in the BP monograph, justify for not complying the EP specifications, when the drug substance manufacturer claimed that the material complied EP specification.	Firm submitted the specification of drug substance in compliance of BP specification.
3.	Submit detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
4.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3	Submitted

	as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	
5.	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."	Submitted
6.	Justify the finished product specifications as "USP specifications" since the drug product monograph is not available in USP Pharmacopoeia. Revise your specifications along with submission of requisite fee	Firm has claimed that they initially claimed USP specification now they revised the specification as per innovator's specification.
7.	• Justify how product comply the USP monograph of "Progesterone Compounded vaginal insert", when the drug product was neither fall under the definition of Pharmaceutical Compounding as per the general chapter of USP <795> nor the applied drug product comply the packaging and storage condition specified in the said monograph. • Provide detailed procedure of dissolution testing of drug product, since the dissolution is included in the finished product specification.	Firm has claimed that they initially claimed USP specification now they revised the specification as per innovator's specification. Firm has later provide detailed procedure of dissolution testing of drug product

- **Decision: Approved with innovator's specification, as per Policy for inspection of Manufacturer abroad and verification of local storage facility. Further, Applicant shall submit PKR 7500/- pre-registration variation fee for change in specification of drug product, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.**

290.	Name, address of Applicant / Marketing Authorization Holder	***Innovegic Pharmaceuticals*** ***Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad.***
	Detail of Drug Sale License	License No:1605 Address: Plot # C-19, Second Floor, Main Road, RCCI, Industrial Area, Rawat, Islamabad. Status: License to sell drug as distributor
	Name and address of Marketing authorization holder(abroad)	Aburaihan Pharmaceutical Co. Address: No.1 Hojrebne Oday Ave, Tehran pars, Tehran, I.R.IRAN.
	Name, address of Manufacturer	M/s Aburaihan Pharmaceutical Co.,Iran
	Status of the applicant	☐ Manufacturer ☑ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting Country	Iran

	Detail of certificate attached (COPP, Free sale certificate, GMP certificate)	Firm has submitted COPP Certificate No:665/106835 valid up to 11-03-2024 issued by Islamic Republic of Iran.
	Detail of letter of authorization/sole agency agreement	M/s. Aburaihan Pharmaceutical Co., No. 1, Hojr Ebne Oday Ave., Tehranpars P.O. Box: 16765/1568 Tehran I.R. Iran. duly authorize to M/s. Innovegic Pharmaceuticals, Plot c-19, 2nd Floor, Rawat Industrial Estate, Rawat Islamabad to act as our agent for the registration, sale and marketing of our products stated below in Pakistan: • Fertigest 200mg suppository • Fertigest 400mg suppository
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☑Domestic and Export sales
	Dy. No. and date of submission	Dy. No.9831 dated 18-04-2022
	Details of fee submitted	PKR 150,000/-: dated 21-10-2022
	The proposed proprietary name / brand name	Fertigest 400mg suppository
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pack contains: progesterone…..400mg
	Pharmaceutical form of applied drug	Suppository
	Pharmacotherapeutic Group of (API)	Antimineralocorticoid:Neurosteroid
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5x2's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cyclogest 400mg L.D Collins& Co.Ltd,UK ,MHRA Approved
	For generic drugs (me-too status)	**Cyclogest Pessary 4**00mg by Excel health care
	GMP status of the Finished product manufacturer	GMP certificate of Aburaihan Pharmaceutical Co. was granted by Islamic Republic of Iran valid upto 21-01-2023.
	Name and address of API manufacturer.	M/s. Symbiotic Pharmalab private limited, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance
	Stability studies of Drug Substance	Stability study conditions: Real time: 30±2°C / 65% ± 5% RH for 24 months Accelerated: 40±2°C / 75% ± 5% RH for 6 months Batches: (ZPGNC15019, ZPGNC15020, ZPGNC15021)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies of Drug Product	Stability study conditions: Real time: 30±2°C / 65% ± 5% RH for 36 months Accelerated: 40±2°C / 75% ± 5% RH for 6 months
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence performed against RMP Cyclogest 200mg,Uk
	Analytical method validation/verification of product	Submitted.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.5**	Provide valid GMP certificate of Manufacturer Abroad, since the submitted GMP certificate was expired in 2021.
2.	**3.2.S.4.1**	Specification of drug substance by drug product manufacturer is different from the specifications specified in the BP monograph, justify for not complying the EP specifications, when the drug substance manufacturer claimed that the material complied EP specification.
3.	**3.2.S.4.2**	Submit detailed analytical procedure of drug substance by drug product manufacturer.
4.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
5.	**3.2.P.2.2.1**	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."
6.	**3.2.P.5.1**	Justify the finished product specifications as "USP specifications" since the drug product monograph is not available in USP Pharmacopoeia. Revise your specifications along with submission of requisite fee
7.	**3.2.P.5.2**	• Justify how product comply the USP monograph of "Progesterone Compounded vaginal insert", when the drug product was neither fall under the definition of Pharmaceutical Compounding as per the general chapter of USP <795> nor the applied drug product comply the packaging and storage condition specified in the said monograph. • Provide detailed procedure of dissolution testing of drug product, since the dissolution is included in the finished product specification.

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide valid GMP certificate of Manufacturer Abroad, since the submitted GMP certificate was expired in 2021.	Firm submitted the GMP certificate of Manufacturer Abroad which issued dated 20/12/2023 and it valid for a period of one year.
2.	Specification of drug substance by drug product manufacturer is different from the specifications specified in the BP monograph, justify for not complying the EP specifications, when the drug substance manufacturer claimed that the material complied EP specification.	Firm submitted the specification of drug substance in compliance of BP specification.
3.	Submit detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
4.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Submitted
5.	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed."	Submitted
6.	Justify the finished product specifications as "USP specifications" since the drug product monograph is not available in USP Pharmacopoeia. Revise your specifications along with submission of requisite fee	Firm has claimed that they initially claimed USP specification now they revised the specification as per innovator's specification.
7.	• Justify how product comply the USP monograph of "Progesterone Compounded vaginal insert", when the drug product was neither fall under the definition of Pharmaceutical Compounding as per the general chapter of USP <795> nor the applied drug product comply the packaging and storage condition specified in the said monograph. • Provide detailed procedure of dissolution testing of drug product, since the dissolution is included in the finished product specification.	Firm has claimed that they initially claimed USP specification now they revised the specification as per innovator's specification. Firm has not Provide detailed procedure of dissolution testing of drug product

Decision: Approved with innovator's specification, as per Policy for inspection of Manufacturer abroad and verification of local storage facility. Further, Applicant shall submit PKR 7500/- pre-registration variation fee for change in specification of drug product, prescribed vide S.R.O 496 (I)/2023 dated 17-04-2023 before issuance of registration letter.

291.	**Name, address of Applicant / Importer**	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road Karachi

	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road Karachi **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564,Greece
	Name, address of manufacturer(s)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS 61st km National Road Athens-Lamia, Schimatari Viotias 32009, Greece
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **original**, legalized CoPP certificate (53850) dated 01-10-2021 issued by National Organization of Medicine for Casglo Powder for concentrate for solution of infusion 50mg/vial. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodicity of routine inspection 3 years. **GMP Certificate:** Firm has submitted GMP Certificate No.:8652/23-02-2021 dated 29-0302021 issued by National Organization for Medicine, Greece. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original, legalized Agency Agreement from Meraki Global PTE Ltd. 20 Collyer Quay #11-05, Singapore. The supply and distribution agreement letter specifies that MERAKI is the supplier of pharmaceutical preparations and Hakimsons involve in the business off distribution, sub distrbutors of pharmaceutical product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 4970 Dated:22-02-2022
	Details of fee submitted	PKR 150,000/ Dated: 08-02-2022
	The proposed proprietary name / brand name	Casglo Powder for concentrate for solution of infusion 50mg/vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 50mg Caspofungin (as acetate) After reconstitution in 10.5ml of water for injection, 1ml of concentrate contains 5.2mg Caspofungin.

	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Antimycotic for systemic use, ATC code J02AX04
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x50mg Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved) **CANCIDAS CASPOFUNGIN ACETATE**.
	For generic drugs (me-too status)	Caspogin Powder for concentrate for solution of infusion 50mg/vial of M/s. AJM Pharma Pvt. Ltd. (Reg.no. 106828)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Teva API India Private Limited Manufacturing Site: Gajraula site Plot Nos, A-2, A-2/1, A-2/2, UPSIDC Industrial Area, Bijnor Road, Distt. Amroha Gajraula - 244 235 (Uttar Pradesh), India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Forced Degradation Studies
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated and real time stability data are conducted at (-18°C±3°C) and (-70°C±5°C) respectively. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the innovator product German Product Cancidas 50mg Merck Sharp & Dhome Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I clear glass vial closed by bromobutyl stoppers. Closed vials are secured by aluminum seal with a plastic flip-off caps.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 4 Three batches of 6500 mL batch size production were tested: 18E032, 18E108 and 18F262 – inverted and upright position. The accelerated stability study data is conducted at 25°C±2°C/60%±5% RH for 6 months. The real time stability study data is conducted at 2-8 °C for 24 months.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid drug sale license of M/s. Hakimson Impex Pvt. Ltd, Karachi.	Firm submitted the valid DSL of applicant which is valid till 19/07/2028.
2.	Submit valid GMP certificate of Manufacturer Abroad ,since the submitted certificate was expired in 2021.	Firm submitted the GMP certificate which was based on inspection conducted on 22-03-2019,issue dated 29-03-2021 and validity was for three years.
3.	Submit legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.	Not submitted.
4.	Submit analytical method verification report of drug substance performed by drug product manufacturer, in accordance with the requirement mentioned in the CTD guidance document approved by Registration Board.	Firm submitted the method transfer for the analytical methods of assay determination, related substances determinations and residual solvents test of Caspofungin Acetate API which are to be transferred from TEVA Laboratories to Anfarm.
5.	Justify the stability conditions adopted for stability studies of drug substance in camparison of stability conditions recommended by innovator product for the drug substance.	Firm replied that they adopted the reference of innovator product approved in USFDA i.e. Cancidas Powder for concentrate for solution of infusion 50mg/vial. According to the review document of innovator brand storage condition of drug substance is -70°C.
6.	Scientific justification is required for an overfill of 9.2% of solution of infusion as evident from the submitted composition table in the requisite section.	Firm replied that the overfill is needed in order to ensure the labelled amount of active in the solution for infusion. Further, the proposed composition is similar to that of reference product i.e. Cancidas.
7.	Justify for not using the succinic acid as buffering agent in the developed formulation, since the review document of innovator product highlights the importance of succinic acid in the formulation in order to ensure stability during compounding and reconstitution, as well as suitable osmolarity for infusion. It also enables	Firm clarified that the applied formulation is qualitatively similar to the innovator product Cancidas, in which sodium hydroxide or glacial acetic acid are used as pH adjusters and not succinic acid.

	production of a satisfactory cake following lyophilisation	
8.	Submit data of Pharmaceutical equivalence of the applied drug of strength 50mg with the innovator / reference/ comparator product of same strength and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	Firm submitted the comparative study report of applied product against the innovator product Cancidas of Merck Sharp & Dhome.
9.	Caspofungin acetate is highly soluble in aqueous media but sensitive to heat, oxygen and extremes of pH, the submitted manufacturing method did not include any of the precautionary measures to avoid the degradation of active substance due to the above said factors, clarification is required in this regard.	Firm submitted the forced degradation study report of drug product in response of this query.
10.	Justify for keeping the column temperature uptill 45°C by keeping in view the heat sensitivity of applied product.	Firm replied that "Kindly note that the keeping time of the drug product at the column temperature until 45°C is so fast that it is not significant as parameter for the heat sensitivity of the drug product".

Decision of 336th meeting of Registration Board:
Deferred for submission of legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.

Response of the Firm:
Firm submit the legalized triparty agreement between M/s. ANAFARM HELLAS SA., Greece, Meraki Global Pte Ltd. Singapore and M/s. Hakimsons (Impex) Pvt. Ltd. In which ANFARM granted Meraki Global the non-exclusive license to use the proprietary information contained in the registration dossier, pertaining to the product in order to obtain the marketing authorization for the products in its own name and on its behalf in the Territory.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

292.	**Name, address of Applicant / Importer**	Hakimsons (Impex) (Pvt.) Ltd. Hakimsons Building, 19 West Wharf Road Karachi
	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road Karachi **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS, Kifissia Attiki,14564,Greece

	Name, address of manufacturer(s)	ANFARM HELLAS S.A.,4 ACHAIAS STR & TRIZINIAS 61st km National Road Athens-Lamia, Schimatari Viotias 32009, Greece
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted **original**, legalized CoPP certificate (53851) dated 21-07-2021 issued by National Organization of Medicine for Casglo Powder for concentrate for solution of infusion 50mg/vial. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodicity of routine inspection 3 years. **GMP Certificate:** Firm has submitted GMP Certificate No.:8652/23-02-2021 dated 29-0302021 issued by National Organization for Medicine, Greece. The GMP conforms the regulations with the requirements of PIC/s and the Directives of the European Commission.
	Details of letter of authorization / sole agency agreement	Firm has submitted Original, legalized Agency Agreement from Meraki Global PTE Ltd. 20 Collyer Quay #11-05, Singapore. The supply and distribution agreement letter specifies that MERAKI is the supplier of pharmaceutical preparations and Hakimsons involve in the business off distribution, sub distrbutors of pharmaceutical product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 3333 Dated:03-02-2022
	Details of fee submitted	PKR 150,000/ Dated: 28-10-2021
	The proposed proprietary name / brand name	Casglo Powder for concentrate for solution of infusion 70mg/vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 70mg Caspofungin (as acetate) After reconstitution in 10.5ml of water for injection, 1ml of concentrate contains 5.2mg Caspofungin.
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Antimycotic for systemic use, ATC code J02AX04
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x70mg Vial
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**(USFDA** Approved) **CANCIDAS CASPOFUNGIN ACETATE**.
	For generic drugs (me-too status)	Caspogin Powder for concentrate for solution of infusion 50mg/vial of M/s. AJM Pharma Pvt. Ltd. (Reg.no. 106828)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Teva API India Private Limited Manufacturing Site: Gajraula site Plot Nos, A-2, A-2/1, A-2/2, UPSIDC Industrial Area, Bijnor Road, Distt. Amroha Gajraula - 244 235 (Uttar Pradesh), India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Forced Degradation Studies
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The accelerated and real time stability data are conducted at (-18°C±3°C) and (-70°C±5°C) respectively. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of critical steps and intermediate products, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence report against the innovator product German Product Cancidas 50mg Merck Sharp & Dhome Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type I clear glass vial closed by bromobutyl stoppers. Closed vials are secured by aluminum seal with a plastic flip-off caps.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of Three batches of 6500 mL batch size production were tested: inverted and upright position. The accelerated stability study data is conducted at 25°C±2°C/60%±5% RH for 6 months. The real time stability study data is conducted at 2-8 °C for 24 months.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm

1.	Submit valid drug sale license of M/s. Hakimson Impex Pvt. Ltd, Karachi.	Firm submitted the valid DSL of applicant which is valid till 19/07/2028.
2.	Submit valid GMP certificate of Manufacturer Abroad ,since the submitted certificate was expired in 2021.	Firm submitted the GMP certificate which was based on inspection conducted on 22-03-2019,issue dated 29-03-2021 and validity was for three years.
3.	Submit legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.	Not submitted.
4.	Submit analytical method verification report of drug substance performed by drug product manufacturer, in accordance with the requirement mentioned in the CTD guidance document approved by Registration Board.	Firm submitted the method transfer for the analytical methods of assay determination, related substances determinations and residual solvents test of Caspofungin Acetate API which are to be transferred from TEVA Laboratories to Anfarm.
5.	Justify the stability conditions adopted for stability studies of drug substance in camparison of stability conditions recommended by innovator product for the drug substance.	Firm replied that they adopted the reference of innovator product approved in USFDA i.e. Cancidas Powder for concentrate for solution of infusion 50mg/vial. According to the review document of innovator brand storage condition of drug substance is -70°C.
6.	Scientific justification is required for an overfill of 9.2% of solution of infusion as evident from the submitted composition table in the requisite section.	Firm replied that the overfill is needed in order to ensure the labelled amount of active in the solution for infusion. Further, the proposed composition is similar to that of reference product i.e. Cancidas.
7.	Justify for not using the succinic acid as buffering agent in the developed formulation, since the review document of innovator product highlights the importance of succinic acid in the formulation in order to ensure stability during compounding and reconstitution, as well as suitable osmolarity for infusion. It also enables production of a satisfactory cake following lyophilisation	Firm clarified that the applied formulation is qualitatively similar to the innovator product Cancidas, in which sodium hydroxide or glacial acetic acid are used as pH adjusters and not succinic acid.
8.	Submit data of Pharmaceutical equivalence of the applied drug of strength 50mg with the innovator / reference/ comparator product of same strength and results of all the quality tests (mentioned in any official pharmacopoeia or	Firm submitted the comparative study report of applied product against the innovator product Cancidas of Merck Sharp & Dhome.

	section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed".	
9.	Caspofungin acetate is highly soluble in aqueous media but sensitive to heat, oxygen and extremes of pH, the submitted manufacturing method did not include any of the precautionary measures to avoid the degradation of active substance due to the above said factors, clarification is required in this regard.	Firm submitted the forced degradation study report of drug product in response of this query.
10.	Justify for keeping the column temperature uptill 45°C by keeping in view the heat sensitivity of applied product.	Firm replied that "Kindly note that the keeping time of the drug product at the column temperature until 45°C is so fast that it is not significant as parameter for the heat sensitivity of the drug product".

Decision of 336th meeting of Registration Board:
Deferred for submission of legalized agreement letter between Meraki Global Pte Ltd. Singapore and product License holder i.e. M/s. ANAFARM HELLAS SA., Greece in which Meraki Global has given the marketing rights of applied product by the said product license holder.

Response of the Firm:
Firm submit the legalized triparty agreement between M/s. ANAFARM HELLAS SA., Greece, Meraki Global Pte Ltd. Singapore and M/s. Hakimsons (Impex) Pvt. Ltd. In which ANFARM granted Meraki Global the non-exclusive license to use the proprietary information contained in the registration dossier, pertaining to the product in order to obtain the marketing authorization for the products in its own name and on its behalf in the Territory.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

293.	**Name, address of Applicant / Importer**	**Biocare Pharmaceutica.** **Address:- 807 Shadman-1, Lahore**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-032069D **Address: 807 Shadman-1, District Lahore**. **Address of Godown:** First floor B-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. **Validity:** 17-04-2022. **Status:** License to sell drugs as distributor **Renewed/New DSL:** Drug sales License is renewed. New Drug Sales License is attached for DRAP reference. (New License No. 05-352-0063-032069D), **Validity**: - 17.04.2027.
	Name and address of marketing authorization holder (abroad)	**License Holder/Supplier:** PT Pratapa Nirmala (Fahrenheit) **Address:** Jl. Industri VI, Tangerang 15135, Indonesia **Phone:** +62-21-5901876 / 77 E-mail: john@fahrenheit.co.id
	Name, address of manufacturer(s)	**Manufactured by: -** PT Pratapa Nirmala (Fahrenheit) **Address:** Jl. Industri VI, Tangerang 15135, Indonesia Phone: +62-21-5901876 / 77, Fax: +62-21-5901984 E-mail: john@fahrenheit.co.id
	Name of exporting country	Indonesia

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP with certificate No. RG.01.05.32.321.01.21.2397, dated January 21, 2021 issued by National Agency of Drug and Food Control, Indonesia. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. **Embassy Attested/Legalized GMP is also attached. GMP Validity is December, 20, 2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of legalized distribution agreement signed by both parties Biocare Pharmaceutica & PT Pratapa Nirmala (Fahrenheit). Agreement clearly mention Aboard License Holder PT Pratapa Nirmala (Fahrenheit) (Indonesia) appoints M/s Biocare Pharmaceutica to register/market/sell/Distribute their product Farpresin (Vasopressin)20 IU/ml. Inj.in Pakistan. **Agreement validity is 5 years with additional 5-years renewal clause.**
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 2945 dated 31-01-2022
	Details of fee submitted	PKR 150,000 /-: Slip # 6700351198, Date:- 05/01/2022
	The proposed proprietary name / brand name	FARPRESIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	20 IU/mL. Each 1 mL contains Vasopressin.
	Pharmaceutical form of applied drug	Farpresin (Vasopressin) is a clear, colorless solution for intravenous administration available as 20 units/mL in 1-mL vial
	Pharmacotherapeutic Group of (API)	Vasopressin and analogues WHO ATC H01BA01
	Reference to Finished product specifications	USP43
	Proposed Pack size	5 Vials per Pack (Box 5 Vials)
	Proposed unit price	Rs 900/Vial. Rs. 4500 for 5 Vials Box
	The status in reference regulatory authorities	Vasopressin 20 IU/ml is US FDA & Health Canada approved drug. In USA it is manufacture/marketed by American Regent,

		Inc. & in Canada it is manufacture/marketed by Fresenius Kabi Canada.
	For generic drugs (me-too status)	M/s. Platinum Pharmaceuticals, Brand: - Vasopressin Injection, Strength: - 20units/ml, Composition: - Vasopressin, Reg. No. 015590, Dosage Form: - Injectable Solution in Vial for Intravenous (IV) Use
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: BCN Peptides S.A. Address: Pol. Ind. Els Vinyets-Els Fogars, II 08777 Sant Quinti de Mediona Barcelona, Spain
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (VP0401, VP0501, VP0701) of API at accelerated (25 °C ± 2° C 60% ± 5%) as well as real time long term (5 °C ± 2° C) conditions. The 6 months accelerated study is complete for 3 batches. The real time 3 batches stability data are conducted till 36 months. [Reference:- Specifications according to the previous Vasopressin monograph USP31-NF26 in accelerated & long term API stability testing].
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference original brand Vasostrict (Vasopressin) 20 unit/ml Solution for Injection manufactured by (Par Pharmaceutical Chestnut Ridge, NY 10977), US., Lot: 36748 Exp Date: 12-2022. Based upon results comparison and details provided, Pharmaceutical equivalence is established between FARPRESIN and reference brand VASOSTRICT.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Farpresin (Vasopressin) 20 unit /ml Inj. is filled into glass type 1 vial-1ml with Bromobutyl rubber stopper.

	Stability study data of drug product, shelf life and storage conditions	24 months real time stability data (Long Term) at 30°C ± 2°C / 75% ± 5%RH of 03 batches (Zone IVB) is Submitted. 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches is submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Please provide legalized documents which established the link between Fahrenhite and PT. Partapa Nirmala,since all your legalized documents including CoPP, Free Sale certificate and GMP inspection report of Manufacturer Abroad revealed that the name of manufacturer is PT. Partapa Nirmala.	
2.	**1.3.4**	Justify for not having segregated manufacturing facility for preparation of hormones, since the Manufacturer Abroad have manufactured the vasopressin injection in non-betalactum Small volume injection section.
3.	**3.2.S.4.2**	Justify for not performing the identification test via Mass Spectral Analysis of drug substance by drug product manufacturer since the USP recommends identification test both via HPLC and Mass spectral analysis.
4.	**3.2.S.4.4**	Batch analysis report of batch no. VP-1803 by drug product manufacturer evident that result of bacterial endotoxin test was out of specification despite of keeping the acceptance limit <100IU/mg, while Limits of BET test recommends by the official Pharmacoepias and the acceptance limit adopted by the drug substance manufacturer (BCN Peptides) is <10IU/mg. Justify for accepting the batch of drug substance which is failed to pass the bacterial endotoxin test, further provide the Pharmaceopial/international literature which recommends the acceptance limit <100IU/mg.
5.	**3.2.S.7**	• Justify for not performing the test of water content, test for acetic acid in peptides, microbial enumeration test and test for specified microorganism while performing the stability study of drug substance despite these test are included in the USP monograph of vasopressin. • Justify for adapting the acceptance limit of assay NLT 300IU/mg in the stability studies comparing the acceptance criteria recommended in USP monograph i.e. NLT 95.0% and NMT 105.0% of vasopressin (C46H65N15O12S2), calculated on the anhydrous, acetic acid-free basis.
6.	**3.2.P.1**	• Please provide calculation along with equivalent factor to established link between 20 units /ml and 0.0667mg/ml along with evidence of reference product approved in Reference regulatory Agencies with the same composition. • Justify for using different excipient from that of 1ml composition of innovator product approved in USFDA, since 1ml of injection of innovator brand contains sodium acetate buffer and water for injection without any preservative.
7.	**3.2.P.2.2.3**	Justify for not performing the sterility test, Bacterial endotoxin test and particulate matter in injection test while performing the pharmaceutical equivalence against the innovator/reference product.
8.	**3.2.P.5.2**	Assay procedure specified in section 3.2.P.5.2 is not in accordance with USP monograph of vasopressin injection, justify for using different assay method from that recommended in USP.

Decision of 326th meeting of Registration Board:

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Please provide legalized documents which established the link between Fahrenhite and PT. Partapa Nirmala,since all your legalized documents including CoPP, Free Sale certificate and GMP inspection report of	Firm replied that "Our manufacturer has given undertaking stating their company name is indeed PT Pratapa Nirmala. According to them Fahrenheit is just their brand, is not an entity. It just a brand associated with PT Pratapa Nirmala. So, they can't

	Manufacturer Abroad revealed that the name of manufacturer is PT. Partapa Nirmala.		provide any document stated PT Pratapa Nirmala-Fahrenheit and PT Pratapa Nirmala is the same because Fahrenheit is not an entity, it's just company brand name. Actual company legalized name is PT Pratapa Nirmala and due to this reason, all legalized document including CoPP, Free Sale Certificate and GMP inspection report is associated with PT. Pratapa Nirmala, since it is their legalized name. For DRAP reference we have attached our manufacturer proper undertaking/justification on their letter head with company signed/stamp".
2.	**1.3.4**	Justify for not having segregated manufacturing facility for preparation of hormones, since the Manufacturer Abroad have manufactured the vasopressin injection in non-betalactum Small volume injection section.	Firm replied that "Kindly note our product FARPRESIN (Vasopressin) 20 units/ml is manufacture in segregated manufacturing room in which only Vasopressin 20 units/ml is filled in vials and no other product is manufacture in that particular room. Kindly note the approval in Indonesia is for Small Volume Injection not for hormone product as this product fall into FDA orange book i.e. Pharma product. So, as per FDA guidelines for Vasopressin we manufacturer this product in segregated room in small volume injection plant and hence therefore provide the GMP for Small Volume Injection. According to FDA Vasopressin fall into orange book i.e. for Pharma product while biological/hormones product fall into purple book. Since Vasopressin fall in orange book so as per FDA guideline we have manufacturer this product in our plant."
3.	**3.2.S.4.2**	Justify for not performing the identification test via Mass Spectral Analysis of drug substance by drug product manufacturer since the USP recommends identification test both via HPLC and Mass spectral analysis.	Firm submitted the revised specification of drug substance which includes identification test via Mass Spectral Analysis as recommended by USP.
4.	**3.2.S.4.4**	Batch analysis report of batch no. VP-1803 by drug product manufacturer evident that result of bacterial endotoxin test was out of specification despite of keeping the acceptance limit <100IU/mg, while Limits of BET test recommends by the official Pharmacoepias and the acceptance limit adopted by the drug substance manufacturer (BCN Peptides) is <10IU/mg. Justify for accepting the batch of drug substance which is failed to pass the bacterial endotoxin test, further provide the Pharmacopeia/international literature which recommends the acceptance limit <100IU/mg.	Firm replied that, previously we did use the old outdated specification during VP-1803 analysis. We've updated our specification now as per current standard. Now all limits are according to official pharmacopoeia and results of Bacterial Endotoxin test is within specifications and in its acceptance limits. For DRAP reference Pls. find attached documents that include new translated (specification) along with the analytical method for drug substance. We also include our COA in it, in which all test results fall within acceptance limits including Bacterial Endotoxin. All these test and results are according to updated official monograph which you will also find attached with Query 8 reply in last attachment.
5.	**3.2.S.7**	Justify for not performing the test of water content, test for acetic acid in peptides, microbial enumeration test and test for specified microorganism	Firm replied that for water and acetic acid in peptide: Specifications according to the previous Vasopressin monograph USP31-NF26. *Water and acetic acid content were not analysed at this time point because

		while performing the stability study of drug substance despite these test are included in the USP monograph of vasopressin.	the original protocol did not establish the analysis at 6 months under accelerated ageing conditions. This protocol was updated in order to include these analyses in the calendar. Since the results obtained for the other two batches of the stability study, show that the water and the acetic acid content agree with the specifications at this time point, it can be assumed that the batch VP0401 meets the specifications for water and acetic acid content at 3 and 6 months when stored under accelerated ageing conditions. We also attached stability test with water and acetic acid parameter for DRAP reference now. • For adapting limit of assay: In this section the results and the primary data obtained from the regular stability studies performed until the moment are shown. It should be noticed that the stability study has been performed according to the USP monograph on Vasopressin (USP31-NF26), where it was stated that the Activity of the product should be not less than 300 IU/mg of Vasopressin. In July 2011 an update of the USP Vasopressin monograph has been published by a Revision Bulletin that will be incorporated in USP-NF 35-30. This update is focused on the assay specification. The update of the USP monograph has changed the Activity specification (300 IU/mg) by the Assay specification (95.0-105.0%). Therefore, future annual stability studies will be done according to the current monograph.
6.	**3.2.S.7**	Justify for adapting the acceptance limit of assay NLT 300IU/mg in the stability studies comparing the acceptance criteria recommended in USP monograph i.e. NLT 95.0% and NMT 105.0% of vasopressin (C46H65N15O12S2), calculated on the anhydrous, acetic acid-free basis.	
7.	**3.2.P.1**	Please provide calculation along with equivalent factor to established link between 20 units /ml and 0.0667mg/ml along with evidence of reference product approved in Reference regulatory Agencies with the same composition.	• We, PT. PRATAPA NIRMALA, would like to clarify the link between 20 units/ml and 0.0667 mg/ml. The calculation has been submitted. However, the innovator review literature claims that the strength of the pitressin is 20 pressor unit/ml that corresponds to 0.0377mg vasopressin/ml.
8.	**3.2.P.1**	Justify for using different excipient from that of 1ml composition of innovator product approved in USFDA, since 1ml of injection of innovator brand contains sodium acetate buffer and water for injection without any preservative.	• We're using chlorobutanol is because we're referring to VASOPRESSIN injection solution (dailymed). We are using Chlorobutanol because Farpresin Injection are manufactured using aseptic method thus we are add preservative to ensure the finished product are met the microbiology parameter (sterility). For DRAP reference Pls. find attached Dailymed document along with our sign/stamp undertaking on our letterhead for both queries with justification.
9.	**3.2.P.2.2.3**	Justify for not performing the sterility test, Bacterial endotoxin test and particulate matter in injection test while performing the pharmaceutical equivalence against the innovator/reference product.	Firm replied that we have updated our pharmaceutical equivalence against the innovator/reference product now by adding the sterility test, Bacterial Endotoxin test and particulate matter in injection test result and change the comparative specification document. For reference kindly see attachment documents/test.
10	**3.2.P.5.2**	Assay procedure specified in section 3.2.P.5.2 is not in accordance with	Firm replied that we have updated our assay procedure specified in section 3.2. P.5.2. in

		USP monograph of vasopressin injection, justify for using different assay method from that recommended in USP.	accordance with USP monograph of Vasopressin Injection. • For reference kindly see our updated SOP, the table (Specification) and the analytical method according to USP monograph. We also attached the USP monograph and the COA of finished product.

Decision: Deferred for clarification regarding the quantity of drug product filled per vial by the manufacturer, since the claimed quantity i.e. 0.0667 mg/ml is not in accordance with the claim label of innovator product i.e. *strength of the pitressin is 20 pressor unit/ml that corresponds to 0.0377mg vasopressin/ml.*

Agenda of Mr. M. Tahir Waqas

Agenda Item No. 01: Routine Applications of Human Drugs (Locally Manufactured) applied on Form - 5F.

294.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 966 dated 11 JAN 2023
	Details of fee submitted	PKR 30,000/- dated 29-12-2022 Challan Number: 72592320068
	The proposed proprietary name / brand name	**MARK INSTA 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole … 20mg Sodium Bicarbonate (as Buffer) … 1680mg
	Pharmacotherapeutic Group of (API)	A02BC01, Proton Pump Inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA 20mg Sachet of M/s Getz Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide approval for Change of Title to "M/s Axis Pharmaceuticals" since in the enclosed DML / Section Approval Letters the name of firm has been mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd."	
ii.	Please provide valid GMP Certificate of API Manufacturer issued by relevant Regulatory Authority of Country of	

	Origin. The enclosed certificate was valid till 05-2023.	
iii.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	
iv.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	
v.	Please provide Stability Study Data (Accelerated and Real Time) along with supporting documents for 6th Month Testing Interval.	

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

295.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-KM Khurrianwala Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 967 dated 11 JAN 2023
	Details of fee submitted	PKR 30,000/- dated 29-12-2022 Challan Number: 5432137667
	The proposed proprietary name / brand name	**MARK INSTA 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole … 40mg Sodium Bicarbonate (as Buffer) … 1680mg
	Pharmacotherapeutic Group of (API)	A02BC01, Proton Pump Inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	RISEK INSTA 40mg Sachet of M/s Getz Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide approval for Change of Title to "M/s Axis Pharmaceuticals" since in the enclosed DML / Section Approval Letters the name of firm has been mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd."	
ii.	Please provide valid GMP Certificate of API Manufacturer issued by relevant	

	Regulatory Authority of Country of Origin. The enclosed certificate was valid till 05-2023.	
iii.	Sodium Bicarbonate has been mentioned as Excipient, throughout the application dossier. However, the same has been mentioned in label claim (as per Innovator). Please justify / provide data & relevant documents of Substance Part for "Sodium Bicarbonate".	
iv.	Finished Product Specifications have been claimed as per Innovator, however USP Monograph for 'Omeprazole Oral Suspension' was available. Please justify.	
v.	Please provide Stability Study Data (Accelerated and Real Time) along with supporting documents for 6th Month Testing Interval.	

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

296.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km Ferozpur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km Ferozpur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 32469 dated 11 NOV 2022
	Details of fee submitted	PKR 30,000/- dated 05-10-2022 Challan Number: 8623210153
	The proposed proprietary name / brand name	**EMPAGLIF 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Empagliflozin … 10mg
	Pharmacotherapeutic Group of (API)	A10BK03, drugs used in diabetes, Sodium-glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	JARDY 10mg Tablets of M/s CCL Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide GMP Certificate of API Manufacturer issued by relevant Regulatory Authority of Country of Origin. Huai'an Market Supervision Administration is not the relevant Authority for issuance of GMP Certificate.	
ii.	Please enclose a legible copy of Clearance / AD (I&E) DRAP attested Invoice for	

	Import of API. The enclosed copy is not readable.	
iii.	3.2.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP.	

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

297.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s FAAS Pharmaceuticals (Pvt.) Ltd, Plot No. F/748-L, S.I.T.E, Karachi.**
	Name, address of Manufacturing site.	M/s FAAS Pharmaceuticals (Pvt.) Ltd, Plot No. F/748-L, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F Dy. No. 12879 dated 26 MAY 2022
	Details of fee submitted	PKR 20,000/- dated 05-05-2021
	The proposed proprietary name / brand name	**TERBFAAS 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Terbinafine HCL USP equivalent to Terbinafine … 250mg
	Pharmacotherapeutic Group of (API)	D01BA02, Antifungals for systemic use
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	TERBISIL 250mg Tablet of M/s Saffron Pharmaceuticals (Pvt.) Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Strength of API in most parts of application dossier has been mentioned as 'Terbinafine HCL 250mg' which is not as per Innovator's label claim. Please justify.	**Typographic Error.** Firm have submitted revised label claim as follows: - Each Tablet contains: Terbinafine HCL USP equivalent to Terbinafine … 250mg **Fee for pre-registration revision / correction of label claim has not been submitted**
ii.	Please provide valid GMP Certificate of API Manufacturer. The enclosed GMP Certificate was valid till 05/2022.	Submitted. However, the re-submitted Certificate was **valid till 04 – 2024.**
iii.	The applicant has submitted Justification of Stability Studies of API being conducted at 25°C ± 2°C and 60%RH ± 5%RH referring to the minutes of 290th Meeting of Registration	The firm have submitted revised Stability Study Sheets of API conducted as per Zone IV(a).

	Board. However, the said decision of 290th Meeting of Registration Board is reproduced as follows: - *Decision: Registration Board on the basis of above cited discussion decided as follows:* *In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.* *Moreover, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.* No such data as required in light of above decision of Registration Board has been submitted. Please clarify.	**Fee for pre-registration revision / correction of data has not been submitted.**
iv.	The Accelerated and Real Time Stability Study Results of Average Weight and Disintegration Time, as mentioned in submitted summary of stability reports, for each time point tested of both batches, are not as per mentioned specifications. Please clarify.	**Typographic Error.** Firm have submitted revised Stability Study Sheets (Accelerated and Real Time). **Fee for pre-registration revision / correction of data has not been submitted.**
v.	Please provide evidence of 21CFR compliance record of HPLC software & audit trail reports as per 21CFR on product testing.	The firm have submitted that their HPLC was **not 21CFR compliant.**

Decision: Approved.

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

Registration Board further decided that the Registration Letter will be issued after submission of:

- **Full fee for pre-registration revision / correction of data / Typographical errors.**
- **Valid GMP Certificate of API Manufacture.**

Agenda Item No. 02: Deferred Cases

298.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17529 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 71707186772)
	The proposed proprietary name / brand name	**ROXISTAT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 5mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors
	Pharmaceutical form of applied drug	Round, biconvex, yellow colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 5mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis

		and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against RUVASTAT 5mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.		
API Lot No.	ROI-7-09210501		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets

Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for 1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

	Deficiencies / Shortcomings	Response of the firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii.	2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.
iii.	2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv.	2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm ×	The firm has claimed that the analytical method was adjusted as per actual practice.

	250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	
v.	2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi.	2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
vii.	2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV(a) conditions.	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	Same as above.
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'RUVASTAT 5mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
xii.	The submitted Audit trail reports on product testing mentions "Year 2017" on multiple instances, whereas the product was developed in the year 2021. Please justify.	The firm has stated that *"Roxistat Tablets were developed in 2021, however, the testing method created in HPLC software are saved in a default folder titled "Year 2017", created in year 2017 which is linked to the backup folder on server. Therefore, Year 2017 apears on Audit Trail Reports indicating project location".*

xiii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiv.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
xv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any)	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision 335th meeting of Registration Board:

Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.**
  - **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
  - **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

The Firm have submitted as follows:

Observation	Firm's Response
Requisite fee for pre-registration correction / Typographical Mistake.	**Not Submitted**
2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.	Firm has submitted revised / updated Method wherein USP recommended "Column: 4.6-mm × 5-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.	Firm has submitted revised / updated Method wherein USP recommended "Column: 3.2-mm × 25-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.	Firm has submitted revised / updated Method in accordance with USP Monograph.
2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide	The firm have submitted that the working standard used in analytical testing was provided

evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	by the supplier along with raw material which is traceable to USP reference standard.

Decision: Approved.

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

Registration Board further decided that the Registration Letter will be issued after submission of:

- **Requisite fee for pre-registration revision / correction of data.**

299.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17530 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 2569143907)
	The proposed proprietary name / brand name	**ROXISTAT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 10mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors

	Pharmaceutical form of applied drug	Round, biconvex, brown colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 10mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against

		RUVASTAT 10mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.		
API Lot No.	ROI-7-09210501		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for 1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

	Deficiencies / Shortcomings	Response of the firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii.	2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.
iii.	2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv.	2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
v.	2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi.	2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
vii.	2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C□± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV(a) conditions.	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in	Same as above.

	the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'RUVASTAT 10mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
xii.	The submitted Audit trail reports on product testing mentions "Year 2017" on multiple instances, whereas the product was developed in the year 2021. Please justify.	The firm has stated that *"Roxistat Tablets were developed in 2021, however, the testing method created in HPLC software are saved in a default folder titled "Year 2017", created in year 2017 which is linked to the backup folder on server. Therefore, Year 2017 apears on Audit Trail Reports indicating project location".*
xiii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiv.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
xv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision 335th meeting of Registration Board:

Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.**
  - **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
  - **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

The Firm have submitted as follows:

Observation	Firm's Response

Requisite fee for pre-registration correction / Typographical Mistake.	**Not Submitted**
2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.	Firm has submitted revised / updated Method wherein USP recommended "Column: 4.6-mm × 5-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.	Firm has submitted revised / updated Method wherein USP recommended "Column: 3.2-mm × 25-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.	Firm has submitted revised / updated Method in accordance with USP Monograph.
2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm have submitted that the working standard used in analytical testing was provided by the supplier along with raw material which is traceable to USP reference standard.

Decision: Approved.

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

Registration Board further decided that the Registration Letter will be issued after submission of:

- **Requisite fee for pre-registration revision / correction of data.**

300.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17531 dated 15 JUN 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 4090317687)
	The proposed proprietary name / brand name	**ROXISTAT 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rosuvastation (as calcium) … 20mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C10AA07, HMG CoA reductase inhibitors
	Pharmaceutical form of applied drug	Round, biconvex, orange colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CROSUVA 20mg Tablets, TGA Approved.
	For generic drugs (me-too status)	RUVASTAT 20mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd.
	Name and address of API manufacturer.	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8 Jing 13 Road, Hangzhou Gulf, Shangyu Economic and Technological Development Zone, 312369 China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 Months. The real time stability data is conducted at 5°C ± 3°C / 65% ± 5% RH

		for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against ROSULIN 20mg Tablets by M/s Highnoon Laboratories Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against ROSULIN 20mg Tablets by M/s Highnoon Laboratories Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Menovo Pharmaceutical Co. Ltd. China.		
API Lot No.	ROI-7-09210501		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2021	10-2021	10-2021
Date of Initiation	09-2021	10-2021	10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Zhejiang Medical Products Services Centre for Information Publicity and Development, **valid till Aug 24, 2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 11450/2021 DRAP dated 02-08-2021) by AD I&E DRAP, Lahore has been submitted for

		1.5KGs Rosuvastatin Calcium Batch No. ROI-7-09210501 vide Invoice No. 21ZJ027 dated 2021-6-30.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Deficiencies / Shortcomings	Response of the firm
i. Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii. 2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section. Please clarify.	The firm has submitted revised Section 2.3.P.3.2 mentioning information of film coating.
iii. 2.3.P.5 Please specify the USP Dissolution Test (1 or 2).	The firm has specified USP Test – I for performing Dissolution Test.
iv. 2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
v. 2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity. Please Justify	The firm has claimed that the analytical method was adjusted as per actual practice.
vi. 2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets. Please justify.	The firm has claimed that the analytical method was adjusted as per actual practice.
vii. 2.2.P.6 It has been mentioned that Working Standard has been used for analytical	

	testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm has committed that USP Reference Standard will be used for standardization upon commercialization of drug product.
viii.	3.2.S.7.1 The real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH, however for locally manufactured products the stability studies of the Drug substance shall be submitted as per Zone-IV(a) conditions.	The firm has submitted that the recommended storage conditions for Rosuvastatin Calcium is 2°C - 8°C as per Drug Substance Manufacturer, hence the real time stability data of drug substance is conducted at 25°C± 2°C/60% RH ± 5% RH.
ix.	Furthermore, in case of use of ingredients whose stability testing has not been done as per Zone-IV(a), the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product along with degradation studies in the finished pharmaceutical product. No such data on degradation studies has been submitted. Please clarify.	Same as above.
x.	3.2.P.2.1.1 Pharmaceutical equivalence / CDP has been performed against 'ROSULIN 20mg Tablets' instead of the Reference / Innovator's Product. Please justify.	The firm has stated that Comparator product was used as it was readily available.
xi.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
xii.	Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate is not from the concerned regulatory authority of country of origin and was valid till Aug 24, 2023.	Copy of GMP Certificate No. ZJ20190121 dated 10/28/2019 issued by CFDA has been submitted.
xiii.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
xiv.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision 335th meeting of Registration Board:

Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Justification / clarification for points mentioned below;**
  - **2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.**
  - **2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant**

has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.

- **2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.**
- **2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.**

The Firm have submitted as follows:

Observation	Firm's Response
Requisite fee for pre-registration correction / Typographical Mistake.	**Not Submitted**
2.3.P.5 USP recommends "Column: 4.6-mm × 5-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Dissolution Analysis.	Firm has submitted revised / updated Method wherein USP recommended "Column: 4.6-mm × 5-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 USP recommends "Column: 3.2-mm × 25-cm; 5-µm packing L1" whereas the applicant has used "Column: 4.6mm × 250mm; 5-µm packing C18" for Assay / Content Uniformity.	Firm has submitted revised / updated Method wherein USP recommended "Column: 3.2-mm × 25-cm; 5-µm packing L1" has been mentioned. Furthermore, the firm have claimed that the same will be used for Commercial Batches.
2.3.P.5 Moreover, the Flow Rate and Injection volume are also different from that recommended in USP Monograph for Rosuvastatin Tablets.	Firm has submitted revised / updated Method in accordance with USP Monograph.
2.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	The firm have submitted that the working standard used in analytical testing was provided by the supplier along with raw material which is traceable to USP reference standard.

Decision: Approved.

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

Registration Board further decided that the Registration Letter will be issued after submission of:

- **Requisite fee for pre-registration revision / correction of data.**

301.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5-Km Khurrianwala- Sahianwala Road Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 106/2020-DRAP(AD-1904818-970) dated 06-07-2020 valid for

		two years from the date of inspection (09-06-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of letter for Renewal of DML vide No. F. 1-20/2006-Lic (Vol-II) dated 30th June, 2020 contains section approval for: - • **Tablet Section (General).** • Capsule Section (General). • Dry Powder Sachet Section (General). • Oral Liquid Section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11997 dated 17 MAY 2022
	Details of fee submitted	PKR 30,000/- Dated 19-05-2022 (Challan / Receipt # 747783462)
	The proposed proprietary name / brand name	**AXITO 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Itopride Hydrochloride … 50mg (Innovator's Specifications)
	Pharmacotherapeutic Group of (API)	A03FA07, Drugs For Functional Gastrointestinal Disorders, Propulsives.
	Pharmaceutical form of applied drug	Round, biconvex, yellowish green colored film coated tablet, with both plain sides.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	M/s Prayosha Healthcare Pvt. Ltd., Plot No. 6209 G.I.D.C Ankleshwar 393 002, Dist. Bharuch, Gujrat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related

		to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd. by performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against GANATON 50mg Tablet by Abbott Laboratories (Pakistan) Ltd. in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Prayosha Healthcare Pvt. Ltd., Gujrat, India.		
API Lot No.	ITP/004/21		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	T-003	T-004	T-005
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate issued by Food and Drugs Control Administration, Gujrat State, India has been submitted. The Certificate was **valid till 24/05/2023.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance (vide No. 12557/2021 DRAP dated 20-08-2021) by AD I&E DRAP, Lahore has been submitted for 550Grams Itopride HCl Batch No. ITP/004/21 vide Invoice No. ZHI-Cl/5548/0821 dated 12-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing has been submitted. **Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:
The following deficiencies / shortcomings have been communicated to the firm:

Deficiencies / Shortcomings	Response of the firm
i. Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on enclosed copy of DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please provide supporting documents for the same.	The firm has submitted correced copy of DML as "M/s Axis Pharmaceuticals".
ii. Finished Product Specifications have been claimed as per 'Innovator's Specifications', whereas in submitted Summary of Product Characteristics (SmPC) & Patient Information Leaflet (PIL) it is mentioned that "the product complies Axis's Specifications". Please clarify.	Typographic Mistake. Firm has submitted revised SmPC & PIL.
iii. Please provide valid GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed copy of GMP Certificate was valid till 24/05/2023.	Valid GMP of API Manufacturer has not been submitted.
iv. 2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of	Firm has submitted revised Section 2.3.P.3.2 mentioning information regarding film coating.

	film coating has been mentioned in this section. Please clarify.	
v.	2.3.P.3.2 Appearance of the Tablet has been mentioned as 'light green colored film coated tablet', whereas the same has been mentioned as 'yellowish green colored film coated tablet' in Pharmaceutical Equivalence and CDP Studies. Please justify.	Typographic Mistake. Firm has stated that the appearance of product is 'light green colored film coated tablet'.
vi.	Dissolution specifications have been mentioned as 'NLT Q+5% in 30 mins' as well as 'NLT 80%(Q)' on separate instances within the application dossier. Please justify.	Firm has submitted that the Dissolution specifications is NLT 80% (Q) in 30 minutes.
vii.	Please provide 6th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Copy of 6th Month Data of Stability Batches has been submitted.
viii.	Please provide Compliance Record of HPLC Software 21CFR.	Certificate of 21CFR Compliance of HPLC Software has not been submitted.
ix.	Please provide GMP status of the FPP manufacturer (not older than 03 years).	Copy of GMP Certificate Ref. No. 100/2022-DRAP(AD-51001963034) dated 20-06-2022 valid for two years from the date of inspection (13-06-2022) has been submitted.
x.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	Cinaxipid Tablet 1mg, Axistart-K Tablets, Trubax Tablets etc.

Decision 335th meeting of Registration Board:
Registration Board deferred the case for submission of:

- **Full fee for pre-registration correction / Typographical Mistakes.**
- **Justification / clarification for points mentioned below;**
- **2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section.**
- **2.3.P.3.2 Appearance of the Tablet has been mentioned as 'light green colored film coated tablet', whereas the same has been mentioned as 'yellowish green colored film coated tablet' in Pharmaceutical Equivalence and CDP Studies.**
- **Dissolution specifications have been mentioned as 'NLT Q+5% in 30 mins' as well as 'NLT 80%(Q)' on separate instances within the application dossier.**
- **Please provide 6th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.**

The Firm have submitted as follows:

Observation	Firm's Response
Full fee for pre-registration correction / Typographical Mistakes.	Fee Challan No. 47599550 dated 23/07/2024 of Rs. 7,500/- has been submitted. **However, case was deferred for submission of Full fee.**

2.3.P.3.2 The application has been claimed to be submitted for 'film coated tablet', whereas no ingredient for preparation of film coating has been mentioned in this section.	The firm have submitted that finished product is a film coated tablet, however, only core tablet composition was described in the section. Revised respective section with complete composition with coating formulation has been submitted.
2.3.P.3.2 Appearance of the Tablet has been mentioned as 'light green colored film coated tablet', whereas the same has been mentioned as 'yellowish green colored film coated tablet' in Pharmaceutical Equivalence and CDP Studies.	**Typographic Mistake.** The appearance of the Tablet is 'light green colored film coated tablet'.
Dissolution specifications have been mentioned as 'NLT Q+5% in 30 mins' as well as 'NLT 80%(Q)' on separate instances within the application dossier.	The firm have submitted that the Finished Product Specification is NLT 80% (Q) in 30 minutes & all the stability study has been conducted & complies against this specification.
Please provide 6th Month Data of Stability Batches, supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.

Decision: Approved.

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

Registration Board further decided that the Registration Letter will be issued after submission of:

- **Full fee for pre-registration revision / correction of data.**

Agenda of Ms. Maham Misbah

I. New cases of Form 5F (CTD) (Human)

302.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6020 : 03-04-2023
	Details of fee submitted	PKR 30,000/- : 846877593
	The proposed proprietary name / brand name	DAPXI-MET XR Tablet 10mg/500mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……10 mg (immediate release) Metformin HCl (as extended release)…….500mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)
	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No. 112539)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	
1.	3.2.P.5.1	Release specifications of innovator include testing for total microbial count and testing for E.coli whereas specifications given in 3.2.P.5.1 do not include these two tests. Submit revised product specifications along with the prescribed fee.	Updated finished product specifications as per innovator including test specifications of total microbial count and E.coli are submitted along with Rs. 7500/- (Deposit Slip 2690101185) for pre-registration change of specifications.
2.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted
3.	3.2.R.1	Filled BMRs of stability batches shall be submitted.	Submitted

Decision: Approved.

303.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6544 : 08-03-2023
	Details of fee submitted	PKR 75,000/- : 172469822
	The proposed proprietary name / brand name	DAPXI-MET XR Tablet 2.5mg/1000mg

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……2.5 mg (immediate release) Metformin HCl (as extended release)…….1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)
	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No. 110357)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.P.5.1	Release specifications of innovator include testing for total microbial count and testing for E.coli whereas specifications given in 3.2.P.5.1 do not include these two tests. Submit revised product specifications along with the prescribed fee.	Updated finished product specifications as per innovator including test specifications of total microbial count and E.coli are submitted along with Rs. 7500/- (Deposit Slip 56625134) for pre-registration change of specifications.

Decision: Approved.

304.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5805 : 01-03-2023
	Details of fee submitted	PKR 30,000/- : 561045851
	The proposed proprietary name / brand name	DAPXI-MET XR Tablet 10mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……10 mg (immediate release) Metformin HCl (as extended release)…….1000mg

	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)
	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No. 105284)
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.P.5.1	Release specifications of innovator include testing for total microbial count and testing for E.coli whereas specifications given in 3.2.P.5.1 do not include these two tests. Submit revised product specifications along with the prescribed fee.	Revised specifications submitted.
2.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted
3.	3.2.R.1	Filled BMRs of stability batches shall be submitted.	Submitted

Decision: Approved. Applicant shall submit Rs. 7500/- fee for pre-registration change of specifications before issuance of registration letter.

305.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6021 : 03-03-2023
	Details of fee submitted	PKR 75,000/- : 9823736207
	The proposed proprietary name / brand name	DAGLOZIN-M Tablet 2.5mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated bilayered tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……2.5 mg (immediate release) Metformin HCl (as extended release) …….1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo XR (USFDA Approved)

	For generic drugs (me-too status)	Dapa-Met XR Tablet By M/s Hilton (Reg. No. 110357)
	Proposed Pack size	7's, 10's, 14's, 20's, 30's, 50's, 60's, 100's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
	3.2.S.4.4	Results and analytical record of test for propendiol content in API performed by drug product manufacturer shall be submitted.
	3.2.S.7	Real time stability studies data and associated record of Dapgliflozin raw material shall be submitted for its complete shelf life i.e. 36months.
4.	3.2.P.8	• Consolidated stability studies data sheets for real time and accelerated stability studies shall be submitted. • Documents for import and clearance of APIs shall be submitted.

Decision: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

306.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd Plot No. 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.13373: 30-05-2023
	Details of fee submitted	PKR 75,000/- : DS No. 2259108470
	The proposed proprietary name / brand name	**AMPRID 100mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL Contains: Amisulpride……..100mg
	Pharmacotherapeutic Group of (API)	Antipsychotics; Benzamides
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	30ml, 60ml, 90ml, 120ml
	The status in reference regulatory authorities	Amisulpride Oral Solution MHRA Approved
	For generic drugs (me-too status)	New drug

Evaluation by PEC (No…XXIII):

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Response
1.	3.2.S.4.4	The CoA of API used in manufacturing of stability batches by drug substance and drug product manufacturer shall be submitted	Submitted.
2.	3.2.P.8	Justify the batch size of 45 bottles. How is it sufficient to perform complete stability testing.	The criteria for fixation of Batch size is based on the minimum requirements of samples being used for the stability analysis of products. Selected batch size was

			sufficient enough for stability time points and to allow the process capability to establish and obtain homogenous solution. Batch Size: 45 Bottles Initial Testing: 13 Bottles Realtime: 12 Bottles Accelerated: 4 Bottles Total: 29 Bottles *Justfication shall be submitted for the number of bottles required for each test.*
3.	3.2.P.8	Consolidated Stability data sheets shall be submitted.	Submitted.

Decision: Deferred for justfication for the number of bottles required for each test conducted during stability studies of drug product.

307.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13771 : 02-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 984295642627
	The proposed proprietary name / brand name	Lansopra-D 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole…30mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Dexilant Capsules by Takeda Japan
	For generic drugs (me-too status)	Razodex 30mg DDR Capsules By M/s Getz Pharma
	Proposed Pack size	30's
308.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13772 : 02-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 98360981946
	The proposed proprietary name / brand name	Lansopra-D 60mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole…60mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Dexilant Capsules by Takeda Japan
	For generic drugs (me-too status)	Razodex 60mg DDR Capsules By M/s Getz Pharma
	Proposed Pack size	30's
Evaluation by PEC (No.XXIII):		

Serial No.	Module/ Section	Shortcomings
1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for complete six months shall be submitted.

Decision: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

309.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14083: 06-06-2023
	Details of fee submitted	PKR 30,000/- : 4250187055
	The proposed proprietary name / brand name	**XIGAPHAGE 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate ~~6.35mg~~ equivalent to Dapagliflozin……5 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Farxiga 5mg (USFDA Approved)
	For generic drugs (me-too status)	Daploz 5mg Tablet by Highnoon Laboratories Ltd. (Reg.No. 098425).
	Proposed Pack size	As per SRO

310.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11780 : 15-05-2023
	Details of fee submitted	PKR 30,000/- : DS No. 6017198809
	The proposed proprietary name / brand name	**XIGAPHAGE 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate ~~12.3mg~~ equivalent to Dapagliflozin……10 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Farxiga (USFDA Approved)
	For generic drugs (me-too status)	Daploz 10mg Tablet by Highnoon Laboratories Ltd. (Reg.No. 098426).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for complete six months shall be submitted.
2.	----------	Clearance documents for imported API(s) shall be submitted.

Decision: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

311.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15815: 22-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 28604331361
	The proposed proprietary name / brand name	**XIGAPHAGE-M 5/850mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…5mg Metformin Hcl…850mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins;

		Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo (MHRA Approved)
	For generic drugs (me-too status)	Daplozmet 5/850 mg Tablet by Highnoon Laboratories Ltd.
	Proposed Pack size	As per SRO
312.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited.** **7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15816: 22-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 5614668565
	The proposed proprietary name / brand name	**XIGAPHAGE 5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…5mg Metformin Hcl…1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo (MHRA Approved)
	For generic drugs (me-too status)	Daplozmet 5/1000 mg Tablet by Highnoon Laboratories Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for complete six months shall be submitted.
2.	----------	Clearance documents for imported API(s) shall be submitted.

Decision: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

313.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13776: 02-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 43723879453
	The proposed proprietary name / brand name	**DYPA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……5 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Farxiga 5mg (USFDA Approved)
	For generic drugs (me-too status)	Daploz 5mg Tablet by Highnoon Laboratories Ltd. (Reg.No. 098425).
	Proposed Pack size	As per SRO
314.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13775: 02-06-2023
	Details of fee submitted	PKR 30,000/- : DS No. 1503841669
	The proposed proprietary name / brand name	**DYPA 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin……10 mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Farxiga (USFDA Approved)
	For generic drugs (me-too status)	Daploz 10mg Tablet by Highnoon Laboratories Ltd. (Reg.No. 098426).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant

1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for complete six months shall be submitted.	Submitted.
2.	----------	Clearance documents for imported API(s) shall be submitted.	Clearacne and loan documents submitted.

Decision: Approved.

315.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13940: 05-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 2917796958
	The proposed proprietary name / brand name	**DYPA-M 5/850mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…5mg Metformin Hcl…850mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo (MHRA Approved)
	For generic drugs (me-too status)	Daplozmet 5/850 mg Tablet by Highnoon Laboratories Ltd.
	Proposed Pack size	As per SRO
316.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13941: 05-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 86290418
	The proposed proprietary name / brand name	**Dypa-M 5/1000mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…5mg Metformin Hcl…1000mg
	Pharmacotherapeutic Group of (API)	Blood glucose lowering drugs, excluding Insulins; Combinations of oral blood glucose lowering drugs
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xigduo (MHRA Approved)
	For generic drugs (me-too status)	Daplozmet 5/1000 mg Tablet by Highnoon Laboratories Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	
1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for complete six months shall be submitted.	Submitted.
2.	----------	Clearance documents for imported API(s) shall be submitted.	Loan and clearance documents submitted.
3.	3.2.P.5.1	Release specifications of innovator include testing for E.coli whereas specifications given in 3.2.P.5.1 does not include this test. Submit revised product specifications along with the prescribed fee.	Revised specifications have been submitted.

Decision: Approved. Applicant shall submit Rs. 7500/- fee for pre-registration change of specifications before issuance of registration letter.

317.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10770: 05-06-2023
	Details of fee submitted	PKR 75,000/- : DS No. 079838195991
	The proposed proprietary name / brand name	**Trella 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…50mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Zafatek Tablets by M/s Takeda Pharmaceutical Co., Ltd. Japan.
	For generic drugs (me-too status)	N/A

	Proposed Pack size	As per SRO
318.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10771: 05-06-2023
	Details of fee submitted	PKR 75,000/- : DS No. 08554609057
	The proposed proprietary name / brand name	**Trella 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Zafatek Tablets by M/s Takeda Pharmaceutical Co., Ltd. Japan.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
Evaluation by PEC (No.XXIII): The applicant has also submitted revised data for both strengths (Dy.No 7843 &7844 dated 31-7-24) which was evaluated later on.		
Decision: Registration Board approved the applications of Trella 50mg & Trella 100mg tablet. The firm shall submit full fee of registration for each strength for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021,before issuance of registration letter.		
319.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15819 : 22-06-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 36537565157
	The proposed proprietary name / brand name	CE-MINE 2mg/5ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Syrup Contains: Chlorpheniramine Maleate…2mg
	Pharmacotherapeutic Group of (API)	Antihistamine for systemic use
	Reference to Finished product specifications	USP Specifications

	The status in reference regulatory authorities	MHRA Approved (PL 00014/0606)
	For generic drugs (me-too status)	Allerphene Syrup 2mg/5ml of M/s PDH Pharmaceuticals Pvt Ltd (Reg No. 002286)
	Proposed Pack size	60ml, 90ml, 120ml.

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response
	1.3.4	Copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP shall be submitted along with section approval letter.	Not submitted.
	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Not submitted.
	3.2.P.8	Documents for procurement and import of API shall be submitted.	Not submitted.
	---	Executed BMRs shall be submitted.	Not submitted.
		The excipients used are different than those of reference product. Justify.	Not justified.

Decision: Deferred for submission of satisfactory reponse to afore-mentioned shortcomings.

II. Deferred cases Form 5F (CTD)

320.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs(Pvt) Ltd. Plot 145, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. THN-M1A-Y7WA: 19-03-2024
	Details of fee submitted	PKR 30,000/- DS No. 494423944
	The proposed proprietary name / brand name	Hydrosone 2.5% Lotion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Hydrocortisone……25mg
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml, 60ml, 120ml
	The status in reference regulatory authorities	Hydrocortisone 2.5% topical lotion (USFDA Approved)
	For generic drugs (me-too status)	Lacticare HC 2.5% Lotion by M/s GSK (Reg. No. 019739)

Evaluation by PEC [(xxiii)] :

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.5.9**	Submit evidence of approval of applied formulation in reference regulatory authority as the formulation has been discontinued in USFDA.	Submitted.
2.	---------	As the applied product is a steroidal preparation, evidence of separate dispensing facility verified by DRAP shall be submitted along with GMP certificate of the relevant section.	Calibration certificate of laminar air flow cabinet for steroidal drugs is submitted. ***Evidence of separate dispensing facility duly verified by DRAP shall be submitted along with GMP certificate of the relevant section shall be submitted.***
3.	**3.2.P.5.1**	Hydrocortisone acetate lotion monograph is available in USP whereas the applied formulation contains Hydrocortisone. How have you assigned USP specifications to the finished product? Justify with evidence.	USP monograph of Hydrocortisone lotion is submitted.
4.	**3.2.P.8**	Documents for procurement of API shall be submitted along with approval of API from relevant country of origin	Submitted
5.	**3.2.P.8**	Long term stability studies of the Drug substance shall be submitted as per Zone-IVa conditions for 6 month time point.	Submitted

Decision of 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Remarks of evaluator: *Evidence of separate dispensing facility duly verified by DRAP shall be submitted along with GMP certificate of the relevant section shall be submitted.*

Decision: Approved. Applicant shall submit evidence of separate dispensing facility duly verified by DRAP along with GMP certificate of the relevant section to Registration section before issuance of registration letter.

321.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi**
	Name, address of Manufacturing site.	M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36122: 12-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit Slip No.:16452579167
	The proposed proprietary name / brand name	**DEXA 0.1% eye drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Dexamethasone……1mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory Agents, Corticosteroids, plain
	Reference to Finished product specifications	USP

	Proposed Pack size	1 x 5ml
	The status in reference regulatory authorities	Maxidex eye drops (MHRA approved)
	For generic drugs (me-too status)	Vegadex Eye drops By M/a Vega (Reg. No. 33870)

Evaluation by PEC (No…XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
	Module 2 & 3	Submit complete, properly arranged, organized and tagged dossier according to "Guidance document for submission of application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use."

Decision of 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Reply of applicant: Firm has submitted arranged dossier for evaluation.

Evaluation by PEC (No…XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.		Executed BMRs of stability batches shall be submitted
2.	3.2.S.4.3	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted
3.	3.2.P.8	Documents of import and clearance of API shall be submitted.

Decision: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

322.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nicholas Pharmaceuticals. Plot No. 34, St. No. SS-02, National Industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Nicholas Pharmaceuticals. Plot No. 34, St. No. SS-02, National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No.1828: 19-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit Slip No.50487151953
	The proposed proprietary name / brand name	**NOOPEM 2gm Powder for Solution for infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem as Trihydrate……2gm (Blended with sodium bicarbonate)
	Pharmacotherapeutic Group of (API)	Carbapenems
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO

	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	New drug. Me-too is not available.

Evaluation by PEC (No…XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.	1.5.8	Submit differential fee since the applied formulation is not yet registered in Pakistan. Me-too is not available
2.		Valid GMP certificate of the applicant shall be submitted.
3.	2.3.R.1.1	Justify the supply of 2g finished product in 20mL glass vial as the required concentration is 50mg/ml for IV infusion and 1mg/ml to 20mg/ml for IV injection, according to reference product literature. Also submit factor
4.	3.2.S.4.1	CoA of drug substance states that the material conforms to USP specifications. Specifications of drug substance in 3.2.S.4.1 shall be submitted according to USP along with requisite fee.
5.	3.2.S.4.4	CoA by drug product manufacturer does not include test for sodium content. Complete CoA with test results of all tests given in USP/ CoA of drug substance manufacturer, shall be submitted.
6.	3.2.P.1	Submit data in section 3.2.P.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".
7.	3.2.P.2.2.1	Pharmaceutical equivalence is conducted against Meronem 1g injection of M/s Pfizer Pakistan Ltd, Karachi. The reference product differs in terms of fill weight. Justification shall be submitted in this regard.
8.	3.2.P.2.6	Compatibility studies shall be submitted for drug product with 0.9% NaCl solution and 5% dextrose solution which are the diluents to be used for solution for **infusion**, according to the reference product literature.
9.	3.2.P.5.2	Atomic absorption spectroscope with sodium hollow cathode lamp is required for testing content for sodium. Evidence of availability of the required instruments shall be submitted.
10.	3.2.P.8	Valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
11.	3.2.P.8	Firm shall submit certificate of 21 CFR compliance and audit trail reports for the HPLC system used in analysis.

Decision of 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Reply of applicant:

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings	Reply of applicant
12.	1.5.8	Submit differential fee since the applied formulation is not yet registered in Pakistan. Me-too is not available	Submitted. (Rs. 45000/- Deposit Slip No. 482465177703)
13.		Valid GMP certificate of the applicant shall be submitted.	Submitted.

14.	2.3.R.1.1	Justify the supply of 2g finished product in 20mL glass vial as the required concentration is 50mg/ml for IV bolus injection and 1mg/ml to 20mg/ml for IV infusion, according to reference product literature. Also submit factor	Container closure is 50ml glass vial as per innovator's product. Factor is also submitted. Applicant has also submitted that previous pack size is a typographical error.
15.	3.2.S.4.1	CoA of drug substance states that the material conforms to USP specifications. Specifications of drug substance in 3.2.S.4.1 shall be submitted according to USP along with requisite fee.	Revised specifications are submitted.
16.	3.2.S.4.4	CoA by drug product manufacturer does not include test for sodium content. Complete CoA with test results of all tests given in USP/ CoA of drug substance manufacturer, shall be submitted.	CoA with test results of sodium content is submitted.
17.	3.2.P.1	Submit data in section 3.2.P.1 as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".	Submitted.
18.	3.2.P.2.2.1	Pharmaceutical equivalence is conducted against Meronem 1g injection of M/s Pfizer Pakistan Ltd, Karachi. The reference product differs in terms of fill weight. Justification shall be submitted in this regard.	Submitted.
19.	3.2.P.2.6	Compatibility studies shall be submitted for drug product with 0.9% NaCl solution and 5% dextrose solution which are the diluents to be used for solution for **infusion**, according to the reference product literature.	Submitted.
20.	3.2.P.5.2	Atomic absorption spectroscope with sodium hollow cathode lamp is required for testing content for sodium. Evidence of availability of the required instruments shall be submitted.	Evidence submitted and discussed in 316th meeting of RB (Case No. 820)
21.	3.2.P.8	Valid DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	GMP certificate valid till 2026 is submitted.
22.	3.2.P.8	Firm shall submit certificate of 21 CFR compliance and audit trail reports for the HPLC system used in analysis.	The firm's HPLC system is not 21CFR compliant.

Evaluation by PEC (No…XXIII):

Decision: Approved.

323.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 km Adyala Road Post Office Daghal, Rawalpindi.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37707: 26-12-2022
	Details of fee submitted	PKR 30,000/- : 816783029
	The proposed proprietary name / brand name	**WOLIDE 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……400 mg
	Pharmacotherapeutic Group of (API)	Antiinfectives For Systemic Use
	Reference to Finished product specifications	Innnovator's Specifications
	Proposed Pack size	12's
	The status in reference regulatory authorities	Zyvox Tablet (USFDA Approved)
	For generic drugs (me-too status)	Ecasil Tablet by M/s Sami (Reg. No. 67162)

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.S.1.2	Applicant has stated that API manufacturer is manufacturing polymorphic Form II. As the drug substance exhibits polymorphism, justification for the use of polymorphic Form II shall be submitted along with credible evidence.
2.	3.2.S.4.2, 3.2.S.4.3 & 3.2.S.4.4	Analytical procedure is not as per USP monograph. API conforms to USP as per CoA in 3.2.S.4.4. Clarify and submit analytical method and analytical method verification, accordingly
3.	3.2.P.5.2 & 3.2.P.5.3	In method of analysis of Linezolid tablets, the chromatographic conditions for dissolution and Assay testing are as follows: Lambda 254nm Flow rate: 1.5ml/min Column: L1 Injection: 10micro L However, the above conditions are not as per USP monograph. Justify. Moreover, validation/verification studies have been submitted for the method given in 3.2.P.5.2 while the method is not as per USP. Justify.
4.	3.2.P.8	Tests results and associated testing record of stability batches shall be submitted for real time and accelerated stability studies *at the six-point time point.* (12-2022)
5.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. Documents for the procurement of API with approval from DRAP shall be submitted as the already submitted invoice is not attested by ADC, DRAP.

Decision in 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Reply of applicant:

Serial No.	Module/ Section	Shortcomings	Reply of applicant
1.	3.2.S.1.2	Applicant has stated that API manufacturer is manufacturing polymorphic Form II. As the drug substance exhibits polymorphism, justification for the use of polymorphic Form II shall be submitted along with credible evidence.	Polymorphic Form II is patented for use in USA. Reference literature is submitted.
2.	3.2.S.4.2, 3.2.S.4.3 & 3.2.S.4.4	Analytical procedure is not as per USP monograph. API conforms to USP as per CoA in 3.2.S.4.4. Clarify and submit analytical method and analytical method verification, accordingly	Submitted.
3.	3.2.P.5.2 & 3.2.P.5.3	In method of analysis of Linezolid tablets, the chromatographic conditions for dissolution and Assay testing are as follows: Lambda 254nm Flow rate: 1.5ml/min Column: L1 Injection: 10micro L However, the above conditions are not as per USP monograph. Justify. Moreover, validation/verification studies have been submitted for the method given in 3.2.P.5.2 while the method is not as per USP. Justify.	After six month stability studies, the firm has revised its product testing method from in-house to USP and performed testing of stability samples of real time stability studies at 12 and 18 month time point as per USP method.
4.	3.2.P.8	Tests results and associated testing record of stability batches shall be submitted for real time and accelerated stability studies *at the six-month time point.* (12-2022)	Submitted.
5.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. Documents for the procurement of API with approval from DRAP shall be submitted as the already submitted invoice is not attested by ADC, DRAP.	GMP certificate is submitted. Drug Import License is submitted. *Clearance certificate shall also be submitted.*

Evaluation by PEC (No…XXIII):

Decision: Approved.

324.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fassgen Pharmaceuticals Plot # 67/1 Block-A Phase III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals Pvt Ltd, 30km Lahore Sargodha Road, Sargodha.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 10-04-2022 is provided)
	GMP status of the firm	GMP certificate of the contract acceptor is not submitted.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-02-2018 specifying Liquid Syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 32010 dated 07-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip No. 7727370183
	The proposed proprietary name / brand name	**VENSET 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syrup contains: Ondensetron Hydrochloride equivalent to Ondensetron …… ……4mg
	Pharmacotherapeutic Group of (API)	Anti-emetics and Anti-nauseants
	Pharmaceutical form of applied drug	Transparent Syrup
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml & 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondensetron Syrup (MHRA Approved)
	For generic drugs (me-too status)	Dantron Oral Solution of M/s Shrooq Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 77076)
	Name and address of API manufacturer.	Aungraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Onseron Syrup. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Anugraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, India.		
API Lot No.	AR/078/19 in Batch No.s 003 & 004. AR/149/20 in Batch No. 005		
Description of Pack (Container closure system)	Amber coloured glass bottle with aluminium cap		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	003	004	005
Batch Size	10000 packs	10000 packs	10000 packs
Manufacturing Date	11-2020	03-2021	05-2021
Date of Initiation	17-11-2020	11-03-2021	28-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate (No. DCD/SPL.CI-I/CR-1884/18-19 dated 16-02-2019 issued by Drugs Control Department, Government of Karnataka. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. The certificate was valid for one year from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.
6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.
9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.
11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.
14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.

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

Response of applicant:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.	Receiving of DML renewal application submitted in Licensing Division of DRAP dated 06-02-2023 is submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.	GMP certificate No. 248/2022-DRAP (AD-0835218-1099) issued on the basis of evaluation conducted on 25-11-2022 is submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.	Submitted
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.	Submitted
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.	Applicant has submitted complete calculations including adjustment of salt factor. Applicant has also clarified that the fill weight is 50mL in 60mL bottle. API quantity is not changed. The applied label claim is correct.
6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.	Submitted
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.	M/s Indus Pharma Pvt Ltd, Karachi. Reg. No. 058677
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.	Submitted
9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.	*PL/ Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product.*
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.	CoA of glycerine Batch No. 0800, Mfg dtae 23-09-2022, Expiry 24-09-2024 from vendor (OleoCorp) is submitted. This batch was manufactured after the manufacturing of stability batches.

			CoA/test report generated by manufacturer is also not submitted. ***Reply is not satisfactory***
11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.	Submitted
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	GMP certificate dated 10/04/2023 and valid till one year from the date of issue is submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.	Firm has submitted clearance certificate dated 22-10-2020 specifying import of 5kg Ondensetron HCl by M/s Winlet. The clearance certificate is issued by AD (I&E) DRAP, Lahore. Batch No. of imported batch is AOND-20013, Mfg 09-2020, Exp 08-2025. Batch No. of API used for manufacturing of stability batches is different. ***Clarification shall be submitted by the applicant.***
14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.	Submitted
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.	Submitted

Remarks of Evaluator[xxiii]: Response of applicant is not satisfactory.

Decision of 336th meeting of RB: Registration Board decided to defer the application for the following reasons:

i. **Submission of CoA/test report of relevant batch of Glycerin generated by manufacturer,**
ii. **Clarification regarding the batch of glycerin used in the manufacturing of stability batches,**
iii. **Clarification regarding the batch of API used in the manufacturing of stability batches,**
iv. **Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product. If excipients of applied formulation are different from reference product, drug-excipient compatibility studies shall also be submitted.**

Reply of applicant:

Serial No.	Reason for deferment	Reply of applicant
1.	Submission of CoA/test report of relevant batch of Glycerin generated by manufacturer	Submitted for two batches**.** ***However, in the in-house CoA's the results for DEG***

		and EG impurities are stated as " As per CoA" so in-house testing of these impurities has not been conducted.
2.	Clarification regarding the batch of glycerin used in the manufacturing of stability batches	Glycerin Lot No. 7920DMS3L used in the manufacturing of Batches 003 and 004. Glycerin Lot No. 3200KMS3L used in the manufacturing of Batch 005.
3.	Clarification regarding the batch of API used in the manufacturing of stability batches	API Lot No. AOND-19017 used in the manufacturing of Batches 003 and 004. API Lot No. AOND-20013 used in the manufacturing of Batch 005. ***Submit CoA's of these batches of API by drug product manufacturer.***
4.	Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product. If excipients of applied formulation are different from reference product, drug-excipient compatibility studies shall also be submitted.	Marketing Authorization number is not submitted. However, drug excipient compatibility studies have been submitted.

Remarks of evaluator:

Decision: Deferred for submission of following:

CoA/test report of relevant batch of Glycerin generated by applicant mentioning test results for EG and DEG impurities.

CoAs of the batches of API by drug product manufacturer, used in the manufacturing of stability batches.

III. Deferred cases of Form 5 (Human)

325.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid Injection (General)
	Brand Name +Dosage Form + Strength	FINZINE injection 25mg
	Composition	Each 1mL ampule contains: Fluphenazine Decanoate..... 25mg
	Diary No. Date of R& I & fee	Dy No. 14557 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900597 dated 05-03-2019.
	Pharmacological Group	Antipsychotics ATC code: N05AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA
	Me-too status	Saviget Injection 25mg ICI Pakistan Limited Reg. No. 69745
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	1. Evidence of approval of applied product in reference regulatory authority is required. 2. Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. ***3. Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision of 329 DRB: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
	Reply of applicant: The reference product is approved in USFDA.	
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
326.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Fitbone 70mg tablet
	Composition	Each tablet contains: Alendronate Sodium Trihydrate Eq. to Alendronic Acid…70mg
	Diary No. Date of R & I & fee	Dy. No. 17439 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901404 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs Affecting Bone Structure and Mineralization ATC Code: M05BA04
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dronal Once Weekly 70mg tablet Mfg. by Merck Sharp & Dohme Limited, Approved by MHRA

	Me-too status	Deonate Tablets 70mg Reg. No. 68396 Mfg. by M/s. ICI Pakistan
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
327.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Spasnem 40mg tablet
	Composition	Each tablet contains: Otilonium Bromide…40mg
	Diary No. Date of R & I & fee	Dy. No. 17437 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815591 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Synthetic anticholinergics, quaternary ammonium compounds ATC code: A03AB06
	Type of Form	Form-5
	Finished product Specification	Rotex Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Otilonio Stada 40 mg by Laboratorio Stada, Sl Approved by CIMA Spain.
	Me-too status	Otomin Tablet Reg. No. 059407 Mfg. by Genome Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
328.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Tezmin 2mg tablet

	Composition	Each tablet contains: Terazosin Hydrochloride dehydrate Eq. to Terazosin…2mg
	Diary No. Date of R & I & fee	Dy. No. 17449 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815559 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code: G04CA03
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Terazosin 2mg tablets approved by MHRA
	Me-too status	Tezim Tablet 5mg Reg. No. 64398 Mfg. by M/s. Genome Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
329.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Mezol 100mg tablet
	Composition	Each tablet contains: Mebendazole…100mg
	Diary No. Date of R & I & fee	Dy. No. 17420 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901402 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Vermox 100mg tablets approved by MHRA
	Me-too status	Meberown tablet Reg. No. 56379 Mfg. by M.s, Crown Pahrmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP)

		Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
330.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Azofan 50mg tablet
	Composition	Each tablet contains: Azathioprine…50mg
	Diary No. Date of R & I & fee	Dy. No. 17446 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815569 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other immunosuppressants ATC Code: L04AX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Azathioprine 50mg Film coated tablets approved by MHRA
	Me-too status	Imuprine Tablet 50mg Reg. No. 107461 Mfg. By M/s. Hiranis Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
331.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Zynex 300mg Tablet
	Composition	Each tablet contains: Allopurinol…300mg
	Diary No. Date of R & I & fee	Dy. No. 17425 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815567 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Allopurinol 300mg tablets approved by MHRA
	Me-too status	Parinol 300mg Tablet Reg. No. 102404 Mfg. by M/s. Pulse Pharmaceuticals

	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
332.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Wormzol 200mg tablet
	Composition	Each Film coated tablet contains: Albendazole…200mg
	Diary No. Date of R & I & fee	Dy. No. 17456 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815558 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA03
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Albendazole 200mg tablets approved by US-FDA
	Me-too status	Larex Tablet Reg. No. 14290 Mfg. by M/s. Standpharm
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
333.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Novimax 10mg/10mg tablet
	Composition	Each tablet contains: Doxylamine succinate…10mg Pyridoxine Hydrochloride…10mg
	Diary No. Date of R & I & fee	Dy. No. 14062 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0610396 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Aminoalkyl ethers

		ATC Code: R06AA59
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	BONJESTA (doxylamine succinate and pyridoxine hydrochloride), extended-release tablets approved by US-FDA
	Me-too status	Vomenax Tablet Reg. No. 90791 Mfg. by M/s. SJ&G Fazul ellahi
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Clarification required for inactive used for the delayed release of the applied formulation. As submitted master formulation does not depicts any inactive for the delayed release effect of applied formulation. iii. Firm has claimed in-house specifications. iv. Revised label claim as Extended release tablet as per reference product with submission of applicable fee is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
334.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Aurora 500mg Dispersible Tablet
	Composition	Each Dispersible tablet contains: Deferasirox…500mg
	Diary No. Date of R & I & fee	Dy. No. 17450 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815566 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Iron chelating agents ATC Code: V03AC03
	Type of Form	Form-5
	Finished product Specification	Rotex specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Deferasirox Alkem 500mg Dispersible Tablets approved by MHRA
	Me-too status	Dasirox 500 mg tablet Reg. No. 93971 Mfg. by M/s. CCL Pharmaceuticals.
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.

	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
335.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Trylin 35mg tablet
	Composition	Each tablet contains: Amitriptyline HCl…25mg
	Diary No. Date of R & I & fee	Dy. No. 17418 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815553 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Non-selective monoamine reuptake inhibitors ATC Code: N06AA09
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amitriptyline 25mg tablets approved by MHRA
	Me-too status	Amitin tablet Reg. No. 38547 Mfg. by M/s. Glitz Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
336.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Exor-H 5/160/25mg tablet
	Composition	Each tablet contains: Amlodipine Besylate Eq. to Amlodipine…5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R & I & fee	Dy. No. 14200 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901418 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX01
	Type of Form	Form-5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	EXFORGE HCT tablets approved by US-FDA
	Me-too status	Sofvasc Hct Tablets 5/160/25mg Reg. No. 77754 Mfg. by M/s. Wilsons Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
337.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Rancol XR 500mg tablet
	Composition	Each tablet contains: Ranolazine…500mg
	Diary No. Date of R & I & fee	Dy. No. 17424 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815596 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other cardiac preparations ATC Code: C01EB18
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ranexa 500 mg prolonged-release tablets approved by MHRA
	Me-too status	Razin ER Tablet 500mg Reg. No. 61103 Mfg. by M/s. Getz Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Reference product is available as Prolonged-release tablets. Clarification required for inactive used for the prolonged-release of the applied formulation. As submitted master formulation does not depict any inactive for the prolonged release effect of applied formulation. iv. Revised label claim as Prolonged-release tablet as per reference product with submission of applicable fee is required
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections:

		Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
338.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Ferolic Tablet
	Composition	Each Tablet contains: Ferrous Fumarate…150mg Folic Acid…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 17442 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815563 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Iron in combination with folic acid ATC Code: B03AD02
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Folfe Tablets Reg. No. 41769 Mfg. by M/s. Wilshire Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
339.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Cardem 2mg Tablet
	Composition	Each Tablet contains: Doxazosin (As Mesylate)…2mg
	Diary No. Date of R & I & fee	Dy. No. 17460 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815560 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code: C02CA04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	Doxazosin 2mg tablet approved by MHRA
	Me-too status	Uri-Dox 2mg Tab Reg. No. 73180 Mfg. by M/s. Valor Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
340.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Urazol 50mg tablet
	Composition	Each tablet contains: Propylthiouracil…50mg
	Diary No. Date of R & I & fee	Dy. No. 17453 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815556 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Thiouracils ATC Code: H03BA02
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Propylthiouracil tablets approved by MHRA
	Me-too status	Procarbizole tablet Reg. No. 40561 Mfg. by M/s. Pharmedic Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
341.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lorem 10mg tablet
	Composition	Each Tablet contains:

		Loratadine…10mg
	Diary No. Date of R & I & fee	Dy. No. 17431 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815597 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Loratadine 10mg tablets approved by MHRA
	Me-too status	Andin Tablets 10mg Reg. No. 100088 Mfg. by M/s. Reign Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
342.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Oxiban 5mg tablet
	Composition	Each tablet contains: Oxybutynin Hydrochloride…5mg
	Diary No. Date of R & I & fee	Dy. No. 17441 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815555 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Oxybutynin Hydrochloride Tablets 5mg approved by MHRA
	Me-too status	Taivor tablet Reg. No. 38385Mfg. by M/s. Razzee Therapeutics
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General)

		Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
343.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Oxiban 3mg tablet
	Composition	Each tablet contains: Oxybutynin Hydrochloride…3mg
	Diary No. Date of R & I & fee	Dy. No. 17457 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901428 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Oxybutynin Hydrochloride Tablets 3mg approved by MHRA
	Me-too status	Oxynin Tablet Reg. No. 30227 Mfg. by M/s. Venus Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
344.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Nebcard 2.5mg tablet
	Composition	Each tablet contains: Nebicolol (as HCl)…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 17428 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901408 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code: C07AB12
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nebivolol 2.5mg tablets approved by MHRA
	Me-too status	Byscard 2.5mg tablet Reg. No. 71104 Mfg. by M/s. The Searle Company
	GMP status	Not Provided

	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
345.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Flunex 100mg tablet
	Composition	Each tablet contains: Nitrofurantoin…100mg
	Diary No. Date of R & I & fee	Dy. No. 17434 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901429 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Nitrofuran derivatives ATC Code: J01XE01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nitrofurantoin 100mg tablet approved by MHRA
	Me-too status	Urotoin 100mg Tablet Reg. No. 98424 Mfg. by M/s. Highnoon Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
346.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Flocin 200mg tablet
	Composition	Each tablet contains: Ofloxacin…200mg
	Diary No. Date of R & I & fee	Dy. No. 17423 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901403 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones

		ATC Code: J01MA01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ofloxacin 200mg tablets approved by MHRA
	Me-too status	Myobid 200mg Tablet Reg. No. 44643 Mfg.by M/s. Panacea Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
347.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Myoson 50mg tablet
	Composition	Each tablet contains: Eperisone HCl…50mg
	Diary No. Date of R & I & fee	Dy. No. 17458 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815562 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other centrally acting agents ATC Code: M03BX09
	Type of Form	Form-5
	Finished product Specification	Rotex specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Eperisone hydrochloride tablets 50 mg approved by PMDA Japan
	Me-too status	Erip-son Tablet 50mg Reg. No. 103075 Mfg. by M/s. Wellmark Pharmaceuticlas
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General)

		Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	
348.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Dinom 50mg tablet
	Composition	Each tablet contains: Dimenhydrinate…50mg
	Diary No. Date of R & I & fee	Dy. No. 17436 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901409 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Aminoalkyl ethers ATC Code: R06AA11
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dimenhydrinate 50mg tablets approved by MHRA
	Me-too status	Danate 50mg Tablet Reg. No. 103291 Mfg. by M/s. Danas Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision in 326th meeting of RB	Deferred for the updated status of GMP of the firm from the QA&LT division.
	Remarks of Evaluator PEC-XXIII	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Decision: Approved.	

IV. Deferred cases of Form 5A (Import) (Veterinary)

349.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing	Not clarified

	authorization holder	
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32053 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 3266953570
	Brand Name +Dosage Form + Strength	Super Lamox-70% WSP
	Composition	Each 1000gm Contains: Amoxicillin Trihydrate…700gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50g,100g, 250g,500g, 1kg, 5kg, 10kg
	International availability	Super Lamox-70% Reg. No.THQ-223-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	Primox 70% WSP M/s Prix Pharma Reg. No. 074032
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)

	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder for solution.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons.

		• Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 0156607334. Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer**. • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the

		applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision of 336th Meeting of RB: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders.	
	Reply of applicant:	In Vietnam, The Ministry of Agriculture & Rural Development, Department of Animals Health only certifies two production divisions of Beta lactam and non-beta lactam. In beta lactam division, our manufacturer has a dedicated facility for Penicillin oral powder. The response by the firm specifies that the manufacturer has dedicated area for penicillin injectable however the applied product is oral powder.
	Remarks of evaluator XXIII:	
	Decision: Deferred for confirmation of dedicated facility for production of penicillin oral powder products.	
350.	Name and address of Applicant	M/s Al-Habib Agencies. Flat No.11, 2nd Floor, Kala Khan Shopping Center, Shamshabad, Murree Road, Rawalpindi
	Detail of Drug Sale License	DSL No. 01-374-0177-032506 Validity: 04-05-2027 Address: As above
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam Address on attached GMP certificate & Free Sales Certificate: Plot 17 F2-F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy district, Can Tho city, Vietnam
	Name and address of marketing authorization holder	Not clarified
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy No.32064 Dated 23-11-2021
	Fee including differential fee	Rs.75,000 Deposit Slip No. 468627042483
	Brand Name +Dosage Form + Strength	ProZSB Plus Powder

	Composition	Each 1000gm Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm
	Finished Product Specification	Not stated
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100g, 250g,500g, 1kg, 5kg, 10kg, 25kg
	International availability	ProZSB Plus Reg. No.THQ-219-XK Registered in Vietnam Validity: 16-12-2022
	Me-too status	PSB 100 M/s Epla Labs Reg. No. 013257
	Detail of certificates attached	**Free sale:** Registered in Vietnam **for export use only** **GMP certificate:** For Non-Betalactam solutions (injection and Oral) and powder for oral use and production line of Betalactam in the form of powder for oral use. Issued by Ministry of Agriculture & Rural Development, Socialist Republic of Vietnam No. 17/16/GCN-GMP dt. **20-12-2016** Validity: 5 years (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) **Sole Distributor Contract/Agreement** Between the applicant & the **exporter**, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. (Copy attested by MOFA, Vietnam and Embassy of Pakistan, Vietnam) Dt. 24-09-2020 Validity: 5 years **Contract Agreement:** Confirmation letter No. CL/HT-THQ/2021 dt. 19-02-2021 between the trading company/exporter, M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam & manufacturer, M/s ThienQuan Joint Stock Company, 39 Nguyen Huu Cau, Con Khuong, Cai Khe Ward, Ninh Kieu District, Can Tho City, Vietnam that all products of the exporter shall be produced by the manufacturer. (Scanned copy attached)
	Remarks of the Evaluator[xxiii]	• Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the provided FSC states that the applied product is registered in Vietnam for export use only. • Valid legalized GMP certificate of the manufacturer is required *for the relevant section/production line i.e. Penicillin Oral Powder.* • The address of manufacturer (M/s ThienQuan Joint Stock Company) mentioned on FSC and GMP

		certificate is different from the address given on Form 5A & contract agreement ((No. THQ-HT/2019 dt 13-12-2019) between manufacturer and distributor abroad (M/s HT Pharma Veterinary Import Export Ltd Liability Company); address of marketing authorization holder in the country of origin needs to be clarified. • Accelerated and Real time stability studies of applied formulation according to Zone IV-A are required • Finished Product Specifications are not provided. • Label is not in accordance with The Drugs (Labelling and Packing) Rules, 1986. • Differential fee of Rs. 75,000 is required. The afore-mentioned shortcomings were communicated to the applicant vide letter No. F.2-1/2023/PEC-DRAP (DD-PEC-XXIII) dated 17-07-2023. The reply of the firm was submitted vide Letter No. AHA/22-23/PEC-DRAP/001 dated 20-07-2023 whereby the applicant has submitted the following: • Clarification on their letterhead that the manufacturer abroad has informed them "that applied products are registered in Vietnam for their local and export business". • Scanned, non-legalized copy of valid GMP certificate of the manufacturer dated 28-04-2022 having validity for five years from the date of approval, *for production lines of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection and production line of Beta lactam in the forms of powder, granule for oral use.* • Clarification that the addresses of manufacturer i.e. M/s ThienQuin Joint Stock Company on GMP and Free Sales Certificate is the factory address whereas the address on Form 5A and contract agreement is the office address of the manufacturer abroad. Further, the applicant has clarified that the name & address of exporter/distributor abroad/marketing authorization holder i.e. M/s HT Pharma Veterinary Import Export Limited Liability Company, 69 Hung Vuong, Thoi Binh Ward, Ninh Kieu District, Can Tho City, Vietnam. • Accelerated and long term stability studies report from the manufacturer. However, the reports are not signed by the manufacturer's representatives/qualified persons. • Finished product specifications containing reference (In-house or pharmacopoeial) for each parameter such as pH, assay etc. However, the applicant has not submitted the final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. • Revised label • Differential fee of Rs.75000 vide Deposit slip No. 2515097727.

		Following are still required: • Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country is required, as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate. • Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976. • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc.
	Decision of 330th meeting of RB:	**Deferred for submission of the following:** • **Free Sales Certificate for the applied product in the country of origin attested by the Embassy of Pakistan in that country as the initially provided FSC states that the applied product is registered in Vietnam for export use only. Moreover, the clarification against the FSC is provided by the applicant whereas it should be provided by the issuing authority of the Free Sales Certificate.** • **Legalized copy of valid GMP certificate of the manufacturer along with clarification from the issuing authority whether the facility for manufacturing Beta Lactam drugs is dedicated for the manufacturing of penicillins, as required under The Drugs (L,R,A) Rules, 1976.** • **Signed copy of stability study report of the applied formulation/product** • **Final specifications of the finished product i.e. whether the finished product conforms to In-house Specifications or USP, BP, JP Specifications etc. (Product monograph is available in USP).** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, .**
	Reply of applicant	Applicant has submitted response vide letter No. AHA/22-23/PEC-DRAP/002 dated 15-01-2024 whereby the following documents are submitted: • Legalized ***copy*** of Free Sales Certificate (406/2023/QLT-CFS dated 06-10-2023) for the applied product in the country of origin attested by the Embassy of Pakistan in that country. Validity of certificate: 2 years • Legalized copy of valid GMP certificates of the manufacturer. (GMP certificate dated 17-10-2023 for production lines of beta lactam in the form of powder

		for injection and suspension for injection; Validity 5years from date of approval; GMP certificate dated 28-04-2022 for production lines of non beta lactam in the form of powder, granule for oral; liquid for oral; solution for injection and production lines of beta lactam in the form of powder, granule for oral; Validity 5years from date of approval) • Signed copy of stability study report of the applied formulation/product • Final specifications of the finished product i.e. Innovator's Specifications
	Remarks of evaluator[xxiii]	GMP certificate does not clarify whether the production line is dedicated for penicillin dosage form as required under LRA Rules 1976.
	Decision of 336th meeting of RB: Deferred for submission of legalized, original GMP certificate which specifies that the manufacturer has dedicated production line for manufacturing of *penicillin* oral powders.	
	Reply of applicant:	In Vietnam, The Ministry of Agriculture & Rural Development, Department of Animals Health only certifies two production divisions of Beta lactam and non-beta lactam. In beta lactam division, our manufacturer has a dedicated facility for Penicillin oral powder. The response by the firm specifies that the manufacturer has dedicated area for penicillin injectable however the applied product is oral powder.
	Remarks of evaluator XXIII:	
	Decision: Deferred for confirmation of dedicated facility for production of penicillin oral powder products.	

Agenda of Mr. Hafiz Asif Iqbal

Routine Cases:
Local Manufacturing

351.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals (Pvt) Ltd. Plot # A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt) Ltd. Plot # A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7087: 10-03-2023
	Details of fee submitted	PKR 30,000/- : 14-02-2023
	The proposed proprietary name / brand name	Vonoprazan 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Vonoprazan Fumarate 10mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker

	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Takecab 10mg Tablet Approved in Japan.
	For generic drugs (me-too status)	Vonozan 10mg tablet of Getz Pharma, Karachi
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
352.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals (Pvt) Ltd. Plot # A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt) Ltd. Plot # A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7088: 10-03-2023
	Details of fee submitted	PKR 30,000/- : 14-02-2023
	The proposed proprietary name / brand name	Vonoprazan 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Vonoprazan Fumarate 20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Takecab 20mg Tablet Approved in Japan.
	For generic drugs (me-too status)	Vonozan 20mg tablet of Getz Pharma, Karachi
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
353.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot # E-127, E128 & E-129 North Western Industrial Zone, Port Qasim Authority, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot # E-127, E128 & E-129 North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7915: 20-03-2023
	Details of fee submitted	PKR 75,000/- :15-08-2022
	The proposed proprietary name / brand name	Azilsart Plus 20mg/2.5mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Azilsartan……20mg Amlodipine …2.5mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Zakras 20mg/2.5mg Tablet Approved in Japan.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
354.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot # E-127, E128 & E-129 North Western Industrial Zone, Port Qasim Authority, Karachi.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. Plot # E-127, E128 & E-129 North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7916: 20-03-2023
	Details of fee submitted	PKR 75,000/- :15-08-2022
	The proposed proprietary name / brand name	Azilsart Plus 20mg/5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Azilsartan……20mg Amlodipine …5mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Zakras 20mg/5mg Tablet Approved in Japan.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
355.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabi Qasim Industries Private Limited, 17/24, E128, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries Private Limited, 17/24, E128, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8066: 22-03-2023

	Details of fee submitted	PKR 75,000/- :10-03-2023
	The proposed proprietary name / brand name	Zapozan Plus 10mg/100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Vonoprazan Fumarate as Vonoprazan……10mg Aspirin …100mg
	Pharmacotherapeutic Group of (API)	Potassium Competitive acid Blocker, NSAID
	Reference to Finished product specifications	Vonoprazan: Innovator's specifications. Aspirin: USP specifications.
	The status in reference regulatory authorities	Cabpirin Combination Tablt Approved by PMDA Japan.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
356.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals, 3B Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad.
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals, 3B Value Addition City, 1.5km Khurrianwala-Sahianwala Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8493: 28-03-2023
	Details of fee submitted	PKR 30,000/- :21-11-2022
	The proposed proprietary name / brand name	Paxizole 40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Pantoprazole (as Sodium Sesquihydrate) …40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Protonix 40mg delayed release tablet.
	For generic drugs (me-too status)	Zotonix 40mg enteric coated tablet of M/s CCL Pharmaceuticals.
	Proposed Pack size	As per SRO
Evaluation by PEC (XXIV):		

Sr.#	Section#	Observation	Response of the Firm
1.	1.5.2	Submitted label claim is for film coated tablet whereas applied formulation is of delayed release tablet, clarify and submit updated label claim along with requisite fee.	Correct label claim is as follow; Each enteric coated tablet contains: Pantoprazole (as sodium) … 40mg Pre-registration Fee Rs7500/- Challan # 15011201434 dated 22/7/2024 submitted.

2.	3.2.S.4.3	Complete analytical method verification studies shall be submitted declaring the details of sample and standard preparation for each parameter performed.	Submitted.
3.	3.2.P.8.3	Document confirming import of drug substance approved by DRAP I&E office shall be submitted.	Submitted.

Decision: Approved.

357.	Name, address of Applicant / Marketing Authorization Holder	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura.
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11788: 15-05-2023
	Details of fee submitted	PKR 30,000/- :23-12-2022
	The proposed proprietary name / brand name	Phloroglucinol Dihydrate + Trimethyl Phloroglucinol Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 4ml Ampule Contains:** Phloroglucinol Dihydrate…40mg Trimethyl Phloroglucinol….0.04mg
	Pharmacotherapeutic Group of (API)	Anti-spasmodic
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Spasfon-teva of M/S Teva, Approved in France.
	For generic drugs (me-too status)	Anafortan plus of AGP, Karachi.
	Proposed Pack size & Proposed price	1's, Rs160 6's, Rs960 10's, Rs1,600 12's, Rs1,920 18's Rs2,880 60's Rs9,600

Evaluation by PEC (XXIV):

Decision: Approved.

358.	Name, address of Applicant / Marketing Authorization Holder	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura.
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13641: 01-06-2023

	Details of fee submitted	PKR 30,000/- :08-05-2023
	The proposed proprietary name / brand name	L-Ornithine L-Aspartate Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 10ml Ampule Contains:** L-Ornithine L-Aspartate …5.0g
	Pharmacotherapeutic Group of (API)	Liver therapy
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	Hepa Merz of M/s Merz Pharmaceuticals, Germany Approved in Germany.
	For generic drugs (me-too status)	Levijon Injection of Sami Pharmaceuticals, Karachi.
	Proposed Pack size & Proposed price	10ml x 1's, Rs500 10ml x 5's, Rs2500 10ml x 10's, Rs5000 10ml x 30's, Rs15000
Evaluation by PEC (XXIV):		
Decision: Approved.		
359.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hudson Pharma (Pvt) Ltd.** **D-93, North Western Industrial Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s Hudson Pharma (Pvt) Ltd. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13018: 26-05-2023
	Details of fee submitted	PKR 75,000/- :26-04-2023
	The proposed proprietary name / brand name	Optidine 0.7% Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml Contains:** Olopetadine …7mg
	Pharmacotherapeutic Group of (API)	Anti Histamine (H1 -Antagonist)
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Pataday 0.7% US FDA Approved.
	For generic drugs (me-too status)	Not avialable
	Proposed Pack size & Proposed price	5ml x 1's, Price as per SRO
Evaluation by PEC (XXIV):		

Decision: Approved.		
360.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13514: 31-05-2023
	Details of fee submitted	PKR 75,000/- :19-05-2023
	The proposed proprietary name / brand name	Voraglob 2.08mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** Vorapaxar 2.08mg eq. to 2.5mg Vorapaxar Sulphate
	Pharmacotherapeutic Group of (API)	Platelets aggregation inhibitor
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Zontivity 2.08mg tablet US FDA Approved.
	For generic drugs (me-too status)	Not avialable
	Proposed Pack size & Proposed price	10's, Price as per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
361.	Name, address of Applicant / Marketing Authorization Holder	M/s Crystolite Pharmaceuticals, Plot No. 1&2, S-2, national Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals, Plot No. 1&2, S-2, national Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13511: 31-05-2023
	Details of fee submitted	PKR 30,000/- :22-05-2023
	The proposed proprietary name / brand name	Itolac 100mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each capsule contains:** Itraconazole 22.2% pellets…100mg
	Pharmacotherapeutic Group of (API)	Anti-fungal
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Sporanox 100mg Capsule, MHRA Approved.

	For generic drugs (me-too status)	Itrapex 100mg capsule of M/s Swera Pharmaceuticals
	Proposed Pack size & Proposed price	30's, Price as per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
362.	Name, address of Applicant / Marketing Authorization Holder	M/s Gallop Water sciences, Plot No. 404, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Gallop Water sciences, Plot No. 404, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12098: 17-05-2023
	Details of fee submitted	PKR 30,000/- :06-04-2023
	The proposed proprietary name / brand name	Gee-Sol NS 500ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 500ml contains:** Sodium Chloride…4.5g (0.9%) w/v
	Pharmacotherapeutic Group of (API)	Parenteral Solution
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Sodium Chloride 0.9% I.V Infusion, MHRA Approved.
	For generic drugs (me-too status)	Plasaline I.V Infusion of M/s Otsuka Limited.
	Proposed Pack size & Proposed price	1's, Price as per SRO
Evaluation by PEC (XXIV):		
Valid GMP required.		
Decision: Approved. Registration Board further decided that the registration letter shall be issued after submission of valid GMP certificate/GMP inspection report conducted within last 3 years.		
363.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals, Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals, Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12098: 17-05-2023
	Details of fee submitted	PKR 30,000/- :06-04-2023
	The proposed proprietary name / brand name	Prazvo 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** Vonoprazan as Fumarate…10mg

	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	Manufacturesr's specifications
	The status in reference regulatory authorities	Takecab 10mg tablet Approved in PMDA Japan.
	For generic drugs (me-too status)	Vonozan 10mg tablet of Getz Pharma, Karachi
	Proposed Pack size & Proposed price	3*10's, Price as per SRO
Evaluation by PEC (XXIV):		
Valid GMP certificate shall be submitted.		
Decision: Approved. Registration Board further decided that the registration letter shall be issued after submission of valid GMP certificate/GMP inspection report conducted within last 3 years.		
364.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals, Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals, Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13778: 02-06-2023
	Details of fee submitted	PKR 30,000/- :06-04-2023
	The proposed proprietary name / brand name	Prazvo 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** Vonoprazan as Fumarate…20mg
	Pharmacotherapeutic Group of (API)	Potassium competitive acid blocker
	Reference to Finished product specifications	Manufacturesr's specifications
	The status in reference regulatory authorities	Takecab 20mg tablet Approved in PMDA Japan.
	For generic drugs (me-too status)	Vonozan 20mg tablet of Getz Pharma, Karachi
	Proposed Pack size & Proposed price	3*10's, Price as per SRO
Evaluation by PEC (XXIV):		
Valid GMP certificate shall be submitted.		
Decision: Approved. Registration Board further decided that the registration letter shall be issued after submission of valid GMP certificate/GMP inspection report conducted within last 3 years.		

Deferred Cases :

365.	Name, address of Applicant / Marketing Authorization Holder	M/s Oncogen Pharma (Pvt) Limited, plot no. WH-26 & 27-A3 , Korangi Creek Industrial Park,, Karachi
	Name, address of Manufacturing site.	M/s Oncogen Pharma (Pvt) Limited, plot no. WH-26 & 27-A3 , Korangi Creek Industrial Park,, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: 17A-5GV-ZN9X dated 17-05-2023
	Details of fee submitted	Rs.30,000/- dated 14-05-2024
	The proposed proprietary name / brand name	**Imatigliv Tablet 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Imatinib Mesylate equivalent to Imatinib…….400mg
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, BCR-ABL tyrosine kinase inhibitors
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Glivec 400mg Tablet of M/s Novartis Pharma (Pakistan) Limited.
	Proposed pack size & MRP	3 x 10's. 100,000/-

Evaluation by PEC(XXIV):

Section#	Observation	Firm's response
1.6.5	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.	
3.2.S.4.4	➢ Submitted COA of drug substance form M/s Oncogen does not declare the batch no.	
3.2.S.5	➢ Source of working standard is different from the source of drug substance. Clarification shall be submitted in this regard.	
3.2.P.2.2.1	➢ Individual results for each unit shall be submitted in the CDP study report.	
3.2.P.8.3	➢ Reconciliation record of the imported quantity of Imatinib mesylate shall be submitted since submitted clearance certificate has been issued for Imatinib 100mg tablet. ➢ Stability data of 6th month time point shall be submitted.	

Decision of 336th RB Meeting: Deferred for submission of reply to above cited shortcomings.

Response by the Firm:

Section#	Observation	Firm's response
1.6.5	➢ Valid DML/GMP certificate for the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.	Submitted.
3.2.S.4.4	➢ Submitted COA of drug substance form M/s Oncogen does not declare the batch no.	Submitted.
3.2.S.5	➢ Source of working standard is different from the source of drug substance. Clarification shall be submitted in this regard.	Clarification submitted.
3.2.P.2.2.1	➢ Individual results for each unit shall be submitted in the CDP study report.	Submitted.
3.2.P.8.3	➢ Reconciliation record of the imported quantity of Imatinib mesylate shall be submitted since	Justification submitted.

	submitted clearance certificate has been issued for Imatinib 100mg tablet. ➢ Stability data of 6th month time point shall be submitted.	
Decision: Approved.		

Agenda of Ms. Najia Saleem

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

a. New Cases

366.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Chlorofas-200 Water Soluble Powder
	Composition	Each gram contains: Chlortetracycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 8555 dated 29-03-2023 Rs.30,000/- dated 20-03-2023 (slip No. 43432502129)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Poul CTC-20 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118498)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
367.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Albamec Drench
	Composition	Each 100ml contains: Albendazole…10gm Triclabendazole…12gm Ivermectin…0.2gm
	Diary No. Date of R& I & fee	Dy.No 8556 dated 29-03-2023 Rs.30,000/- dated 20-03-2023 (slip No. 98680001)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Atizol Suspension of M/s Farm Aid Group, Haripur. (Reg. No. 117248)

	GMP status	
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goat **Liquid (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
368.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Insha Tone Liquid
	Composition	Each 1000ml contains: Vitamin E…200,000mg Sorbitol…50,000mg Choline Chloride…50,000mg Vitamin C…20,000mg Selenium (Sodium Selenite) …150mg Zinc (Zinc Sulphate)…4000mg
	Diary No. Date of R& I & fee	Dy.No 5795 dated 01-03-2023 Rs.30,000/- dated 01-03-2023 (slip No. 5335866627)
	Pharmacological Group	Antitumor and antioxidant
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Vestol-Forte Oral Liquid of M/s Sanna Laboratories, Faisalabad. (Reg. No. 078272)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator	**Target species:** Poultry, calves, sheep, goat **Liquid Section(General) (Veterinary**) confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
369.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxzym-P Injection 50ml
	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 6355 dated 06-03-2023 Rs.30,000/- dated 01-03-2023 (slip No. 9922263825)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Phenoxy-M Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 057002)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
370.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxzym-P Injection 30ml
	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 6356 dated 06-03-2023 Rs.30,000/- dated 01-03-2023 (slip No. 810572041182)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	30ml; Decontrolled
	Me-too status	Phenoxy-M Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 057002)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
371.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxzym-P Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 6544 dated 08-03-2023 Rs.30,000/- dated 06-03-2023 (slip No. 166698574461)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Meproxyfen Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 035125)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
372.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt. Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Losant Drench
	Composition	Each ml contains: Levamisole HCl…100mg Closantel…100mg
	Diary No. Date of R& I & fee	Dy. No 6357 dated 06-03-2023 Rs.30,000/- dated 01-03-2023 (slip No. 817022306382)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Anthel-ZK Oral Liquid of M/s Mallard Pharmaceutical (Pvt) Ltd Multan (Reg. No. 058923)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Oral Liquid (General) (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved.	
373.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	AD-FAS Injection 100ml
	Composition	Each ml contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 5799 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 001857318)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	AD VETZ Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 117207)

	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, calf, foal, sheep, goat, Lamb, Goat kid, cat and dog **Liquid Injection (General) Vet section** confirmed vide panel inspection report based on inspection dated 10-03-2021 for renewal of DML. **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
374.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Synocab Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 5801 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 27044820291)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No.119706)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, goats, cats **Liquid Injection (General) Vet section** confirmed vide panel inspection report based on inspection dated 10-03-2021 for renewal of DML. **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
375.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Iver Super Gold Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 5802 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 4312274813)
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5

	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Actimec DS Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, camel **Liquid Injection (General) Vet section** confirmed vide panel inspection report based on inspection dated 10-03-2021 for renewal of DML. **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
376.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Dizen Injection 10ml
	Composition	Each vial contains: Diminazine Aceturate…1050mg Phenazone…1312mg
	Diary No. Date of R& I & fee	Dy.No 5803 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 709671060514)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Antiprotoz Injection (**30ml, 50ml, 100ml**) of M/s Elko Organization (Pvt) Ltd., Karachi (Reg. No. 043122)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, horses, dogs and goat **Shortcomings:** • Confirmation of **Dry powder injectable section (Vet)** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of Dry powder injectable section (Vet)** • **Latest GMP inspection report conducted within the period of last three years.**	
377.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Ox Zole Drench
	Composition	Each Liter contains: Oxfendazole…22.65gm Triclabendazole…85gm

	Diary No. Date of R& I & fee	Dy.No 5800 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 060838587007)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	OT-Zole Drench of M/s Farm Aid Group, Haripur. (Reg. No. 114885)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goat **Oral Liquid (General antibiotic) Vet** confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 06-07-2021. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
378.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Ectolfeece-100 Liquid
	Composition	Each ml contains: Cypermethrin…100mg
	Diary No. Date of R& I & fee	Dy.No 5794 dated 01-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 6817599063)
	Pharmacological Group	Pyrethroid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 500ml, 1000ml, 2000ml, 2500ml; Decontrolled
	Me-too status	Ectosel-10 Solution of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore.(Reg. No. 114805)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goat, camel, horses, and buffaloes **Shortcomings:** • Confirmation of **topical solution/aerosol/ spray section** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of topical solution/aerosol/ spray section** • **Latest GMP inspection report conducted within the period of last three years.**	
379.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	T-Gent Injection 50ml
	Composition	Each ml contains:

		Gentamycin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 7162 dated 13-03-2023 Rs.30,000/- dated 27-02-2023 (slip No. 652779034333)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tylogent Injection of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concluded good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Large animals, sheep, goat, poultry **Liquid Injectable (Vet)** confirmed vide letter No. F. 2-44/84-Lic (Vol-IV) dated 20-09-2021. **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
380.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Ketto 100mg/ml Injection
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 7163 dated 13-03-2023 Rs.30,000/- dated 27-02-2023 (slip No. 831014254753)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Hansi Pro 10% Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg. No. 114839)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concluded good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, equine **Liquid Injectable (Vet)** confirmed vide letter No. F. 2-44/84-Lic (Vol-IV) dated 20-09-2021. **Shortcomings:** The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
381.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Tef Powder
	Composition	Each Kg contains: Erythromycin Thiocyanate…30mg Tylosin Tartrate…25mg **Furaltadone**…50mg
	Diary No. Date of R& I & fee	Dy.No 7161 dated 13-03-2023 Rs.30,000/- dated 27-02-2023 (slip No. 116406178544)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20gm; Decontrolled
	Me-too status	Tylofurcin Dispersible Powder of M/s Symans Pharmaceuticals Lahore (Reg. No. 013683)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concluded good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder Veterinary (General)** confirmed vide letter No. F. 2-44/84-Lic (Vol-IV) dated 20-09-2021. The Registration Board in its 335th meeting, deliberated on the matter in detail, keeping in view absence of any recognized scientific data regarding the use of **Furaltadone** by any Reference Regulatory Authority (RRA) and based on the recommendation of the Sub-committee on Veterinary Drugs, Registration Board decided to issue show cause notices to all the firm holding registrations of "Furaltadone for veterinary use only" for the cancellation of registration under section 42 of the Drugs Act, 1976 and rules framed thereunder.
	Decision: Registration board disposed of the case keeping in view absence of any recognized scientific data regarding the use of Furaltadone by any Reference Regulatory Authority (RRA) and based on the recommendation of the Sub-committee on Veterinary Drugs.	
382.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Trebac-N Oral Powder
	Composition	Each 1000gm contains: Neomycin Sulphate…720gm
	Diary No. Date of R& I & fee	Dy.No 7160 dated 13-03-2023 Rs.30,000/- dated 28-02-2023 (slip No. 79491809262)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm; Decontrolled

	Me-too status	Neokam-72 Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119740)
	GMP status	Inspection conducted on 16-01-2020 concluded fair level of GMP compliance in veterinary sections.
	Remarks of the Evaluator	**Target species:** Calves, sheep, goat, Poultry **Shortcomings:** • Confirmation of **topical solution/aerosol/ spray section** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for following: • **Confirmation of topical solution/aerosol/ spray section** • **Latest GMP inspection report conducted within the period of last three years.**	
383.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Zental Oral Suspension
	Composition	Each 100ml contains: Levamisole HCl…10gm Closantel…10mg
	Diary No. Date of R& I & fee	Dy.No 7386 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.78076520)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goat, dogs and cats **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
384.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Xantal 5% Oral Suspension
	Composition	Each ml contains: Closantel Sodium…50mg
	Diary No. Date of R& I & fee	Dy.No 7377 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.13403713468)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L, 10L and 20L; Decontrolled
	Me-too status	Clant Oral Suspension of M/s Elko Organization (Private) Ltd., Karachi. (Reg. No. 075649)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications before issuance of registration letter.
	Decision: Approved. The Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
385.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bentin Oral Suspension
	Composition	Each ml contains: Albendazole…25mg Ivermectin…1mg Sodium Selenite…0.5mg Cobalt Sulphate…2.2mg
	Diary No. Date of R& I & fee	Dy.No 7384 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.54072157)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, dogs and cats **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
386.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Livosil Forte oral liquid

	Composition	Each 100ml contains: Silyamarin…2100mg Vitamin E…1500mg
	Diary No. Date of R& I & fee	Dy.No 7382 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.5456705624)
	Pharmacological Group	Hepatoprotective agent with antioxidant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L, 10L and 20L; Decontrolled
	Me-too status	Hepatocare Oral Suspension of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.062167)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, horses, foals **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
387.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Minrex Oral Solution
	Composition	Each ml contains: Calcium Chloride Hexahydrate…2mg Magnesium Chloride Hexahydrate…4mg Potassium Chloride…8mg Sodium Chloride…120mg Cyanocobalamin…0.025mg Sodium Lactate…42.7mg
	Diary No. Date of R& I & fee	Dy.No 7378 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.662138540120)
	Pharmacological Group	Rehydration solution of mineral supplements
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L, 10L and 20L; Decontrolled
	Me-too status	Supplitol Oral Solution of M/s ICI Pakistan Limited, Life Sciences, Lahore. (Reg. No. 099367)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, horses, foals, sheep, goats **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

388.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Benthol Oral Suspension
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 7387 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No.3332757228)
	Pharmacological Group	Mucolytic/ Expectorant/ bronchodilator
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1L, 2.5L, 5L, 10L and 20L; Decontrolled
	Me-too status	Bronchoment-20 Oral Liquid of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119754)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Poultry/ turkeys **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
389.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tilmix Injection
	Composition	Each ml contains: Tilmicosin…300mg
	Diary No. Date of R& I & fee	Dy.No 7385 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 549188918)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	Emicosin Injection **(100ml)** of M/s Manhattan Pharma, Karachi. (Reg. No. 116881) Mycofar-30 Injection **(50ml)** M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No.113659)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** Choice of only one pack size before issuance of registration letter.

	Decision: Approved. The Firm shall submit following before issuance of registration letter: • **Firm shall submit fee Rs. 30,000/- for revision of label claim (salt form completion) in line with reference product and FPP specifications** • **Choice of only one pack size**	
390.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Apracent Injection
	Composition	Each ml contains: Apramycin Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 7381 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 6530875217)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	Apracon-200 Injection **(5ml, 10ml, 20ml)** of M/s Vetcon Pharmaceuticals (Pte.) Ltd. (Reg. No. 057097)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goats, poultry **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** Choice of only one pack size before issuance of registration letter.
	Decision: Approved. The Firm shall submit only one demanded pack size before issuance of registration letter.	
391.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tylo-DC Injection 100ml
	Composition	Each 100ml contains: Tylosin Tartrate…5gm Colistin sulphate…60 MIU **Dimetridazole**…10gm
	Diary No. Date of R& I & fee	Dy.No 7376 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 83295357153)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry, dogs and cats **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.

		Shortcomings: • Formulation is already under review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters • Conversion of Colistin sulfate from MIU to mg and accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Conversion of Colistin sulfate from MIU to mg** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
392.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	NCO Mix Oral Powder
	Composition	Each Kg contains: Neomycin Sulphate…250gm Colistin Sulphate…300 MIU Oxytetracycline HCl…250gm
	Diary No. Date of R& I & fee	Dy.No 7380 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 968791368)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 5Kg, 10Kg, 20Kg; Decontrolled
	Me-too status	Neox-C Powder of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 117144)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** calves, sheep, goats, poultry **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
393.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dirostop Powder
	Composition	Each 12gm Contains: Neomycin Sulphate…400mg Streptomycin Sulphate…400mg Sulfaguanidine…4gm Kaolin…4gm Pectin…400mg Bismuth Subnitrate…2gm

		Vitamin A Acetate…80,000 IU
	Diary No. Date of R& I & fee	Dy.No 7383 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 5633734530)
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	12gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	Pectorin Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 117176)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, horses, foals, sheep, goats, cats and dogs **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
394.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dairytone-M Powder
	Composition	Each Kg contains: Calcium as Dicalcium Phosphate…155gm Phosphorous as Dicalcium Phosphate…135gm Magnesium as Magnesium Oxide…55gm Sodium as Sodium Chloride…45gm Iron as Ferrous Sulphate…1gm Zinc as Zinc Sulphate...3gm Manganese as Manganese Sulphate...2gm Copper as Copper Sulphate...0.6gm Cobalt as Cobalt Chloride...0.01gm Iodine as Potassium Iodide...0.04gm Selenium as Sodium Selenite...0.003gm
	Diary No. Date of R& I & fee	Dy.No 7379 dated 14-03-2023 Rs.30,000/- dated 14-03-2023 (slip No. 36358257072)
	Pharmacological Group	Dietary supplement of essential macro and micro minerals
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 5Kg, 10Kg, 20Kg; Decontrolled
	Me-too status	HS-Minerals Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 112272)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal **Shortcomings:**

		The applied formulation contains different salt form of Sodium than the reference product. So, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
395.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver 3.15% Injection 10ml
	Composition	Each 100ml contains: Ivermectin…3.15%
	Diary No. Date of R& I & fee	Dy.No 8586 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 40718445042)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Actimec 3.15% Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 114924)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
396.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver 3.15% Injection 100ml
	Composition	Each 100ml contains: Ivermectin…3.15%
	Diary No. Date of R& I & fee	Dy.No 8587 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 49712562)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Actimec 3.15% Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 114926)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.

	Decision: Approved.	
397.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver 2% Injection 10ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 8584 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 6833170038)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Ivozon 2% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119697)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
398.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver 2% Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 8585 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 50993847302)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Ivozon 2% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119699)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
399.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver Forte Injection 100ml

	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…10gm
	Diary No. Date of R& I & fee	Dy.No 8589 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 8968080319)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Mecloxon-110 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117259)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
400.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver Forte Injection 10ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…10gm
	Diary No. Date of R& I & fee	Dy.No 8588 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 395577278128)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Mecloxon-110 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117257)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
401.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ivoren Injection 10ml
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy.No 8580 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 574612496)

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119700)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
402.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ivoren Injection 50ml
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy.No 8581 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 9182419029)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119701)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
403.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ivoren Injection 100ml
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy.No 8583 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 72310970)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119702)

	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
404.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ivoren Injection 500ml
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy.No 8582 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 498534922432)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	500ml,: Decontrolled
	Me-too status	Axomec 1% Injection of M/s Farm Aid Group, Haripur. (Reg. No. 117327)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. The firm has submitted that Biosign Injection (Reg. No. 122030) and Metagen Injection (Reg. No. 113547) has already been approved **in 500ml pack sizes**. The firm has also provided copies of registration letters.
	Decision: Approved.	
405.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Evoron Injection 50ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 8579 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 723911559)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Clorotin LA Injection (**100ml**) of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 116869)
	GMP status	GMP certificate dated 31-08-2022 based on inspection

		conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
406.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Flor 10 Injection 10ml
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 8567 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 811713188)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Rold Flo 10 Liquid Injection of M/s Haarolds Pharmaceuticals (Pvt) Ltd.,,Bhimber, AJK (Reg. No. 109012)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** All domestic animals **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
407.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Evoron Injection 10ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 8578 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 9712759882)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Clorotin LA Injection (**100ml**) of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 116869)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:**

		Cattle, calves **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
408.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Oxytetracycline 10% Injection 250ml
	Composition	Each ml contains: Oxytetracycline HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 8568 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 78657477)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	250ml,: Decontrolled
	Me-too status	Oxyvetz Pvp 10% Injection (**50ml, 100ml**) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 117180,117181)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goat **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. The firm has submitted that Biosign Injection (Reg. No. 122030) and Metagen Injection (Reg. No. 113547) has already been approved **in 500ml pack sizes**. The firm has also provided copies of registration letters.
	Decision: Approved.	
409.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Bro Injection 10ml
	Composition	Each ml contains: Enrofloxacin…10% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 8574 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 16023369409)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Cruser Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 117304)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
410.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Bro Injection 100ml
	Composition	Each ml contains: Enrofloxacin…10% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 8575 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 97230532190)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Cruser Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 117306)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
411.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Tilmyco Injection 100ml
	Composition	Each ml contains: Tilmicosin as Phosphate…300mg
	Diary No. Date of R& I & fee	Dy.No 8569 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 15053928)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Emicosin Injection of M/s Manhattan Pharma, Karachi. (Reg. No. 116881)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
412.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Dano Flox Injection 50ml

	Composition	Each ml contains: Danofloxacin Mesylate Eq. to Danofloxacin…25mg
	Diary No. Date of R& I & fee	Dy.No 8570 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 8239407989)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Dinax Injection of M/s Star Laboratories (Pvt) Ltd, Lahore. (Reg. No. 116811)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, cattle, buffalos, sheep, goats, Dogs and cats **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
413.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Mega OTC Injection 50ml
	Composition	Each ml contains: Oxytetracycline as Oxytetracycline Dihydrate…300mg Flunixin as Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 8576 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 52656864820)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Oxy-Loxy Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117316)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, calves, cattle, buffalos, horses, sheep, goats, Dogs and cats **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
414.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Mega OTC Injection 100ml
	Composition	Each ml contains: Oxytetracycline as Oxytetracycline Dihydrate…300mg Flunixin as Meglumine…20mg

	Diary No. Date of R& I & fee	Dy.No 8577 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 32892062914)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir (Reg. No. 114810)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, calves, cattle, buffalos, horses, sheep, goats, Dogs and cats **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
415.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Metagen Injection 100ml
	Composition	Each 100ml contains: L-Carnitine HCl Eq. to L-Carnitine…500mg Thioctic Acid…20mg Pyridoxine HCl…15mg Cyanocobalamine…3mg DL-Acetylmethionine…2000mg L-Arginine…240mg L-Ornithine HCl Eq. to L-Ornithine…120mg L-Citrulline…120mg L-Lysine HCl…62.5mg Glycine...150mg Taurine...150mg Aspartic Acid...150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 8572 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 352532150470)
	Pharmacological Group	Amino acids
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Metagen Injection of M/s Genome Pharma, Islamabad (Reg. No. 057147)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, Large animals, middle animals

		Liquid Injectable General (Veterinary) Section confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
416.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Metagen Injection 250ml
	Composition	Each 100ml contains: L-Carnitine HCl Eq. to L-Carnitine…500mg Thioctic Acid…20mg Pyridoxine HCl…15mg Cyanocobalamine…3mg DL-Acetylmethionine…2000mg L-Arginine…240mg L-Ornithine HCl Eq. to L-Ornithine…120mg L-Citrulline…120mg L-Lysine HCl…62.5mg Glycine...150mg Taurine...150mg Aspartic Acid...150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 8573 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 80236004826)
	Pharmacological Group	Amino acids
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	250ml,: Decontrolled
	Me-too status	Metagen Injection of M/s Genome Pharma, Islamabad (Reg. No. 057147)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, Large animals, middle animals **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. The firm has submitted that Biosign Injection (Reg. No. 122030) and Metagen Injection (Reg. No. 113547) has already been approved **in 500ml pack sizes**. The firm has also provided copies of registration letters.
	Decision: Approved.	
417.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Zine Injection 100ml
	Composition	Each ml contains: Sodium as Iodide...50mg Potassium as Iodide...50mg

		Potassium as Chloride...4.282mg Zinc as Chloride...0.135mg Manganese as Chloride...0.885mg Magnesium as Chloride...19.640mg Copper as Chloride...0.220mg Ferrous as Chloride...12.960mg Molybdenum as Ammonium Molybdate...0.018mg Cobalt as Chloride...0.164mg Calcium as Gluconate…300mg
	Diary No. Date of R& I & fee	Dy.No 8571 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 198229045)
	Pharmacological Group	Minerals
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Minerasol Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 029664)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Horses, cattle, calves, sheep, goats **Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
418.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	AD Mineral Powder
	Composition	Each Kg contains: Vitamin A…0.5 MIU Vitamin D3…0.080 MIU Vitamin E…0.300gm Calcium…225gm Phosphorus…120gm Magnesium…25gm Sodium…20gm Iron as Ferrous sulphate…1gm Zinc…3gm Manganese…2gm Copper…0.600gm Cobalt…0.010gm Iodine…0.020gm Selenium…0.003gm
	Diary No. Date of R& I & fee	Dy.No 8561 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 58097407)
	Pharmacological Group	Multivitamins/Minerals
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	1Kg, 5Kg: Decontrolled

	Me-too status	ADE Minerals of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No.035063)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
419.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Vita Gold Powder
	Composition	Each Kg contains: Vitamin A…6,000,000 IU Vitamin D3…2,000,00 IU Vitamin E…3,000 IU Vitamin C…2,000mg Vitamin K3...1,000mg Vitamin B1...3,000mg Vitamin B2...5,000mg Vitamin B6...1,000mg Vitamin B12...2mg Vitamin H...10mg Calcium Pantothenate...5,000mg Nicotinamide...5,000mg DL Methionine...10,000mg L-Lysine...2,000mg Folic Acid...100mg Choline Bitartrate...30,000mg
	Diary No. Date of R& I & fee	Dy.No 8562 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 7060437658)
	Pharmacological Group	Multivitamins/Amino acids/Minerals
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vita Gold Super Powder of M/s Selmore Agencies Lahore (Reg. No. 016298) **Could not be confirmed in the applied strength**
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goat, camel **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

420.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Triben WSP
	Composition	Each gram contains: Trimethoprim…80mg Sulphadiazine Sodium…420mg
	Diary No. Date of R& I & fee	Dy.No 8560 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 7628520383)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Cotrim 50 Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043295)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, camel, sheep, goat **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The Firm shall submit fee Rs. 7,500/- for revision of FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
421.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver CS Drench
	Composition	Each ml contains: Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 8559 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 461710663044)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L and 2.5L: Decontrolled
	Me-too status	Mecrold More Drench of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109036)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves, camel, sheep, goat **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
422.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eto Iver Drench

	Composition	Each 100ml contains: Ivermectin…0.10gm
	Diary No. Date of R& I & fee	Dy.No 8558 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 478940707)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L and 2.5L: Decontrolled
	Me-too status	Mecrold Drench of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109039)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, calves, camel, sheep, goat **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
423.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Boxer Drench
	Composition	Each ml contains: Oxyclozanide…62.50mg Oxfendazole…25mg Cobalt Sulphate…2mg Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy.No 8557 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 0502555737)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Nidozole Drench of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No.109084)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, camel, sheep, goat **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
424.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Waricid Suspension
	Composition	Each Liter contains: Oxfendazole…22.65gm Triclabendazole…85gm
	Diary No. Date of R& I & fee	Dy.No 8564 dated 29-03-2023 Rs.30,000/- dated 22-03-2023 (slip No. 54209752910)

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1L, 2.5L: Decontrolled
	Me-too status	Vorcid Suspension of M/s Breeze Pharma (Pvt.) Ltd., Islamabad. (Reg. No. 063563)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** sheep **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
425.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Trisole SC 19.5 Suspension
	Composition	Each ml contains: Triclabendazole…120mg Levamisole…75mg Cobalt Chloride…0.75mg Sodium Selenite…0.35mg
	Diary No. Date of R& I & fee	Dy.No 8563 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 58755963310)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Tenxazole 12% Oral Suspension of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111356)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goat, calves, buffaloes, horses **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
426.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Wormicidel Oral Suspension
	Composition	Each 100ml contains: Oxyclozanide…3gm

		Levamisole HCl…1.500gm Sodium Selenite…0.167gm Cobalt Chloride…0.050gm
	Diary No. Date of R& I & fee	Dy.No 8565 dated 29-03-2023 Rs.30,000/- dated 28-03-2023 (slip No. 1623613298)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Harryzen Oral Suspension of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109069)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goat, calves, buffaloes, horses **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
427.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Leva 150 Oral Liquid
	Composition	Each 100ml contains: Levamisole HCl…1.5gm
	Diary No. Date of R& I & fee	Dy.No 8566 dated 29-03-2023 Rs.30,000/- dated 29-03-2023 (slip No. 543864298)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml: Decontrolled
	Me-too status	Vetzole Drench of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 116994)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, Cattle, sheep, goat **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
428.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Tygent Injection 10ml
	Composition	Each ml contains: Tylosin Tartrate…100mg Gentamycin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 8949 dated 03-04-2023 Rs.30,000/- dated 20-03-2023 (slip No. 9933830431)
	Pharmacological Group	Antibiotic combination

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Tygencin Injection (**100ml**) of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118579)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Target species:** Large animals, Poultry, sheep, goat **Injectable vial General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 24-01-2023 & 25-01-2023. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
429.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Tygent Injection 10ml
	Composition	Each ml contains: Tylosin Tartrate…100mg Gentamycin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 8949 dated 03-04-2023 Rs.30,000/- dated 20-03-2023 (slip No. 9933830431)
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Tygencin Injection (**100ml**) of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118579)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Target species:** Large animals, Poultry, sheep, goat **Injectable vial General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 24-01-2023 & 25-01-2023. **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
430.	Name and address of manufacturer / Applicant	M/s QAS International, Plot No. 153/155, Mustafaabad Tehsil Kamoki, District Gujranwala.

	Brand Name +Dosage Form + Strength	Respizone Oral Powder
	Composition	Each gram contains: Bromhexine HCl…10mg Tartaric Acid…150mg
	Diary No. Date of R& I & fee	Dy.No 9476 dated 07-04-2023 Rs.30,000/- dated 07-04-2023 (slip No. 700706212652)
	Pharmacological Group	Expectorant
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 10Kg, 12.5Kg, 25Kg: Decontrolled
	Me-too status	Broexine Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 117244)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 22-12-2022 for grant of DML.
	Decision: Approved.	
431.	Name and address of manufacturer / Applicant	M/s QAS International, Plot No. 153/155, Mustafaabad Tehsil Kamoki, District Gujranwala.
	Brand Name +Dosage Form + Strength	Fosfozone Oral Powder
	Composition	Each 100gm contains: Calcium Fosfomycin …20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 9570 dated 10-04-2023 Rs.30,000/- dated 07-04-2023 (slip No. 4816341300)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	-
	Me-too status	Ty Fos Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 117245)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 22-12-2022 for grant of DML. **Shortcomings:** • Pack size • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter:	

	• **Demanded pack size** • **fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
432.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45 Km, Off Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Linoxin 11% Powder
	Composition	Each 100gm contains: Lincomycin HCl…1100mg
	Diary No. Date of R& I & fee	Dy.No 10390 dated 19-04-2023 Rs.30,000/- dated 18-04-2023 (slip No. 26819790940)
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	5Kg HDPE plastic bucket, 25Kg Nylon bag; Decontrolled
	Me-too status	Linco Premix 1100 of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075703)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Dry Powder (General) Veterinary section** confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 30-09-2021 **Shortcomings:** • The firm shall submit fee Rs. 30,000/- for correction in label claim in line with pharmacopeia prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with pharmacopoeia prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
433.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45 Km, Off Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenox Oral Powder
	Composition	Each 100gm contains: Oxytetracycline HCl…30% Florfenicol…30%
	Diary No. Date of R& I & fee	Dy.No 10391 dated 19-04-2023 Rs.30,000/- dated 18-04-2023 (slip No. 11278819)
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg; Decontrolled
	Me-too status	Biofoxy 30% Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 117173)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.

	Remarks of the Evaluator	**Oral Dry Powder (General) Veterinary section** confirmed vide letter No. F.1-41/2007-Lic (Vol-I) dated 30-09-2021 **Shortcomings:** • The firm shall submit fee Rs. 7,500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 7500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
434.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd., Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Bovilex Injection 20ml
	Composition	Each ml contains: Buparavaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 11127 dated 04-05-2023 Rs.30,000/- dated 14-04-2023 (slip No. 798372004705)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Bupex Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118636)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle **Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved.	
435.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Neo Tic W/S Powder
	Composition	Each Kg contains: Neomycin Sulphate…1000gm
	Diary No. Date of R& I & fee	Dy.No 11129 dated 04-05-2023 Rs.30,000/- dated 03-05-2023 (slip No. 209084248)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Neokam-100 Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119739)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry, calves **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML

	Decision: Approved.	
436.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Vita CID 30% Powder
	Composition	Each gram contains: Vitamin C…300mg
	Diary No. Date of R& I & fee	Dy.No 11130 dated 04-05-2023 Rs.30,000/- dated 03-05-2023 (slip No. 9524686402)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Ceprix 300 Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043287)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML
	Decision: Approved.	
437.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tele Fos W/S Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…5gm Fructose 1, 6 Di Phosphate…18gm Soidum Phosphate…15gm Magnesium Phosphate…10gm Sodium Chloride…100gm
	Diary No. Date of R& I & fee	Dy.No 11128 dated 04-05-2023 Rs.30,000/- dated 03-05-2023 (slip No. 5411707103)
	Pharmacological Group	Antibacterial, electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Sparkofos Forte Water Soluble Powder of M/ Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 118605)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Calves, sheep, goats, Poultry **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML **Shortcomings:**

		The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee Rs. 30,000/- for correction in label claim in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
438.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Panthia 25 Oral Liquid
	Composition	Each ml contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 12371 dated 19-05-2023 Rs.30,000/- dated 04-05-2023 (slip No. 019122245)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1L; Decontrolled
	Me-too status	Thiamax Solution of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 118454)
	GMP status	
	Remarks of the Evaluator	**Target species:** Broilers, Turkeys **Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
439.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Panfenicol 25 Oral Liquid
	Composition	Each ml contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 12374 dated 19-05-2023 Rs.30,000/- dated 04-05-2023 (slip No. 403240569)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1000ml; Decontrolled
	Me-too status	Poul Flor-25 Oral Solution of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118545)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019

		Shortcomings: Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
440.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Neomax 100 Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…1000mg
	Diary No. Date of R& I & fee	Dy.No 12370 dated 19-05-2023 Rs.30,000/- dated 04-05-2023 (slip No. 33925548)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1000gm; Decontrolled
	Me-too status	Neom-100 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118507)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry, calves **Oral General Powder section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
441.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Pantofos 20 Water Soluble Powder
	Composition	Each Kg contains: Fosfomycin Calcium…200gm Tylosin Tartrate…100gm Fructose…180gm Soidum Phosphate…150gm Magnesium Sulphate…100gm
	Diary No. Date of R& I & fee	Dy.No 12373 dated 19-05-2023 Rs.30,000/- dated 04-05-2023 (slip No. 76094507)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1000gm; Decontrolled
	Me-too status	Fosiril Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118610)
	GMP status	

	Remarks of the Evaluator	**Target species:** Poultry **Oral General Powder section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
442.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Pantamox Gold Oral Powder
	Composition	Each gram contains: Amoxicillin Trihydrate 1000mg eq. to Amoxicillin....871.2mg
	Diary No. Date of R& I & fee	Dy.No 12372 dated 19-05-2023 Rs.30,000/- dated 04-05-2023 (slip No. 23959529)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500gm; Decontrolled
	Me-too status	Aciphen Oral Powder of M/s Vet Line International, Lahore. (Reg. No. 088651)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry, cattle **Oral Powder Section Penicillin (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
443.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Thrust 100mg/ml injection 10ml
	Composition	Each ml contains: Tulathromycin…100mg
	Diary No. Date of R& I & fee	Dy.No 11779 dated 15-05-2023 Rs.30,000/- dated 08-05-2023 (slip No. 2988058198)
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Dravin Injection (10ml) of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 112382)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, sheep **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
444.	Name and address of manufacturer / Applicant	M/s Bioskils Pharmaceuticals, 4-Km Tamboly, GT Road, Sadhoke, District Gujranwala.
	Brand Name +Dosage Form + Strength	Bio Para C Powder
	Composition	Each 100gm contains: Paracetamol…20gm Vitamin C…5gm Potassium Chloride…12.5gm Sodium Carbonate…12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 133371 dated 30-05-2023 Rs.30,000/- dated 30-05-2023 (slip No. 230232924788)
	Pharmacological Group	Electrolytes/vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg: Decontrolled
	Me-too status	Cemol Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 103909) (**composition is different than the applied product**)
	GMP status	DML issued: 02-06-2021
	Remarks of the Evaluator	**Target species:** Calves, poultry **Shortcomings:** • The applied formulation contains different salt form of Potassium than the reference product. So, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	

445.	Name and address of manufacturer / Applicant	M/s Bioskils Pharmaceuticals, 4-Km Tamboly, GT Road, Sadhoke, District Gujranwala.
	Brand Name +Dosage Form + Strength	Asper C Skill powder
	Composition	Each 1000gm contains: Acetylsalicylic Acid…67gm Vitamin C…20gm Sodium Citrate…7gm Potassium Chloride…3gm
	Diary No. Date of R& I & fee	Dy.No 13372 dated 30-05-2023 Rs.30,000/- dated 30-05-2023 (slip No. 38302842419)
	Pharmacological Group	Electrolytes/vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg: Decontrolled
	Me-too status	Asperlyte-C Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074789)
	GMP status	DML issued: 02-06-2021
	Remarks of the Evaluator	**Target species:** Calves, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
446.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neo-Peeflox Oral Liquid
	Composition	Each 100ml contains: Pefloxacin Methanesulfonate 13.960gm eq. to Pefloxacin Base…10gm
	Diary No. Date of R& I & fee	Dy.No 13140 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 2151336245)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	CIPSIN ORAL LIQUID M/s Vetrox Pharma, Toba Tek Singh. Reg No.112363
	GMP status	
	Remarks of the Evaluator	**Target species:** Cats, dogs, cows, poultry The instant formulation (applied vide Dy.No 33766 dated 27-12-2021) of M/s Neotech Pharmaceuticals Pvt Ltd., 28-

		Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan **has already been approved in 330th meeting** of Registration Board.
	Decision: Registration Board disposed of the case since the instant formulation (applied vide Dy.No 33766 dated 27-12-2021) of M/s Neotech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan has already been approved in 330th meeting of Registration Board.	
447.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Tyloprim Oral Solution
	Composition	Each ml contains: Tylosin Tartrate…55mg Sulphadiazine…175mg Trimethoprim…35mg
	Diary No. Date of R& I & fee	Dy.No 13149 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 78133965)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Respibar-250 Oral Solution M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 071095)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
448.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Spectolin Oral Liquid
	Composition	Each 100ml Contains: Lincomycin HCl…3.33gm Spectinomycin HCl…6.67gm
	Diary No. Date of R& I & fee	Dy.No 13158 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 02810808416)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	B-Cid Liquid of M/s A & K Pharmaceutical Faisalabad (Reg. No. 049794)

	GMP status	
	Remarks of the Evaluator	**Target species:** dogs, cats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
449.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neo-Esel Oral Liquid
	Composition	Each 1000ml contains: Vitamin E…150,000mg Selenium as Sodium Selenite…2300mg Zinc…8000mg
	Diary No. Date of R& I & fee	Dy.No 13157 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 239386120)
	Pharmacological Group	Vitamin/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Sel-EZ Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073949)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cow, sheep, goats, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
450.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Respiquin AG Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…10gm Aminophylline…4gm

		Guaiphenesin…10gm
	Diary No. Date of R& I & fee	Dy.No 13146 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 207973369)
	Pharmacological Group	Antibiotic/ bronchodilator/ expectorant
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	AG-Flox Oral Liquid of M/s Acme Pharmaceuticals, Rawat, Islamabad (Reg. No. 117034)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
451.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neocid Liquid
	Composition	Each 100ml contains: Didecyl Dimethyl Ammonium Bromide…10gm
	Diary No. Date of R& I & fee	Dy.No 13144 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 367401365852)
	Pharmacological Group	Antimicrobial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Micro-Kill Liquid of M/s A & K Pharmaceutical Faisalabad. (Reg. No. 053974)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **Target species**	
452.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neodeak Oral Liquid
	Composition	Each 1000ml contains: Vitamin A…30,000,000 IU Vitamin D3…1,000,000 IU

		Vitamin E…5000mg Vitamin K3…6000mg
	Diary No. Date of R& I & fee	Dy.No 13156 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 88554022076)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Adekbar Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073950)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
453.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neominovit Oral Solution
	Composition	Each liter contains: Vitamin A... 4,000,000 IU Vitamin D3...800,000 IU Vitamin E...1600mg Vitamin B1...2000mg Vitamin B2...1000mg Vitamin B6...1000mg Vitamin B12...1000mcg Vitamin C...1000mg Vitamin K3...1000mg Calcium Pantothenate...5000mg Nicotinamide…5000mg Folic Acid…100mg DL-Methionine…10,000mg Choline Chloride…50,000mg Lysine HCl…1,000mg Biotin…25mg
	Diary No. Date of R& I & fee	Dy.No 13155 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 44461893)
	Pharmacological Group	Vitamins and amino acids
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Energizer Oral Solution of M/s Biogen Pharma, Rawat (Reg. No. 063814)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cows, sheep, goats, dogs, horses

		Shortcomings: • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
454.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neovit-C Oral Solution
	Composition	Each ml contains: Vitamin C…250mg
	Diary No. Date of R& I & fee	Dy.No 13160 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 191903477)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Vita-C Oral Solution of M/s ICI Pakistan Limited, Life Sciences, Lahore. (Reg. No. 092187)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
455.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Lincol Water Soluble Powder
	Composition	Each gram contains: Lincomycin HCl…100mg Colistin Sulphate…800,000 IU
	Diary No. Date of R& I & fee	Dy.No 13141 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 285970111994)
	Pharmacological Group	Antibiotic/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Col-Link Powder of M/s Farm Aid Group, Haripur (Reg. No. 118584)
	GMP status	
	Remarks of the Evaluator	**Target species:** dogs, cats **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
456.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Paratech-C Powder
	Composition	Each 100gm contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 13139 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 86474454582)
	Pharmacological Group	Analgesic, antipyretic with vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	C-Rox Para Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112366)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
457.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Levatech Water Soluble Powder
	Composition	Each 100gm contains: Levamisole…15%
	Diary No. Date of R& I & fee	Dy.No 13143 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 8039132732)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications

	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Levapoul Water Soluble Powder of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 116808)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cattle, calves, sheep, goats, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
458.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neoquindox Powder
	Composition	Each 1000gm contains: Olaquindox…100gm
	Diary No. Date of R& I & fee	Dy.No 13152 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 0689556089)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Olaquine Oral Powder of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 101443)
	GMP status	
	Remarks of the Evaluator	**Target species:** livestock, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **Specific target species**	
459.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Cocci Tech-AK Water Soluble Powder
	Composition	Each 100gm contains:

		Sulphaquinoxaline Sodium…20gm Sulphadimidine Sodium…20gm Diaverdine Hcl…4gm Vitamin K3…0.2gm Vitamin A…280,000 IU
	Diary No. Date of R& I & fee	Dy.No 13154 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 72579041414)
	Pharmacological Group	Anticoccidial/Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Coxibar Water Soluble of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073954)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
460.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neosp3 Oral Powder
	Composition	Each 100gm contains: Sulphachlorpyridazine…30gm
	Diary No. Date of R& I & fee	Dy.No 13150 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 3536839039)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Coxiriq Oral Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 079814)
	GMP status	
	Remarks of the Evaluator	**Target species:** Chicken, turkeys, geese **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
461.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Oxytech Water Soluble Powder

	Composition	Each 100gm contains: Oxytetracycline HCl…95gm
	Diary No. Date of R& I & fee	Dy.No 13142 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 999888576)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Oxykam-95% Water Soluble Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119738)
	GMP status	
	Remarks of the Evaluator	**Target species:** Dog, cats, camel, pets, cattle, calves, sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
462.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Respibrom Water Soluble Powder
	Composition	Each 1000gm contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Bromhexine HCl…2.5gm
	Diary No. Date of R& I & fee	Dy.No 13147 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 59452138606)
	Pharmacological Group	Antibiotic/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Dobroxin Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 118607)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	

	• **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
463.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Flonox Water Soluble Powder
	Composition	Each gram contains: Florfenicol…150mg Oxytetracycline HCl…150mg
	Diary No. Date of R& I & fee	Dy.No 13145 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 6839656857)
	Pharmacological Group	Antibiotic/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Fenix Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 117261)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
464.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Tydoc Water Soluble Powder
	Composition	Each 1000gm contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 13148 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 6957454734)
	Pharmacological Group	Antibiotic/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	I-Tcolidox Powder of M/s International Pharma Labs. Lahore. (Reg. No. 117348)
	GMP status	
	Remarks of the Evaluator	**Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

		• Confirmation of **relevant manufacturing facility** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
465.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Neo Asper-C Granules
	Composition	Each 100gm contains: Acetylsalicylic Acid…6.70gm Vitamin C…20gm
	Diary No. Date of R& I & fee	Dy.No 13137 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 8178840970)
	Pharmacological Group	NSAID with Vitamin C
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Hyper-C Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 081732)
	GMP status	
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility** • **Specific target species**	
466.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Saraquin Powder
	Composition	Each 100gm contains: Sarafloxacin HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 13151 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 2826209037)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled

	Me-too status	Sarak-10 Powder of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 049666)
	GMP status	
	Remarks of the Evaluator	**Target species:** Chicken **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
467.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Amantatech Water Soluble Powder
	Composition	Each 1000gm contains: Amantadine HCl…100gm
	Diary No. Date of R& I & fee	Dy.No 13153 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 5060279567)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Krypdine 100 Oral Powder of M/s Krypton Pharma (Pvt) Ltd., Faisalabad (Reg. No. 113425)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
468.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Nephritech Powder
	Composition	Each 100gm contains: Hexamethylene Tetramine…9.5gm Vitamin B2…1gm Nicotinamide…2.5gm Calcium Pantothenate…0.5gm
	Diary No. Date of R& I & fee	Dy.No 13138 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 45668383)
	Pharmacological Group	Antibiotic/vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications

	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Hexa-Vit Powder of M/s A & K Pharmaceutical Faisalabad. (Reg. No. 053976)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
469.	Name and address of manufacturer / Applicant	M/s NeoTech Pharmaceuticals Pvt Ltd., 28-Km, Gujranwala Lahore GT Road, Chak Hinda, Kamoke, Pakistan.
	Brand Name +Dosage Form + Strength	Renaltech Powder
	Composition	Each 1000gm contains: Ammonium Chloride…650gm Methionine…100gm Sorbitol…50gm Vitamin A…25000 IU Vitamin C…100gm
	Diary No. Date of R& I & fee	Dy.No 13159 dated 29-05-2023 Rs.30,000/- dated 25-05-2023 (slip No. 033161263502)
	Pharmacological Group	Expectorant/Antibiotic/vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Ultra Nephron Plus Powder of M/s A & K Pharmaceutical Faisalabad. (Reg. No. 048123)
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years.** • **Confirmation of relevant manufacturing facility**	
470.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Spirafas Water Soluble Powder
	Composition	Each 1000gram contains: Lincomycin as HCl…25gm Spiramycin Adipate…75gm
	Diary No. Date of R& I & fee	Dy.No 15110 dated 15-06-2023 Rs.30,000/- dated 02-06-2023 (slip No. 200396487458)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Sipariq-L Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117281)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Broiler and breeder birds **General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
471.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Neo-Oxy-S Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…60mg Oxytetracycline HCl…200mg Streptomycin Sulphate…20mg
	Diary No. Date of R& I & fee	Dy.No 15107 dated 15-06-2023 Rs.30,000/- dated 29-05-2023 (slip No. 5607960471)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Sondex (Vet) Dry Powder of M/s Biorific Pharma, Islamabad. (Reg. No. 088138)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter:	

	• **Latest GMP inspection report conducted within the period of last three years** • **Fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
472.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Fencol Plus Solution
	Composition	Each ml contains: Florfenicol…230mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 15111 dated 15-06-2023 Rs.30,000/- dated 02-06-2023 (slip No. 74698666)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Makflor C-23 Liquid of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119749)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Liquid (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years** • **Fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
473.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Bro-Men Plus Solution
	Composition	Each 100ml contains: Bromhexine HCl…2gm Menthol…3gm Aminophylline…2gm Guaifenesin…5gm Chlorpheniramine Maleate…1gm
	Diary No. Date of R& I & fee	Dy.No 15109 dated 15-06-2023 Rs.30,000/- dated 30-05-2023 (slip No. 637981395310)
	Pharmacological Group	Mucolytic, expectorant and respiratory antiseptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 400ml, 500ml, 1000ml: Decontrolled
	Me-too status	Bronchogel Solution of M/s Evergreen pharma **Could not be confirmed**
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:**

		Poultry **Liquid (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within the period of last three years.**	
474.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Tonofas Injection 50ml
	Composition	Each ml contains: Toldimfos Sodium…200mg Vitamin B12…50mcg
	Diary No. Date of R& I & fee	Dy.No 15112 dated 15-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 58052756)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Tolivetz-B Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 099472)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horses, calves, sheep, goat, dog, cat **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years** • **Fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
475.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Naflofas 30% Injection 50ml
	Composition	Each ml contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 15108 dated 15-06-2023 Rs.30,000/- dated 29-05-2023 (slip No. 193897501)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Resflo Injection of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 118566)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years** • **Fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
476.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Intervit- B Complex Injection
	Composition	Each 100ml contains: Vitamin A…5,000,000 IU Vitamin D3…2,500,000 IU Vitamin E…2000 IU Vitamin B1…0.2gm Vitamin B3…0.06gm Vitamin B6…0.06gm Vitamin B12…0.4mg
	Diary No. Date of R& I & fee	Dy.No 15113 dated 15-06-2023 Rs.30,000/- dated 30-05-2023 (slip No. 917038500)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	ADE B-complex injection of M/s Pace pharma **Could not be confirmed**
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horses, calves, foals, sheep, goat, dog, cat **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

	• **Latest GMP inspection report conducted within the period of last three years before issuance of registration letter.**	
477.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uriphos 50ml Injection
	Composition	Each ml contains: Sodium Acid Phosphate .....400mg eq. to 79.4mg of elemental phosphorus
	Diary No. Date of R& I & fee	Dy.No 15680 dated 21-06-2023 Rs.30,000/- dated 16-06-2023 (slip No. 2894561898)
	Pharmacological Group	Phosphorus supplement
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Alphos-40 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 046573)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, Horses, sheep, goats, dogs, cats, camel **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
478.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uriphos 10ml Injection
	Composition	Each ml contains: Sodium Acid Phosphate .....400mg eq. to 79.4mg of elemental phosphorus
	Diary No. Date of R& I & fee	Dy.No 15679 dated 21-06-2023 Rs.30,000/- dated 16-06-2023 (slip No. 0282667647)
	Pharmacological Group	Phosphorus supplement
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Alphos-40 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 046573)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, Horses, sheep, goats, dogs, cats, camel **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

479.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uriphos 100ml Injection
	Composition	Each ml contains: Sodium Acid Phosphate .....400mg eq. to 79.4mg of elemental phosphorus
	Diary No. Date of R& I & fee	Dy.No 15681 dated 21-06-2023 Rs.30,000/- dated 16-06-2023 (slip No. 70962089)
	Pharmacological Group	Phosphorus supplement
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Alphos-40 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore. (Reg. No. 046573)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, Horses, sheep, goats, dogs, cats, camel **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021following before issuance of registration letter.	
480.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Coli Cycline W/S Powder
	Composition	Each Gram contains: Neomycin Sulphate…70mg Colistin Sulphate…4mg Chlortetracycline HCl…80mg
	Diary No. Date of R& I & fee	Dy.No 16722 dated 05-07-2023 Rs.30,000/- dated 05-07-2023 (slip No. 963864574)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Poul CNC Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118517)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML
	Decision: Approved.	
481.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Ery Nox W/S Powder
	Composition	Each 1000gm contains: Neomycin Sulphate…100gm Oxytetracycline HCl…200gm Erythromycin Thiocyanate…100gm
	Diary No. Date of R& I & fee	Dy.No 16723 dated 05-07-2023 Rs.30,000/- dated 05-07-2023 (slip No. 9299159930)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Neoxeryth Powder of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 117146)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML
	Decision: Approved.	
482.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Strep Line W/S Powder
	Composition	Each gram contains: Neomycin Sulphate…60mg Chlortetracycline HCl…200mg Streptomycin Sulphate…20mg
	Diary No. Date of R& I & fee	Dy.No 16724 dated 05-07-2023 Rs.30,000/- dated 05-07-2023 (slip No. 963250401254)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg; Decontrolled
	Me-too status	Nechlocin Powder of M/s Farm Aid Group, Haripur. (Reg. No. 117249)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder Section-I and Oral Powder Section-II (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 05-09-2019 for grant of DML
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	G-Tylo Injection 10ml

	Composition	Each ml Contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 18520 dated 24-07-2023 Rs.30,000/- dated 20-07-2023 (Slip No. 9384980160)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Gtrise Injection of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112178)
	GMP status	cGMP certificate dated 20-02-2023 based on evaluation conducted on 09-03-2022
	Remarks of the Evaluator	**Target species:** Large animals, sheep, goats, poultry **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
484.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Vet-Oxy-F Injection 10ml
	Composition	Each ml contains: Oxytetracycline Dihydrate…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 18521 dated 24-07-2023 Rs.30,000/- dated 20-07-2023 (Slip No. 21512466)
	Pharmacological Group	Anti-bacterial, anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Oxy-Loxy Injection (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117316)
	GMP status	cGMP certificate dated 20-02-2023 based on evaluation conducted on 09-03-2022
	Remarks of the Evaluator	**Target species:** Cattle **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference

		product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
485.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Buparvetz 20ml Injection
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 18519 dated 24-07-2023 Rs.30,000/- dated 20-07-2023 (Slip No. 00147828047)
	Pharmacological Group	Anti-protozoa
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Bupex Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118636)
	GMP status	cGMP certificate dated 20-02-2023 based on evaluation conducted on 09-03-2022
	Remarks of the Evaluator	**Target species:** Large animals **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved.	
486.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tilmosin Plus Liquid
	Composition	Each ml contains: Tilmicosin Phosphate…250mg
	Diary No. Date of R& I & fee	Dy.No 18239 dated 19-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 5711684782)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Tilco Mal Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118612)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Livestock **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012. **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference

		product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
487.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Belimin 10 Injection 10ml
	Composition	Each 1ml contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 16708 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 3726649801)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Mecloxon-110 Injection (10ml) of M/s Farm Aid Group, Haripur. (Reg. No. 117257)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle and sheep **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
488.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bursamall 100ml Injection
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 16709 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 9242821752)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Triface Injection (10ml, 50ml, 100ml) of M/s Genome Pharma, Islamabad (Reg. No. 057135)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Sheep, goat, calves, foals, horses, buffaloes

		Shortcomings: Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
489.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bursamall 10ml Injection
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 16695 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 87053834667)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Triface Injection (10ml, 50ml, 100ml) of M/s Genome Pharma, Islamabad (Reg. No. 057135)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Sheep, goat, calves, foals, horses, buffaloes **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
490.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Gentamall 100ml Injection
	Composition	Each 1ml contains: Gentamycin Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 16698 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 0117408670)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Gentariq-10 Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117373)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Sheep, goat, calves, foals, horses, buffaloes **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
491.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bupra Mall Injection 20ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 16697 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 2722262653)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Bupex Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118636)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **Rs. 7500/- for correction in pharmacological group prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
492.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ivermall 1% Injection 100ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 16699 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 491333158909)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119702)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle, buffaloes, camels, goats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
493.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ivermall 1% Injection 10ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 16700 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 25173796808)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Ivozon 1% Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119700)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Cattle, buffaloes, camels, goats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
494.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ketomall 10% Injection 100ml
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 16707 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 09423428941)
	Pharmacological Group	Analgesic, antipyretic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Eagle Ketop 10% Injection of M/s U.M. Enterprises, Karachi. (Reg. No. 117299)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Horse, cattle, sheep, goats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years**	

	• **Fee Rs. 7500/- for correction in pharmacological group prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
495.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ketomall 10% Injection 20ml
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 16701 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 1309918265)
	Pharmacological Group	Analgesic, antipyretic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Catoprofen Injection of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No. 101472)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Horse, cattle, sheep, goats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **Fee Rs. 7500/- for correction in pharmacological group prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
496.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Hepamall 100ml Injection
	Composition	Each ml contains: Phenoxy-2-Methyl-2-Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 16702 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 09341582)
	Pharmacological Group	Hepatoprotectant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Propion Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118412)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Horse, cattle, sheep, goats, dogs **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **Fee Rs. 7500/- for correction in pharmacological group prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **Scientific justification for use of Phenoxy-2-Methyl-2-Propionic Acid in dogs**	
497.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Megtramall 10ml injection
	Composition	Each ml contains: Oxytetracycline HCl…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 16704 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 04630656967)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 114810)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Horse, cattle, buffaloes **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **Fee Rs. 7500/- for correction in pharmacological group prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
498.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Fluxin Injection 10ml
	Composition	Each ml Contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 16703 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 6624083445)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Floxon Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119707)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:**

		Horse, cattle, buffaloes **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
499.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Meloxmall 100ml injection
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 16706 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 4479107527)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Diclozon 10 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119694)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
500.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Enromall 10% Injection
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 16696 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 70783626091)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	APA Enro 10 I Injection of M/s Vetynex Pharma, Lahore. (Reg. No. 118490)
	GMP status	

	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** cattle, sheep, goat, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
501.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Synogent 100ml injection
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 16705 dated 05-07-2023 Rs.30,000/- dated 08-06-2023 (slip No. 193579383704)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	APA Gentylo I Injection of M/s Vetynex Pharma, Lahore. (Reg. No. 118492)
	GMP status	
	Remarks of the Evaluator	**Liquid injection (Vial) (General) section (Veterinary)** confirmed vide letter No. F.1-14/2004-Lic (Vol-II) dated 26-10-2020 **Target species:** Large animals, sheep, goat, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **Fee Rs. 7500/- for correction in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
502.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	SC Injection
	Composition	Each vial contains: Ceftiofur Sodium…1gm
	Diary No. Date of R& I & fee	Dy.No 18517 dated 24-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 427881031200)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	1gm vial: Decontrolled

	Me-too status	Ceftisel Dry Powder Injection 1gm of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 114794)
	GMP status	Panel inspection conducted on **10-03-2021** for renewal of DML and grant of additional section.
	Remarks of the Evaluator	**Target species:** Cattle **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • Confirmation of relevant manufacturing facility
	Decision: Deferred for submission of following: • **Latest GMP inspection report conducted within the period of last three years** • **Confirmation of relevant manufacturing facility**	
503.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Pyrinozine 50ml Injection
	Composition	Each ml contains: Diminazine Aceturate…105mg Antipyrine…131mg
	Diary No. Date of R& I & fee	Dy.No 18518 dated 24-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 0194441853)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pronifas Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080724)
	GMP status	Panel inspection conducted on **10-03-2021** for renewal of DML and grant of additional section.
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, sheep, horses, dogs, goats **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
504.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Tri-Leva Plus Drench 19.5%
	Composition	Each ml contains: Levamisole HCl…75mg Triclabendazole…120mg Sodium Selenite…0.35mg Cobalt Chloride…0.75mg
	Diary No. Date of R& I & fee	Dy.No 18515 dated 24-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 031706698369)
	Pharmacological Group	De-wormer/ Anthelmintic, mineral supplement
	Type of Form	Form 5

	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	Tenxazole12% Oral Suspension of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111356)
	GMP status	Panel inspection conducted on **10-03-2021** for renewal of DML and grant of additional section.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goats **Oral Liquid (Antibiotic) (Veterinary)** section confirmed from Panel inspection report based on inspection conducted on 10-03-2021 for renewal of DML and grant of additional section. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
505.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd., 25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Iver Thar Drench
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 18516 dated 24-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 942128329748)
	Pharmacological Group	De-wormer/ Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Iverbar Drench of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117376)
	GMP status	Panel inspection conducted on **10-03-2021** for renewal of DML and grant of additional section.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goats, calves, camels **Oral Liquid (Antibiotic) (Veterinary)** section confirmed from Panel inspection report based on inspection conducted on 10-03-2021 for renewal of DML and grant of additional section. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
506.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Marbohil 100mg/ml Injection
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 18836 dated 26-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 5293883223)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml, 50ml, 100ml: Decontrolled
	Me-too status	Marboxin 100 Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 117121)
	GMP status	cGMP certificate dated 24-01-2023 based on inspection dated 23-01-2023
	Remarks of the Evaluator	**Target species:** Cattle **Veterinary Sterile Liquid Injection (vials)** section confirmed from Panel inspection report based on inspection conducted on 23-01-2023 for issuance of GMP certificate **Shortcomings:** • Choice of only one pack size
	Decision: Approved. The firm shall choose only one pack size before issuance of registration letter.	
507.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Mint Oral Liquid
	Composition	Each liter contains: Peppermint…40gm Eucalyptus…50gm Menthol…50gm Vitamin A…30,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 18418 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 4702609692)
	Pharmacological Group	Expectorant/ decongestant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Fenetime Oral Solution of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat. (Reg. No. 063815) .
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Cattle, sheep, goat, poultry • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
508.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Mucosolvan Plus Oral Solution
	Composition	Each 1000ml contains: Menthol…40gm Bromhexine HCl…20gm

	Diary No. Date of R& I & fee	Dy.No 18419 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 705017411521)
	Pharmacological Group	Expectorant/ mucolytic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Minto Mall Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118611)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** poultry • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
509.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Power Immune Plus Solution
	Composition	Each 1000ml contains: Vitamin E…200,000mg Selenium…2000mg Zinc…9000mg
	Diary No. Date of R& I & fee	Dy.No 18420 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 32935590177)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml: Decontrolled
	Me-too status	Baxsel-E Solution of M/s Baxter Pharmaceuticals, Karachi (Reg. No.072636)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** poultry • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
510.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Super Thiam Oral Liquid
	Composition	Each ml contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 18428 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 9107926053)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Thiamax Solution of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 118454)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** poultry • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
511.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Etrocina Oral Liquid
	Composition	Each ml contains: Enrofloxacin…75mg Sulphamethoxypyridazine…50mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 18423 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 48745057130)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad (Reg. No. 074786)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, cattle, buffaloes, sheep, goats, dogs, cats • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
512.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Hepato Grow Liquid
	Composition	Each 100ml Contains: L-Carnitine…5% Magnesium Sulphate…1% Sorbitol…20% Choline Chloride…10% Betain…2% Inositol…0.7%
	Diary No. Date of R& I & fee	Dy.No 18425 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 14355241)
	Pharmacological Group	Amino acids

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml: Decontrolled
	Me-too status	Le Vox Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 081720)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry, cattle, buffaloes, sheep, goats, dogs, cats • **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
513.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enrocam Forte Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…10gm Aminophylline…4gm Guaiphenesin…10gm
	Diary No. Date of R& I & fee	Dy.No 18426 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 754559672)
	Pharmacological Group	Antibacterial/ bronchodilator/ expectorant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml: Decontrolled
	Me-too status	EG Enro Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No. 074099)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
514.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Super Cal Liquid
	Composition	Each 100ml contains: Aspirin…6.70gm Vitamin C…10gm Lysine HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 18427 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 75724922691)
	Pharmacological Group	Restorative/ anti-inflammatory

	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Aircool Liquid of M/s Intervac (Pvt) Ltd. Sheikhupura. (Reg. No. 069654)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
515.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	E-immune Solution
	Composition	Each ml contains: Vitamin E…200mg Sorbitol…50mg Choline Chloride…50mg Sodium Selenite as Selenium…2.3mg Zinc Chloride as Zinc…4mg
	Diary No. Date of R& I & fee	Dy.No 18421 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 79325532197)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Supertone Solution.of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049629)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
516.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enrotrim Forte Oral Liquid
	Composition	Each ml contains: Enrofloxacin…75mg Sulphamethoxypyridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 18424 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 18635218465)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	50ml, 100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Cenatin Oral Liquid of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 078379)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
517.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Cyclo Mix Plus WSP
	Composition	Each gram contains: Chlortetracycline as HCl…250mg
	Diary No. Date of R& I & fee	Dy.No 18416 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 00508501)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Meralin 250 Water Soluble Powder of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 101462)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Large animals, Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
518.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter-C 300 WSP
	Composition	Each gram contains: Vitamin C…300mg
	Diary No. Date of R& I & fee	Dy.No 18415 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 179969982813)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Ceprix 300 Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043287)
	GMP status	GMP certificate dated 31-08-2022 based on inspection

		conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
519.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Thiclor Oral Powder
	Composition	Each 100gm contains: Tiamulin Hydrogen Fumarate…10gm Chlortetracycline HCl…30gm
	Diary No. Date of R& I & fee	Dy.No 18413 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 994676410888)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Mycochlor Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 074028)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
520.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Gumbo Kick Powder
	Composition	Each 100gm contains: Ammonium Chloride…65gm Methionine…10gm Sorbitol…10gm Vitamin A…250,000 IU Vitamin C…10gm
	Diary No. Date of R& I & fee	Dy.No 18414 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 91529904)
	Pharmacological Group	Antitoxin/expectorants
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled

	Me-too status	Gumbovit Powder of M/s Intervac (Pvt) Ltd., Lahore. (Reg. No.046599)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
521.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Timu 45% Powder
	Composition	Each 100gm contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…45gm
	Diary No. Date of R& I & fee	Dy.No 18412 dated 21-07-2023 Rs.30,000/- dated 21-07-2023 (slip No. 8959695800)
	Pharmacological Group	Anti-infective/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Tiamubak 45% Oral Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 048170) .
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Large animals, Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
522.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Flush WSP
	Composition	Each 100gm contains: Furosemide…2gm Belladona Extract…0.2gm
	Diary No. Date of R& I & fee	Dy.No 18417 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 2683706820)
	Pharmacological Group	Diuretic/ Antimuscarinic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Bella Flush Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075724)

	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Target species:** Poultry **Oral Powder General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
523.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ADEK Power Liquid
	Composition	Each Litre contains: Vitamin A…10,000,000 IU Vitamin D…2,000,000 IU Vitamin E…4000mg Vitamin K…2000mg
	Diary No. Date of R& I & fee	Dy.No 18422 dated 21-07-2023 Rs.30,000/- dated 20-07-2023 (slip No. 715579522226)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Deka Max Liquid of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 079780)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.
	Decision: Approved.	
524.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dimfos-12 Injection 50ml
	Composition	Each 100ml contains: Toldimfos Sodium…20gm Vitamin B12…5mg
	Diary No. Date of R& I & fee	Dy.No 18073 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 116558249)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Toldibar Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118648)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, calves, sheep, goat, dogs, cats **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021

		on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
525.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Balavit-12 100ml Injection
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 18069 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 274745161597)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cyanocob 250 Injection of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 072692)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, calves, foals, sheep, goat, dogs, cats **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021 on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
526.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prmido 10ml Injection
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 18070 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 4480887910)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Bioimido Injection of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No.118602)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021

		on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Scientific justification for use of Imidocarb Dipropionate in dogs**	
527.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prmido 50ml Injection
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 18071 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 397361105)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Imidobar Injection of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117367)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021 on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **fee Rs. 30,000/- for revision of label claim in line with reference product and FPP specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Scientific justification for use of Imidocarb Dipropionate in dogs**	
528.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	B-Para-50 Injection 20ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 18074 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 804796224)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Bupex Injection of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 118636)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021 on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
529.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Pred Dx Injection 10ml
	Composition	Each ml contains: Prednisolone Acetate…7.5mg Dexamethasone…2.5mg
	Diary No. Date of R& I & fee	Dy.No 18072 dated 18-07-2023 Rs.30,000/- dated 18-07-2023 (slip No. 6921316581)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Solodex 10ml Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112371)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator	**Target species:** Cattle, horse, calves, foals, sheep, goat, dogs, cats **Liquid Injection Vial (General) Veterinary section** –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021 on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section **Shortcomings:** Firm shall submit fee Rs. 30,000/- for completion of salt form/revision of label claim in line with reference product before issuance of registration letter.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for completion of salt form/revision of label claim in line with reference product before issuance of registration letter.	
530.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Oxarise SC Oral Drench
	Composition	Each ml contains: Oxfendazole…22.65mg Cobalt…1.67mg Selenium…0.5mg

	Diary No. Date of R& I & fee	Dy.No 20227 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 73080959)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Wantox Plus Drench of M/s Breeze Pharma Islamabad (Reg. No. 059110)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep, goat, horses, poultry
	Decision: Approved.	
531.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Albelos Oral Drench
	Composition	Each 100ml contains: Albendazole…10gm Closantel…2gm
	Diary No. Date of R& I & fee	Dy.No 20230 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 69970025272)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Clobendol Suspension of M/s Vety-Care Pharmaceuticals (Pvt) Ltd., Islamabad. (Reg. No. 028523)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep
	Decision: Approved.	
532.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biomisol Oral Suspension
	Composition	Each ml contains: Levamisole HCl…1.50%
	Diary No. Date of R& I & fee	Dy.No 20224 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 28968508)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Sanamisol Oral Suspension of M/s Sanna Labs Faisalabad (Reg. No. 025717)

	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** sheep, goat
	Decision: Approved.	
533.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Revozan Gold Oral Drench
	Composition	Each 100ml Contains: Levamisole HCl…1.5gm Oxyclozanide…3gm Cobalt Sulphate…0.382gm
	Diary No. Date of R& I & fee	Dy.No 20229 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 448200507)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Vital Cure Oral Drench of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 063690)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
534.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Cinarise TS Oral Suspension
	Composition	Each ml contains: Enrofloxacin…75mg Sulphamethoxypyridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 20225 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 6567741992)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Cinariq Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 117139)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep, goat, poultry
	Decision: Approved.	

535.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Mec Oral Drench
	Composition	Each ml contains: Ivermectin…0.24%
	Diary No. Date of R& I & fee	Dy.No 20228 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 990630692)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Activer-S Oral Solution of M/s Acme Pharmaceuticals, Rawat, Islamabad (Reg. No. 117383)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep
	Decision: Approved.	
536.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Oxarise-T Oral Suspension
	Composition	Each ml contains: Oxfendazole…22.65mg Triclabendazole…85mg
	Diary No. Date of R& I & fee	Dy.No 20223 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 639805848)
	Pharmacological Group	Anthelmintic/dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Hawk Vorex Oral Suspension of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat. (Reg. No.118615)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, sheep
	Decision: Approved.	
537.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Tilmorise Oral Liquid
	Composition	Each 100ml contains: Tilmicosin Phosphate…25gm
	Diary No. Date of R& I & fee	Dy.No 20222 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 66518613)
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Tilco Mal Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118612)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Chickens (except hens producing eggs for human consumption), calves **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
538.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Trizin Oral Suspension
	Composition	Each ml contains: Sulphadiazine…400mg Trimethoprim…80mg
	Diary No. Date of R& I & fee	Dy.No 20226 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 2845902823)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Triph Oral Suspension of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118547)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral Liquid section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cows, goats, sheep, dogs, horses
	Decision: Approved.	
539.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Pro Injection 50ml
	Composition	Each ml contains: Diminazine Aceturate…105mg Antipyrine…131mg
	Diary No. Date of R& I & fee	Dy.No 20239 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 66224645515)
	Pharmacological Group	Antipyretic, antiprotozoal

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pronifas Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080724)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, goats, sheep, horses
	Decision: Approved.	
540.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Pro Injection 10ml
	Composition	Each ml contains: Diminazine Aceturate…105mg Antipyrine…131mg
	Diary No. Date of R& I & fee	Dy.No 20237 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 7423922863)
	Pharmacological Group	Antipyretic, antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Durazene Easy Injection of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074017)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cattle, goats, sheep, horses
	Decision: Approved.	
541.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Linspire Injection 100ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin Adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 20242 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 485062499598)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	L-S Vetz Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118424)
	GMP status	DML granted on 02-06-2021

	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
542.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Linspire Injection 50ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin Adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 20241 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 140550541152)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	L-S Vetz Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118424)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
543.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Revo-Ox Injection 50ml
	Composition	Each ml contains: Oxytetracycline as HCl…200mg Ketoprofen…30mg
	Diary No. Date of R& I & fee	Dy.No 20240 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 34881162)
	Pharmacological Group	Antibacterial and NSAID

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep
	Decision: Approved.	
544.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Revo-Ox Injection 100ml
	Composition	Each ml contains: Oxytetracycline as HCl…200mg Ketoprofen…30mg
	Diary No. Date of R& I & fee	Dy.No 20238 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 99757814211)
	Pharmacological Group	Antibacterial and NSAID
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep
	Decision: Approved.	
545.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Revo-Ox Injection 10ml
	Composition	Each ml contains: Oxytetracycline as HCl…200mg Ketoprofen…30mg
	Diary No. Date of R& I & fee	Dy.No 20243 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 337998180609)
	Pharmacological Group	Antibacterial and NSAID
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	DML granted on 02-06-2021

	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep
	Decision: Approved.	
546.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Dor-Rise 10mg/ml Injection 50ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 20236 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 81573684547)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Doramax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 117222)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
547.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Dor-Rise 10mg/ml Injection 10ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 20245 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 9787600380)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Doramax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 117222)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
548.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biocobal 1000 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 20258 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 889828496)

	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No.119706)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, cattle, horses, sheep
	Decision: Approved.	
549.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biocobal 1000 Injection 50ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 20259 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 51374202139)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No.119706)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, cattle, horses, sheep
	Decision: Approved.	
550.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biocobal 1000 Injection 10ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 20257 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 8788291890)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Cynozon Extra Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No.119706)
	GMP status	DML granted on 02-06-2021

	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, cattle, horses, sheep
	Decision: Approved.	
551.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biocobal 250 Injection 50ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 20255 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 9269743875)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 117157)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, cattle, horses, sheep
	Decision: Approved.	
552.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biocobal 250 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 20256 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 892377740772)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cormax Injection of M/s Nawan Laboratories (Pvt.) Ltd, Karachi (Reg. No. 117157)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, cattle, horses, sheep
	Decision: Approved.	
553.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Floxy 10ml Injection

	Composition	Each ml contains: Oxytetracycline…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 20247 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 71660413)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Azad Kashmir (Reg. No. 114810)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
554.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Floxy 100ml Injection
	Composition	Each ml contains: Oxytetracycline…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 20246 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 85349664427)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Azad Kashmir (Reg. No. 114810)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
555.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Floxy 50ml Injection
	Composition	Each ml contains: Oxytetracycline…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 20235 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 915360630213)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Xenox Injection of M/s D-Haans Pharmaceuticals, Azad Kashmir (Reg. No. 114810)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Dogs, cats, camels, cattle, calves, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
556.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Micrise Super Injection 50ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…10gm
	Diary No. Date of R& I & fee	Dy.No 20253 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 10289942011)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Evo-C Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117311)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	

557.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Micrise Super Injection 100ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…10gm
	Diary No. Date of R& I & fee	Dy.No 20251 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 52959678580)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Evo-C Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117311)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Micrise Super Injection 10ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…10gm
	Diary No. Date of R& I & fee	Dy.No 20252 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 99835186832)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Evo-C Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117311)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
559.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Micrise Super DS 100ml Injection
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 20254 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 472629483253)
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	USP specifications

	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Evo-C Forte Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 117312)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biotrim Injection 50ml
	Composition	Each ml contains: Tylosin Tartrate…50mg Sulphamethoxypyridazine…150mg Trimethoprim…30mg
	Diary No. Date of R& I & fee	Dy.No 20250 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 04024529130)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Tri Vetrim-S Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118422)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cows, goats, Dogs, horses, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
561.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Biotrim Injection 100ml
	Composition	Each ml contains: Tylosin Tartrate…50mg Sulphamethoxypyridazine…150mg Trimethoprim…30mg
	Diary No. Date of R& I & fee	Dy.No 20234 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 76324739036)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled

	Me-too status	Tylotrim Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 046515)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cows, goats, Dogs, horses, sheep **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
562.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Vt Injection 10ml
	Composition	Each 100ml contains: Toldimfos Sodium…20gm Vitamin B12…5mg
	Diary No. Date of R& I & fee	Dy.No 20248 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 124539513489)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Cynofos Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 118599)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
563.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Bio-Vt Injection 50ml
	Composition	Each 100ml contains: Toldimfos Sodium…20gm Vitamin B12…5mg
	Diary No. Date of R& I & fee	Dy.No 20249 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 67143885497)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Cynofos Injection of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 118599)
	GMP status	DML granted on 02-06-2021

	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
564.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Butarise 200mg/ml Injection 50ml
	Composition	Each ml contains: Phenylbutazone…200mg
	Diary No. Date of R& I & fee	Dy.No 20244 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 28066199356)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Vutazon SS Injectable Solution.of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 048280)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Liquid Injection vial section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cats, Dogs, horses, cattle, calf, foal
	Decision: Approved in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
565.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Ampotad-50 Water Soluble Powder
	Composition	Each 100gm contains: Amprolium HCl…50gm
	Diary No. Date of R& I & fee	Dy.No 20232 dated 16-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 634311479)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Prolin Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 118447)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral powder section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Calves, sheep, goats, poultry
	Decision: Approved.	

566.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Fosforise Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Magnesium Sulphate…10gm Sodium Phosphate…15gm
	Diary No. Date of R& I & fee	Dy.No 20231 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 9547624272)
	Pharmacological Group	Antibiotic/Antibacterial/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Sparkofos Forte Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 118605)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral powder section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021. **Target Species:** Cow, goat, sheep, dogs, horses **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
567.	Name and address of manufacturer / Applicant	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road Multan, Pakistan
	Brand Name +Dosage Form + Strength	Revotone Water Soluble Powder
	Composition	Each 1000gm contains: Calcium Propionate…201gm Sodium Propionate…402.7gm Magnesium Sulphate...124gm Iron Sulphate...0.41gm Sodium Chloride...264.3gm Vitamin A... 750,000 IU Vitamin D3...350,000 IU Zinc Sulphate...0.11gm Manganese Sulphate...0.21gm Copper Sulphate...0.45gm Cobalt Chloride...0.4gm Sodium Selenite...0.11gm Di Calcium Phosphate...3000mg Vitamin E...1000mg
	Diary No. Date of R& I & fee	Dy.No 20233 dated 16-08-2023 Rs.30,000/- dated 07-08-2023 (slip No. 61316503)

	Pharmacological Group	Minerals and vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Sanatone Water Soluble Oral Powder of M/s Sanna Laboratories, Faisalabad. (Reg. No. 035128)
	GMP status	DML granted on 02-06-2021
	Remarks of the Evaluator	**Oral powder section (General) Veterinary** confirmed vide Letter No. F.1-12/2014-Lic dated 08-06-2021.
	Decision: Approved.	
568.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Oxyton 95 Oral Powder
	Composition	Each 1000gm contains: Oxytetracycline HCl…950gm
	Diary No. Date of R& I & fee	Dy.No 21326 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 32935331252)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Oxyfag-950 Powder of M/s Farm Aid Group, Haripur. (Reg. No. 118568)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
569.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Hi-Chlor 200 Oral Powder
	Composition	Each 1000gm contains: Chlortetracycline HCl…200gm
	Diary No. Date of R& I & fee	Dy.No 21346 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 3217011489)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Poul CTC-20 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118498)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
570.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.

	Brand Name +Dosage Form + Strength	Hi-Chlor 250 Oral Powder
	Composition	Each 1000gm contains: Chlortetracycline HCl…250gm
	Diary No. Date of R& I & fee	Dy.No 21341 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 700616116)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Poul CTC-25 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 118499)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
571.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Sovi Tyl 10 Powder
	Composition	Each 1000gm contains: Tylosin Phosphate…100gm
	Diary No. Date of R& I & fee	Dy.No 21351 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 61668233)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Avilosin 10 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 118657)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
572.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Ampre Sove 50 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…500gm

	Diary No. Date of R& I & fee	Dy.No 21354 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 139821520463)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Coxbar-50 Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118645)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
573.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Ampre Sove 30 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…300gm
	Diary No. Date of R& I & fee	Dy.No 21336 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 4019730057)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Poul Amp-30 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 118508)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
574.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Ampre Sove 20 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…200gm
	Diary No. Date of R& I & fee	Dy.No 21308 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 81869167829)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Acmepro-20 Water Soluble Powder of M/s Acme Pharmaceuticals, Rawat, Islamabad (Reg. No. 118474)
	GMP status	DML granted on 08-11-2022

	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
575.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Ampre Sove 60 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…600gm
	Diary No. Date of R& I & fee	Dy.No 21312 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 660712341558)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Poul Amp-60 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118509)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
576.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Neomy Sove 60 Oral Powder
	Composition	Each 100gm contains: Neomycin Sulphate…60gm
	Diary No. Date of R& I & fee	Dy.No 21357 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 3429292793)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Neoritis-60 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke (Reg. No. 111419)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
577.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Neomy Sove 70 Oral Powder

	Composition	Each 100gm contains: Neomycin Sulphate…70gm
	Diary No. Date of R& I & fee	Dy.No 21331 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 5347956478)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Neoritis-70 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke (Reg. No. 111420)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
578.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Linco-Hi Oral Powder
	Composition	Each 1000gm contains: Lincomycin as HCl…400gm
	Diary No. Date of R& I & fee	Dy.No 21325 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 798603876615)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Biogistic 40% Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 113573)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
579.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Lincosa 4.4 Powder
	Composition	Each 100gm contains: Lincomycin as HCl…4.4gm
	Diary No. Date of R& I & fee	Dy.No 21319 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 5612206293)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled

	Me-too status	Lincos-P Powder of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 049667)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
580.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Doxicat 50 Oral Powder
	Composition	Each 1000gm contains: Doxycycline HCl…500gm
	Diary No. Date of R& I & fee	Dy.No 21320 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 2724948397)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Doxy-Mix 50 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113531)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
581.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Spara LN Oral Powder
	Composition	Each 100gm contains: Lincomycin HCl…25gm Spiramycin Adipate…75gm
	Diary No. Date of R& I & fee	Dy.No 21311 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 949547627879)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg: Decontrolled
	Me-too status	ESPIRA POWDER of M/s Elegance Pharmaceuticals,

		Distt. Rawalpindi. (Reg. No. 105020)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
582.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Lincal Sol Oral Powder
	Composition	Each 1000gm contains: Lincomycin as HCl…100gm Colsitin Sulphate…800 MIU
	Diary No. Date of R& I & fee	Dy.No 21350 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 689446756266)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg: Decontrolled
	Me-too status	Apla Sole Oral Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093866)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
583.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Oxy Neoco 500 Oral Powder
	Composition	Each 1000gm contains: Oxytetracycline HCl…300gm Neomycin Sulphate…250gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 21342 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 00838993094)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled

	Me-too status	N-Colis 105 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113448)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
584.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Frusa Flush Oral Powder
	Composition	Each 1000gm contains: Furosemide…20gm Potassium Chloride…4gm Calcium Carbonate…45gm Magnesium Sulphate…1gm
	Diary No. Date of R& I & fee	Dy.No 21332 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 9944437107)
	Pharmacological Group	Flusher/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Biofurose Water Soluble Powder of M/s Biorise Pharmaceuticals, Multan (Reg. No. 111220)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
585.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Specralin Oral Powder
	Composition	Each 100gm Contains: Lincomycin as HCl…5gm Spiramycin Adipate…2.5gm Spectinomycin HCl…7.5gm Bromhexine HCl…0.5gm
	Diary No. Date of R& I & fee	Dy.No 21334 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 3568427808)
	Pharmacological Group	Antibacterial and antimycoplasmal
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Linc-S Bro Oral Powder of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111370)
	GMP status	DML granted on 08-11-2022

	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
586.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Retrival Oral Powder
	Composition	Each 100gm contains: Acetylsalicyic Acid…6.7gm Vitamin C…20gm
	Diary No. Date of R& I & fee	Dy.No 21310 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 58647655557)
	Pharmacological Group	Restorative/ vitamin
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Vantage Asper-C Oral Powder of M/s Vantage Pharmaceutical, District Faisalabad. (Reg. No. 081712)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
587.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Sovi Mox 15 Oral Powder
	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…15gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 21347 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 70592164252)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Colistin-Mox 15/50 Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113575)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (Penicillin) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.

	Decision: Approved.	
588.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Sovi Mox 23 Oral Powder
	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…23gm Colistin Sulphate…100 MIU
	Diary No. Date of R& I & fee	Dy.No 21317 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 215462813)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Col Moxter-D 23% Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 111487)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (Penicillin) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
589.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Oxy Neoco 240 Oral Powder
	Composition	Each 100gm contains: Oxytetracycline HCl…20gm Neomycin Sulphate…20gm Colistin Sulphate…24 MIU
	Diary No. Date of R& I & fee	Dy.No 21327 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 80755190023)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	N-Colis 44/240 Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No.113450)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
590.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Combo Tech Oral Powder
	Composition	Each 1000gm contains: Tylosin as Tartrate…100gm Doxycycline HCl…200gm Bromhexine HCl…2.5gm

	Diary No. Date of R& I & fee	Dy.No 21335 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 97562249870)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Deltarox D Oral Water Soluble Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112359)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
591.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Floxy Tech Oral Powder
	Composition	Each 1000gm contains: Florfenicol…150gm Oxytetracycline HCl…150gm
	Diary No. Date of R& I & fee	Dy.No 21314 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 13417845)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Cycloflox -30 Water Soluble Powder of M/s Biorise Pharmaceuticals, Multan (Reg. No. 111215)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
592.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydo Co Oral Powder
	Composition	Each 1000gm contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 21318 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 55275632706)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications

	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Milityldox C Oral Powder of M/s Mili Vet Pharmaceuticals (Pvt) Ltd District Lahore (Reg. No. 112203)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
593.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Renal Sove Oral Powder
	Composition	Each 100gm contains: Methenamine Mandelate…90gm Vitamin B1…700mg Vitamin C…100mg Sorbitol…5gm
	Diary No. Date of R& I & fee	Dy.No 21340 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 605455161218)
	Pharmacological Group	Diuretic/vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	THENAMINE 90 POWDER of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 105037)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
594.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Super Tech Powder
	Composition	Each 1000gm Contains: Vitamin D3…2gm L Lysine…25gm Vitamin E…9gm DL Methionine…50gm Choline Chloride…100gm Virginiamycin…12gm
	Diary No. Date of R& I & fee	Dy.No 21322 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 30678199883)
	Pharmacological Group	Antibiotic/vitamins/ amino acids
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications

	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg,10Kg, 25Kg: Decontrolled
	Me-too status	Supercine-TM Powder of M/s Vety-Care Islamabad (Reg. No.019946) **Could not be confirmed in the applied strength**
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
595.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Hexavet Oral Powder
	Composition	Each 100gm contains: Hexamethylene Tetramine (Methenamine)…9.5gm Riboflavin…1gm Nicotinamide…2.5gm Calcium Pantothenate…0.5gm
	Diary No. Date of R& I & fee	Dy.No 21306 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 7863632632)
	Pharmacological Group	Diuretic/Flusher
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Hexa-Vit Powder of M/s A & K Pharmaceutical Faisalabad. (Reg. No. 053976)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
596.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Hi Tech Fosomin Oral Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin as Tartrate…5gm Fructose 1,6 Diphosphate…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm

	Diary No. Date of R& I & fee	Dy.No 21309 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 751110899)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Fosforox-20 Oral Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112343)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved. Firm shall submit fee Rs. 30,000/- for correction in formulation in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
597.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Sprinter C Oral Powder
	Composition	Each 100gm contains: Paracetamol…2gm Vitamin C…20gm Calcium Carbonate…4.5gm Magnesium Sulphate…3.5gm Potassium Chloride…4gm
	Diary No. Date of R& I & fee	Dy.No 21328 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 90186352384)
	Pharmacological Group	Analgesic/ vitamin
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Bimrol-C Water Soluble Powder of M/s D-Haans Pharmaceuticals, Azad Kashmir (Reg. No. 102232)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral powder (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML.
	Decision: Approved.	
598.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Floras Col 23 Oral Liquid
	Composition	Each 100ml contains: Florfenicol…23gm Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 21316 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 7140181189)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled

	Me-too status	Poliflor Liquid of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No. 078383) **Could not be confirmed in the applied strength**
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
599.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Tozal 250 Oral Liquid
	Composition	Each 100ml contains: Toltrazuril…2.5gm
	Diary No. Date of R& I & fee	Dy.No 21333 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 76032686488)
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Zurox Oral Solution of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113517)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
600.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Bermint Sove 10 Oral Liquid
	Composition	Each 1000ml contains: Bromhexine HCl…100gm Menthol…200gm
	Diary No. Date of R& I & fee	Dy.No 21356 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 786994974333)
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 1000ml, 5000ml: Decontrolled

	Me-too status	B-Menthol Liquid of M/s Farm Aid Group, Haripur (Reg. No. 093825) **Could not be confirmed in the applied strength**
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry, cattle **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
601.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Adeck VP Oral Liquid
	Composition	Each 1000ml contains: Vitamin A…. 30,000,000 IU Vitamin D3…1,000,000 IU Vitamin E…5000mg Vitamin K3…6000mg
	Diary No. Date of R& I & fee	Dy.No 21355 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 105584320795)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Adekbar Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073950)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML
	Decision: Approved.	
602.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Livo Sove Oral Liquid
	Composition	Each 500ml contains: L-Carnitine HCl…50mg Betain HCl…20mg Inositol…7mg Choline Chloride…100mg Sorbitol…200mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 21353 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 7635950186)
	Pharmacological Group	Nutrients/Vitamins

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Pro Livojest Oral Solution of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111350) **Could not be confirmed in the applied strength**
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
603.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Colitat 20 Oral Liquid
	Composition	Each 1000ml contains: Colistin Sulphate…2,000,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 21337 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 72274678)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Colibar Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 075784)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
604.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Immune Pro Oral Liquid
	Composition	Each 1000ml contains: Vitamin E as Alphatocopherol Acetate…150mg Selenium as Sodium Selenite…2300mg Zinc as Zinc Sulphate…8000mg
	Diary No. Date of R& I & fee	Dy.No 21352 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 250954950)
	Pharmacological Group	Vitamins/minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml, 5000ml: Decontrolled

	Me-too status	Sel-EZ Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073949)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry, cattle, goats
	Decision: Approved.	
605.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Enrolin-G Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…10gm Aminophylline…4gm Guaiphenesin…10gm
	Diary No. Date of R& I & fee	Dy.No 21305 dated 29-08-2023 Rs.30,000/- dated 23-08-2023 (slip No. 8082344534)
	Pharmacological Group	Antibiotic/mucolytic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Enrophylin Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080730)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:** Poultry
	Decision: Approved.	
606.	Name and address of manufacturer / Applicant	M/s Suave Pharmaceuticals Pvt. Ltd., Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Flori Sove 10 Oral Liquid
	Composition	Each 1000ml contains: Florfenicol…100gm
	Diary No. Date of R& I & fee	Dy.No 21345 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 108098966158)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Kariflor 100mg Solution for Oral Administration of M/s Unicare Enterprises, Faisalabad (Reg. No. 111214)
	GMP status	DML granted on 08-11-2022
	Remarks of the Evaluator	**Oral Liquid (General & Antibiotic) Veterinary section** confirmed vide panel inspection report dated 10-10-2022 for grant of DML. **Target Species:**

		Poultry
	Decision: Approved.	
607.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Tycobrox Plus Water Soluble Powder
	Composition	Each 1000gm contains: Tylosin Tartrate…200gm Doxycycline HCl…400gm Colistin Sulphate…1000 MIU Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 20082 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 3778788473)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Bromotyl-70 Water Soluble Powder of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113406)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Cows, goats, sheep, dogs, horses, Poultry
	Decision: Approved.	
608.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Amprofiz Water Soluble Powder
	Composition	Each 100gm contains: Amprolium HCl…50gm
	Diary No. Date of R& I & fee	Dy.No 20083 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 1744772509)
	Pharmacological Group	Anti-coccidial
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Opromo 50 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113519)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Calves, goats, sheep, dogs, Poultry
	Decision: Approved.	

609.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Colifiz Water Soluble Powder
	Composition	Each 100gm Contains: Colistin Sulphate…500,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 20085 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 85040615037)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Colibect Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 075791)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Cows, goats, sheep, dogs, horses
	Decision: Approved.	
610.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Tetroxy Water Soluble Powder
	Composition	Each 100gm Contains: Oxytetracycline HCl…95gm
	Diary No. Date of R& I & fee	Dy.No 20084 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 985187553303)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Eter Oxytetracycline-95 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 109842)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Cattle, pets, calves, sheep, dogs, cats, camels
	Decision: Approved.	
611.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Enrostin Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…20gm

		Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 20078 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 19551001)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Floxa-C Oral Solution of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 071094)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral Liquid section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Cattle, pets, calves, sheep, dogs, cats, camels
	Decision: Approved.	
612.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Adekvit Oral Solution
	Composition	Each 1000ml contains: Vitamin A…30,000,000 IU Vitamin D3…1,000,000 IU Vitamin E…5000mg Vitamin K3…6000mg
	Diary No. Date of R& I & fee	Dy.No 20079 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 82138451796)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml: Decontrolled
	Me-too status	Adekbar Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073950)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral Liquid section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary).
	Decision: Approved.	
613.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Lincorgo Premix Powder
	Composition	Each 100gm contains: Lincomycin HCl…4.40gm
	Diary No. Date of R& I & fee	Dy.No 20080 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 27750411858)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Malinco 44 Oral Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 112112)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Target Species:** Poultry, dogs, cats
	Decision: Approved.	
614.	Name and address of manufacturer / Applicant	M/s Fizi Pharmaceutical & Chemical Laboratories, Bhubatian Sikka Street, 8-km, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fostyl Oral Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 20081 dated 15-08-2023 Rs.30,000/- dated 03-08-2023 (slip No. 27159186839)
	Pharmacological Group	Antibiotic/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Fas-Fo 73 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113592)
	GMP status	cGMP certificate dated 07-08-2024 based on inspection conducted on 02-08-2024.
	Remarks of the Evaluator	**Oral dry powder section** confirmed vide panel inspection report dated 30-05-2019 for verification of facility for grant of DML by way of formulation (veterinary). **Shortcomings:** • The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation/label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation/label claim in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
615.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	GP-Pred 2.5% Injection 10ml
	Composition	Each ml contains: Prednisolone Acetate…25mg

	Diary No. Date of R& I & fee	Dy.No 19114 dated 01-08-2023 Rs.30,000/- dated 26-07-2023 (slip No. 6201450514)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Premsone 25 Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111331)
	GMP status	GMP inspection report dated 18-01-2023 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision: Deferred for confirmation of relevant manufacturing facility.	
616.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri Scour Oral Suspesnion
	Composition	Each ml contains: Sulfadiazine…35.50mg Sulfadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine Methyl Bromide…0.04mg Pectin…7.10mg Kaolin…103.30mg Vitamin B1…0.15mg Vitamin B2…0.22mg
	Diary No. Date of R& I & fee	Dy.No 19976 dated 11-08-2023 Rs 30,000/- dated 03-08-2023 (slip No. 95808852259)
	Pharmacological Group	Antibiotic/ vitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Scour-X Oral Suspension of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 029661)
	GMP status	
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed vide letter No.F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
617.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Dimidine 100 Water Soluble Powder

	Composition	Each gram contains: Sulphadimidine Sodium…1000mg
	Diary No. Date of R& I & fee	Dy.No 19381 dated 04-08-2023 Rs.30,000/- dated 17-07-2023 (slip No. 601595866370)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30gm,100gm, 500gm, 1000gm; Decontrolled
	Me-too status	Sulphexicol Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 082500)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of relevant manufacturing facility • latest GMP inspection report conducted within the period of last three years • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision: Deferred for submission of following: • **Confirmation of relevant manufacturing facility** • **latest GMP inspection report conducted within the period of last three years** • **fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
618.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avicloze Oral Liquid
	Composition	Each ml contains: Oxyclozanide…45mg Cobalt Sulphate…3.82mg Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy.No 20283 dated 17-08-2023 Rs.30,000/- dated 17-08-2023 (slip No. 7660282822)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Oxyclo Plus Suspension of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062171)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
619.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Clobenda M Oral Liquid

	Composition	Each ml contains: Closantel…50mg Mebendazole…75mg Cobalt Sulphate…9mg
	Diary No. Date of R& I & fee	Dy.No 20282 dated 17-08-2023 Rs.30,000/- dated 17-08-2023 (slip No. 9736775321)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Everzantel-M Suspension of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088864)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
620.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Fendazole Oral Liquid
	Composition	Each ml contains: Oxfendazole…45.30mg Cobalt Sulphate…9mg
	Diary No. Date of R& I & fee	Dy.No 20281 dated 17-08-2023 Rs.30,000/- dated 17-08-2023 (slip No. 71185421334)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Oxavet Super Suspension of M/s Medi-Vet (Pvt) Ltd., Lahore (Reg. No. 046586)
	GMP status	
	Remarks of the Evaluator	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
621.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Lincotin Injection 50ml
	Composition	Each ml contains: Lincomycin as HCl…50mg Spectinomycin as Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 21181 dated 28-08-2023 Rs.30,000/- dated 22-08-2023 (slip No. 568139767)

	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Lincoject S Injection of M/s International Champharma Lahore (Reg. No. 016282)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved.	
622.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pro-V Injection 10ml
	Composition	Each ml contains: Progesterone…50mg Vitamin A…50,000 IU Vitamin E…15 IU
	Diary No. Date of R& I & fee	Dy.No 21511 dated 31-08-2023 Rs.30,000/- dated 08-08-2023 (slip No. 89054155749)
	Pharmacological Group	Hormone and vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Pregton-V Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No.102258)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable vial (Hormones) (veterinary)** section confirmed vide cGMP certificate dated 20-07-2020
	Decision: Approved.	
623.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pro-V Injection 50ml
	Composition	Each ml contains: Progesterone…50mg Vitamin A…50,000 IU Vitamin E…15 IU
	Diary No. Date of R& I & fee	Dy.No 21512 dated 31-08-2023 Rs.30,000/- dated 08-08-2023 (slip No.26164261)
	Pharmacological Group	Hormone and vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Progest-AE Injection of M/s Alina Combine Pharmaceutical Karachi (Reg. No. 063699)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.

	Remarks of the Evaluator	**Liquid injectable vial (Hormones) (veterinary)** section confirmed vide cGMP certificate dated 20-07-2020
	Decision: Approved.	
624.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Trivetz Injection 50ml
	Composition	Each ml contains: Vitamin A Palmitate…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 21510 dated 31-08-2023 Rs.30,000/- dated 28-08-2023 (Slip No. 770716983976)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Vitamall Injection (50ml) of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 113632)
	GMP status	cGMP certificate dated 20-02-2023 based on evaluation conducted on 09-03-2022
	Remarks of the Evaluator	**Target species:** Cattle, cat, dog, horse, goat, sheep **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
625.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Vetzveta Injection 50ml
	Composition	Each ml contains: Vitamin B1...4mg Vitamin B6...0.34mg Vitamin B2...0.17mg Vitamin C...4mg L-Arginine HCl...1.44mg L-Cystine HCl...3.2mg L-Glutamine HCl...3.2mg Glycin...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg L-Leucine HCl...4.28mg L-Lysin HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Trypton...0.86mg L-Valine...3.6mg Nicotinamide...8mg Glucose...21mg Magnesium Sulphate...0.08mg

		L-Phenylalanine...5mg
	Diary No. Date of R& I & fee	Dy.No 21509 dated 31-08-2023 Rs.30,000/- dated 28-08-2023 (Slip No. 39016401)
	Pharmacological Group	Amino acid/ electrolytes/ vitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Glucovit Forte Injection of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052322) **Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 20-02-2023 based on evaluation conducted on 09-03-2022
	Remarks of the Evaluator	**Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

b. Deferred Cases

626.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	DMG Booster Oral Powder
	Composition	Each Kg contains: Vitamin A…2,000,000 IU Vitamin D3…400,000 IU Vitamin E…160 IU Vitamin K…900mg Vitamin B1…125mg Vitamin B2…2000mg Vitamin B6…600mg Vitamin B12…3000mg Vitamin C…1000mg Folic Acid…200mg Nicotinic Acid…10,000mg Calcium Pantothenate…3000mg L-Lysine...50,000mg DL-Methionine...30,000mg
	Diary No. Date of R& I & fee	Dy.No 5674 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 941626168)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg: Decontrolled
	Me-too status	Kerry Vit Amino Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 031480) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	The submitted reference to generic product is of different strength than applied.

		Shortcomings: • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • **Me-too/generic status:** Kerry Vit Amino Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 031480) **Remarks:** The submitted generic product contains same quantities of APIs, as in applied formulation, per 100gm instead of per Kg **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Decision: Deferred for submission of evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
627.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Trisulf Granules
	Composition	Each 100gram contains: Trimethoprim…4.62gm Sulphaquinoxaline…15.02gm
	Diary No. Date of R& I & fee	Dy.No 5675 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 444031460913)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • **Me-too/generic status:** Triquin granules of M/s Alton Pharmaceuticals (Pakistan)	

	Remarks: The submitted reference to generic product could not be confirmed **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Decision: Deferred for submission of evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
628.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Danocin Oral Powder
	Composition	Each 100gm Contains: Danofloxacin Mesylate…10gm
	Diary No. Date of R& I & fee	Dy.No 5671 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 30428452752)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	KP-Dano 10% Oral Powder of M/s Krypton Pharma (Pvt) Ltd., Faisalabad (Reg. No. 109223)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • The firm shall submit fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility and fee Rs. 30,000/- for correction in formulation (salt form) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • Firm has submitted fee Rs. 30,000/- for correction in formulation vide challan No. 56005106 dated 26-07-2024	
	Decision: Approved with innovator's specification and with following label claim in line with reference product. **Each 100gm Contains:** **Danofloxacin as Mesylate…10gm**	
629.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Neogen Oral Powder
	Composition	Each gram contains: Neomycin Sulphate 720mg eq. to Neomycin base…500mg
	Diary No. Date of R& I & fee	Dy.No 5672 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 241811520328)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Neom-72 Water Soluble Powder of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118506)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision of 336th meeting: Deferred for submission of following: • confirmation of relevant manufacturing facility • fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • Firm has submitted fee Rs. 7,500/- for correction in FPP specifications vide challan No. 5059384662.	
	Decision: Approved.	
630.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Vitagen Super Powder
	Composition	Each 100gm contains: Vitamin A…2,000,000 IU Vitamin D3…400,000 IU Vitamin E…160 IU Vitamin K…900mg Vitamin B1…125mg Vitamin B2…2000mg Vitamin B6…600mg Vitamin B12…3000mcg Vitamin C…1000mg Folic Acid…200mg Nicotinamide…10,000mg Calcium Pantothenate…3000mg
	Diary No. Date of R& I & fee	Dy.No 5677 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 4572877458)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vital-P Powder of M/s A & K Pharmaceuticals, Faisalabad (Reg. No. 031567)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022	

	Decision: Approved.	
631.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Biomax Paste
	Composition	Each 100gm contains: Ivermectin…1.87gm Praziquantel…14.03gm
	Diary No. Date of R& I & fee	Dy. No 28648 dated 10-10-2022 Rs.30,000/- dated 30-09-2022 (slip No. 84088937)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, 30gm, 40gm, 50gm, 100gm: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • The instant formulation is not already registered in Pakistan. The firm has submitted reference of Equimax paste sold/registered in South Africa. • Confirmation of **relevant manufacturing facility.**
	Decision of 336th meeting: Deferred for following: • availability of the said formulation in any reference country or PICs member country or ML-4 country. • Confirmation of relevant manufacturing facility**.**	
	Updated status: The firm has submitted the following: • Equimax **(**Each milligram of paste contains 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel) is **approved in USFDA** • **Oral Liquid (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • Registration for **Biotak Oral Paste** was already granted to the firm vide Reg. No.109881	
	Decision: Approved.	
632.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Biomectin Oral Paste
	Composition	Each 100gm contains: Ivermectin…1.87gm
	Diary No. Date of R& I & fee	Dy. No 28647 dated 10-10-2022 Rs.30,000/- dated 30-09-2022 (slip No. 7025086734)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, 30gm, 40gm, 50gm, 100gm: Decontrolled
	Me-too status	**Not registered in DRAP**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**

		• approval status of product in different Reference Regulatory Authorities, WHO Maturity Level-4 (ML-4) Authorities and PICs member countries
	Decision of 336th meeting: Deferred for following: • availability of the said formulation in any reference country or PICs member country or ML-4 country. • Confirmation of relevant manufacturing facility**.**	
	Updated status: The firm has submitted the following: • Powermectin Paste (1.87%) is **approved in Health Canada.** • **Oral Liquid (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • Registration for **Biotak Oral Paste** was already granted to the firm vide Reg. No.109881	
	Decision: Approved.	
633.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Sulftrim-NPB Oral Solution
	Composition	Each ml contains: Norfloxacin…50mg Sulphamethoxypyridazine…50mg Trimethoprim…10mg **Phenylbutazone**…12mg Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 5673 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 145491093)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Anti Crd/B Oral Solution of M/s Rajupt Enterprises Karachi (Reg. No. 018434)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision of 336th meeting: Deferred for submission of following: • Confirmation of relevant manufacturing facility • Target species	
	Updated status: The firm has submitted the following: • **Oral Liquid (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • **Target species: Poultry**	
	Decision: Approved in the light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to these animals only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in equine animals, should also be shown clearly.	
634.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Anti-Scour Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.50mg

		Sulphadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine Methylbromide…0.040mg Kaolin…103.30mg Pectin…7.10mg Vitamin B1…0.150mg Vitamin B2…0.220mg
	Diary No. Date of R& I & fee	Dy.No 5676 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 29311067)
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 2L, 2.5L: Decontrolled
	Me-too status	Baarex Oral Suspension of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 118551)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Shortcomings:** • Confirmation of **relevant manufacturing facility.**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Liquid (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022	
	Decision: Approved.	
635.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxazol Plus Drench
	Composition	Each ml contains: Oxfendazole.....22.65mg Triclabendazole.....85mg
	Diary No. Date of R& I & fee	Dy.No 29742 dated 20-10-2022 Rs.30,000/- dated 17-10-2022 (slip No. 3148850625)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	500ml, 1000ml; Decontrolled
	Me-too status	Hawk Vorex Oral Suspension of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat (Reg. No. 118615)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Liquid/ Drench (Veterinary-General) section** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023	
	Decision: Approved.	
636.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Vernil-400 Bolus

	Composition	Each bolus contains: Levamisole HCl.....400mg
	Diary No. Date of R& I & fee	Dy.No 29859 dated 21-10-2022 Rs.30,000/- dated 18-10-2022 (slip No. 830338306860)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Famisol 400 Bolus of M/s Farm Aid Group, Haripur (Reg. No. 114878)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Bolus section (General)-Veterinary** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023	
	Decision: Approved.	
637.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Vernil-1125 Bolus
	Composition	Each bolus contains: Levamisole HCl.....1125mg
	Diary No. Date of R& I & fee	Dy.No 29860 dated 21-10-2022 Rs.30,000/- dated 18-10-2022 (slip No. 636984544)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Famisol 1125 Bolus of M/s Farm Aid Group, Haripur (Reg. No. 114876)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Bolus section (General)-Veterinary** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023	
	Decision: Approved.	
638.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenzole-750 Bolus
	Composition	Each bolus contains: Fenbendazole.....750mg
	Diary No. Date of R& I & fee	Dy.No 29741 dated 20-10-2022 Rs.30,000/- dated 17-10-2022 (slip No. 782539267459)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	20's, 50's; Decontrolled
	Me-too status	Fensel Bolus of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 109970)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Bolus section (General)-Veterinary** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023	
	Decision: Approved.	
639.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Alvenax-152 Bolus
	Composition	Each bolus contains: Albendazole…152mg
	Diary No. Date of R& I & fee	Dy.No 27159 dated 26-09-2022 Rs.30,000/- dated 22-09-2022 (slip No. 0424605649)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20's and 50's; Decontrolled
	Me-too status	Marozole-152 Bolus of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 112292)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • **Oral Bolus section (General)-Veterinary** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023	
	Decision: Approved.	
640.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxynic Drench
	Composition	Each ml contains: Oxyclozanide…94mg Oxfendazole…34mg Selenium as Sodium Selenite…0.50mg Cobalt as Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 2101 dated 23-01-2023 Rs.30,000/- dated 20-01-2023 (slip No. 21745074123)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled

	Me-too status	Combiox Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 057004)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	**Shortcomings:** Confirmation of **relevant manufacturing facility**
	Decision of 336th meeting: Deferred for submission of following: • confirmation of relevant manufacturing facility • latest GMP inspection report conducted within period of last three years	
	Updated status: The firm has submitted the following: • **Oral Liquid/ Drench (Veterinary-General) section** confirmed vide letter No. F. 1-27/85-Lic (vol-III) dated 31-10-2023 • cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.	
	Decision: Approved.	
641.	Name and address of manufacturer / Applicant	M/s Kohinoor Industries Sahiwal, Plot No. 159-160/B Small Industries Estate, Sahiwal.
	Brand Name +Dosage Form + Strength	Policol-Forte Oral Powder
	Composition	Each gram contains: Colistin Sulphate…60MIU
	Diary No. Date of R& I & fee	Dy.No 3661 dated 08-02-2023 Rs.30,000/- dated 07-02-2023 (slip No.055781942)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 5Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	panel inspection report based on evaluation dated 17-01-2023 recommends renewal of DML.
	Remarks of the Evaluator [X]	**Oral Dry Powder (General) Veterinary** section confirmed vide panel inspection report based on evaluation dated 17-01-2023 for renewal of DML and grant of additional section. **Shortcomings:** • The submitted reference of generic product "Grand Colistin Oral Powder" of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 106754) is of different strength (i.e 6MIU/gram) than applied.
	Decision of 336th meeting: Deferred for evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has revised label claim in line with reference product as follows: **Each gram contains:** **Colistin Sulphate…6MIU** • Me-too status: Grand Colistin Oral Powder of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 106754) **Shortcomings:** The firm shall submit fee Rs. 30,000/- for correction in formulation in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
	Decision: Approved with following label claim: **Each gram contains:** **Colistin Sulphate…6MIU**	

	The firm shall submit fee Rs. 30,000/- for correction in formulation in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
642.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur AJK, Pakistan.
	Brand Name +Dosage Form + Strength	CCNS Powder
	Composition	Each gram Contains: Chlortetracycline hydrochloride …200mg Colistin sulphate …10mg Neomycin sulphate …60mg Streptomycin sulphate …20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8532 dated 07-03-2018 Rs.20,000/- Dated 06-03-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	CHLOROCEPT Water Soluble Powder by M/s D-Maarson Pharmaceuticals (Reg#073996)
	GMP status	Last inspection report dated 08-11-2016: Firm is GMP compliant
	Remarks of the Evaluator	Latest GMP status not confirmed.
	Decision of 290th meeting: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
	Updated status: The firm has submitted panel inspection report dated 12-01-2024 for renewal of DML concluding recommendation of renewal of DML.	
	Decision: Approved.	
643.	Name and address of manufacturer / Applicant	Noble Pharma B-1 Old Industrial Area Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Zentol 11% Suspension
	Composition	Each 100 ml contain: Closantel base…..11%
	Diary No. Date of R& I & fee	Dy No. 6975: 23.02.2018 PKR 20,000/-: 23.02.2018 PKR 5,000/-: 04.03.2019
	Pharmacological Group	Phenol derivatives, incl. salicylanilides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L; the firm has mentioned that the price is decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	CENNATAL LIQUID. Reg. # 63659 (100ml, 500ml, 1000ml, 2.5 L, 5 L)
	GMP status	The firm was inspected on 08.11.2016, wherein the FID concluded that "The company is found complying GMP as of today. The management is directed to rectify the minor shortcomings and submit compliance accordingly."

	Remarks of the Evaluator	• The firm applied for 11% suspension and has mentioned 5% in the label claim (in Form 5 only). The firm corrected the label claim along with submission of Rs. 5000/- fee. • The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision of 290th meeting: Deferred for submission of differential fee for revision of strength	
	Updated status: The firm has submitted panel inspection report dated 12-01-2024 for renewal of DML concluding recommendation of renewal of DML. **Shortcomings:** • The firm shall submit prescribed fee for typographical error in label claim (in form 5 only) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter. • complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria).	
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **prescribed fee for typographical error in label claim (in form 5 only) prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023** • **complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria).**	
644.	Name and address of manufacturer / Applicant	Noble Pharma B-1 Old Industrial Area Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobicomb Suspension
	Composition	Each 5ml Contains Oxyclozanide…150mg Levamisole as HCL…75mg
	Diary No. Date of R& I & fee	Dy No. 21496: 14.06.2018 PKR 20,000/-: 14.06.2018
	Pharmacological Group	Anthelmintics (not in ATC)
	Type of Form	Form 5
	Finished product Specification	Manufacturer specs
	Pack size & Demanded Price	100ml, 150ml, 500ml, 1000ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	COMBAT ORAL DRENCH. Reg. No. 043275 (does not depict suspension form)
	GMP status	The firm was inspected on 08.11.2016, wherein the FID concluded that "The company is found complying GMP as of today. The management is directed to rectify the minor shortcomings and submit compliance accordingly."
	Remarks of the Evaluator	The firm was asked to revise levamesol as HCl to levamesol HCl in Form 5. The firm did not revise the same. Revision is required. The firm was asked to justify the statement "Appropirate overage is added to compensate the potency loss on storage".The firm removed the statement in revised master formula. However, in the revised master formula, the quantities of API do not correspond to the batch size. The firm was asked to provide reference for finished product specifications. The firm did not provide the same.
	Decision of 291st meeting: Deferred for the following:	

	□ Revise levamesol as HCl to levamesol HCl in Form 5 □ Correct Master Formula with the quantities of API/addtiives corresponding to the batch size	
	Updated status: The firm has submitted panel inspection report dated 12-01-2024 for renewal of DML concluding recommendation of renewal of DML. **Shortcomings:** • Revised Form 5 with correct formulation in line with reference product • Correct Master Formula with the quantities of API/additives corresponding to the batch size • The firm shall submit fee Rs. 30,000/- for correction in formulation in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.	
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Revised Form 5 with correct formulation in line with reference product** • **Correct Master Formula with the quantities of API/additives corresponding to the batch size** • **fee Rs. 30,000/- for correction in formulation in line with reference product prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
645.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Ami-Vicom 50ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.4mg L-Cysteine HCl...3.2mg L-Glutamine...3.2mg Glycine...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg L-Lysine HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Tryptophan...0.86mg L-Phenylalanine...5mg L-Valine...3.60mg Thiamine HCl...4mg Riboflavin Sodium Phosphate...0.17mg Pyridoxine HCl...0.34mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg
	Diary No. Date of R& I & fee	Dy.No 27635 dated 29-09-2022 Rs.30,000/- dated 20-09-2022 (slip No. 08642351029)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.

		Shortcomings: • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • Unit carton of Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294) as evidence of metoo/ generic status **Shortcomings:** Latest GMP inspection report conducted within the period of last three years	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
646.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur
	Brand Name +Dosage Form + Strength	Ami-Vicom 100ml Injection
	Composition	Each ml contains: L-Arginine HCl...1.4mg L-Cysteine HCl...3.2mg L-Glutamine...3.2mg Glycine...3.2mg L-Histidine...1.32mg L-Isoleucine...3.6mg L-Lysine HCl...5.44mg L-Methionine...3.2mg L-Threonine...3.2mg L-Tryptophan...0.86mg L-Phenylalanine...5mg L-Valine...3.60mg Thiamine HCl...4mg Riboflavin Sodium Phosphate...0.17mg Pyridoxine HCl...0.34mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg
	Diary No. Date of R& I & fee	Dy.No 27634 dated 29-09-2022 Rs.30,000/- dated 21-09-2022 (slip No. 47615553041)
	Pharmacological Group	Amino acids, vitamins and electrolytes
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**Liquid injection (General) Veterinary** section confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.

		Shortcomings: Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • Unit carton of Ami-Vicom Injection of M/s Selmore Agencies Lahore (Reg. No. 016294) as evidence of metoo/ generic status **Shortcomings:** Latest GMP inspection report conducted within the period of last three years	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
647.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F Dine 33.3 injection 250ml
	Composition	Each ml contains: Sulfadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 22365 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Sulphadimidine Sodium Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 058714)
	GMP status	**New Section**
	Remarks of the Evaluator	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision of 326th meeting: Deferred for confirmation of relevant manufacturing facility(LVP)	
	Updated status: The firm has submitted the copy of panel inspection report dated 15-04-2022 for renewal of DML stating 10ml to 500ml facility.	
	Decision: Approved.	
648.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F Dine 33.3 injection 500ml
	Composition	Each ml contains: Sulfadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 22366 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Sulphadimidine Sodium Injection (500ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 058714)
	GMP status	**New Section**

	Remarks of the Evaluator	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision of 326th meeting: Deferred for confirmation of relevant manufacturing facility(LVP)	
	Updated status: The firm has submitted the copy of panel inspection report dated 15-04-2022 for renewal of DML stating 10ml to 500ml facility.	
	Decision: Approved.	
649.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Vetz-ADE-M Granular Powder
	Composition	Each Kg Contains: Vitamin A…0.5 MIU Vitamin D…0.08 MIU Vitamin E…0.3gm Calcium…225gm Phosphorous…120gm Magnesium…25gm Sodium…20gm Iron as Ferrous…1gm Zinc…3gm Manganese…2gm Copper…0.6gm Cobalt…0.01gm Iodine…0.02gm Selenium…0.003gm
	Diary No. Date of R& I & fee	Dy.No 32480 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Multivitamin and minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm,20gm, 30gm, 50gm, 100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	ADE Minerals of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 035063) **Could not be confirmed**
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of testing facility.
	Decision of 326th meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of testing facility • Completion of salt forms	
	Updated status: The firm has submitted the following:	

	• **Metoo status:** Rumatone Ade Oral Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. 093615 • QC instruments list mentioning Atomic absorption spectrophotometer **Shortcomings:** Label claim with complete salt forms.	
	Decision: Approved. Firm shall submit label claim with complete salt form before issuance of registration letter.	
650.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Vetz-Vita Oral Powder
	Composition	Each gram contains: Vitamin A...800gm Vitamin D3... 160gm Vitamin E... 380gm Vitamin B1...1000gm Vitamin B2...1250gm Vitamin B12...1gm Vitamin B3...6250gm Vitamin B6...4000gm Copper Sulphate...250gm Magnesium Sulphate...25000gm Calcium Chloride...23gm Zinc Sulphate...2170gm Manganese Sulphate...10000gm Potassium Iodide...500gm Sodium Selenite...10gm D.C.P (Phosphorous)...150000gm Sodium Chloride...120000gm
	Diary No. Date of R& I & fee	Dy.No 863 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 058842)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	• **Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision of 329th meeting: Deferred for confirmation of testing facility.	
	Updated status: The firm has submitted the following: • QC instruments list mentioning Atomic absorption spectrophotometer	
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs (Priority Registration applications of Export Facilitation)

a. New cases

Deputy Director PR-II/EFD vide letter NO.1-6/2019-PR-II (EFD) dated 29-05-2024 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year.

In compliance to the aforementioned decision, **M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore** has achieved the benchmark of more than 100,000 USD during the fiscal Year **2022-2023.** Following applications submitted by the firm for priority consideration/ evaluation in lieu of export facilitation are submitted before the Board for its consideration please:

651.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Cefanome Intramammmary Suspension (For lactating cows)
	Composition	Each 8gm Syringe Contains: Cefquinome as Cefquinome Sulphate…75mg
	Diary No. Date of R& I & fee	Dy.No 28347 dated 08-12-2023 Rs 30,000/- dated 29-11-2023 (slip No. 3589248906)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	8gm x 20's: Decontrolled
	Me-too status	Cefanil IMM Injector (Intramammary Suspension) of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 111473)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Liquid Injection Hormone (Veterinary) Section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
652.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Selprost injection 10ml
	Composition	Each ml contains: D-Cloprostenol Eq. to D-Cloprostenol Sodium…0.075mg
	Diary No. Date of R& I & fee	Dy.No 28346 dated 08-12-2023 Rs 30,000/- dated 29-11-2023 (slip No. 75091526459)
	Pharmacological Group	Prostaglandin F2 alpha analogue/ hormones
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	I-Dalmadin Injection (**2ml**) of M/s International Pharma Labs. Lahore. (Reg. No. 094453)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023

	Remarks of the Evaluator	**Liquid Injection Hormone (Veterinary) Section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
653.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Selprost injection 2ml
	Composition	Each ml contains: D-Cloprostenol Eq. to D-Cloprostenol Sodium…0.075mg
	Diary No. Date of R& I & fee	Dy.No 28343 dated 08-12-2023 Rs 30,000/- dated 29-11-2023 (slip No. 429494876335)
	Pharmacological Group	Prostaglandin F2 alpha analogue/ hormones
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2ml: Decontrolled
	Me-too status	I-Dalmadin Injection (2ml) of M/s International Pharma Labs. Lahore. (Reg. No. 094453)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Liquid Injection Hormone (Veterinary) Section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

Case no. 03 Registration applications of import cases

a. New Cases (Veterinary)

654.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5798 Dated 01-03-2023
	Fee including differential fee	Rs : 150,000 Dated 22-02-2023(slip No. 8866474830)
	Brand Name +Dosage Form + Strength	MS-Tylodoxy Powder
	Composition	Each 100gm contains: Tylosin Tartrate…20gm Doxycycline Hyclate…20gm
	Finished Product Specification	CVP

	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	0.5Kg, 1Kg, 5Kg
	International availability	Afghanistan, Nigeria, Kuwait, Egypt, Syria, Jordan
	Me-too status	Doximac-Forte Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore (Reg. No. 080927)
	Detail of certificates attached	➢ Scanned copy of COPP No. 2021-00623 dated 20-12-2021 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Calves, poultry **Shortcomings:** • Copy of valid DSL • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP, since already submitted is scanned copy.**	
655.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5797 Dated 01-03-2023
	Fee including differential fee	Rs : 150,000 Dated 22-02-2023(slip No. 564766330629)
	Brand Name +Dosage Form + Strength	MS-Penstrep Injection
	Composition	Each ml contains: Procaine Penicillin G…200,000 IU Dihydrostreptomycin as Sulphate…200mg
	Finished Product Specification	CVP
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml, 100ml, 500ml

	International availability	Bangladesh, Afghanistan, Libya, Syria, Kenya, Philippines, Turkey
	Me-too status	Strepto 400 Injection of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119718)
	Detail of certificates attached	➢ Scanned copy of COPP No. 2020-00146 dated 10-11-2020 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5% RH) and 24-month real time **(25±2ºC/ 60±10%RH)** stability studies data of three batches. **Shortcomings:** **Target species:** Cattle, calves, goats, sheep **Shortcomings:** • Copy of valid DSL • Choice of only one pack size • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • Long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • Confirmation of **dedicated manufacturing facility for penicillin production lines**
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Choice of only one pack size** • **In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP, since already submitted is scanned copy.** • **Long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life.** • **Confirmation of dedicated manufacturing facility for penicillin production lines**	
656.	Name and address of Applicant	M/s ASN Healthcare Pvt. Ltd., Suit No. 405, 4th Floor, Wind song Place, Block-7/8, K.C.H.S Union, Shahrah-e-Faisal, Karachi, Pakistan.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name and address of marketing authorization holder	M/s Henan Muxiang Veterinary Pharmaceutical Co., Ltd. Konggang Wu Road, Xinzheng Comprehensive Bonded Zone, Zhengzhou, P.R. China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5796 Dated 01-03-2023
	Fee including differential fee	Rs : 150,000 Dated 22-02-2023(slip No. 3703078192)

	Brand Name +Dosage Form + Strength	MS-Multivita-Inj Injection
	Composition	Each ml contains: Vitamin A…4,000 IU Vitamin D3…4,000 IU Vitamin E…4mg Vitamin B12…0.0725mcg Vitamin C…1mg Vitamin B1…8mg Vitamin B6…2.4mg Vitamin B2…3mg Vitamin B3…25mg D. Panthenol…10mg D. Biotin…10µg
	Finished Product Specification	CVP
	Pharmacological Group	Vitamin and trace element
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml, 100ml, 500ml
	International availability	Afghanistan, Bangladesh, Nigeria, Kuwait, Turkey, Kenya, Egypt, Qatar
	Me-too status	Multina Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 049512) **Could not be confirmed in the applied strength and combination**
	Detail of certificates attached	➢ Scanned copy of COPP No. 2020-00023 dated 20-09-2019 issued by Zhengzhou bureau of animal husbandry, P.R. China confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Letter of authorization (LOA) is **not provided.**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** • Copy of valid DSL • Original notarized letter of authorization (LOA) from PLH. • Original legalized valid CoPP, since already submitted is scanned copy. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Choice of only one pack size
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original notarized letter of authorization (LOA) from PLH.** • **Original legalized valid CoPP, since already submitted is scanned copy.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size**	
657.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore.

		Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6360 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 79890632)
	Brand Name +Dosage Form + Strength	Colistin 6M Oral Powder
	Composition	Each gram Contains: Colistin as Sulphate…6,000,000 IU
	Finished Product Specification	
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Lebanon, Russia, Dubai
	Me-too status	Elecol Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 118625)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003618 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Original legalized GMP certificate No. 5/5/10/003095 dated 11-04- 2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. ➢ Original legalized letter of authorization (LOA) dated 01-04-2018, issued in the name of applicant by PLH
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry, lambs, calves **Shortcomings:** • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since already submitted certificates are expired now but valid upon submission.

		• In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.** • **Original legalized valid FSC and GMP certificate, since already submitted certificates are expired now but valid upon submission.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
658.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore. Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6359 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 8973214821)
	Brand Name +Dosage Form + Strength	Doxycycline-50 Water Soluble Powder
	Composition	Each gram contains: Doxycycline HCl…500mg
	Finished Product Specification	
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Lebanon
	Me-too status	Vetroxin Oral Water Soluble Powder of M/s Athan Pharmaceuticals, Hattar (Reg. No. 115052)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003616 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Copy of GMP certificate No. 5/5/10/003095 dated 11-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. (**Original in Colistin 6M Oral Powder**) ➢ Scanned copy of legalized letter of authorization (LOA)

		dated 01-04-2018, issued in the name of applicant by PLH (**Original in Colistin 6M Oral Powder**)
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry **Shortcomings:** • Form 5A is not attached in the dossier. • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since already submitted certificates are expired now but valid upon submission. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **Original signed Form 5A** • **Copy of valid DSL** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.** • **Original legalized valid FSC and GMP certificate, since already submitted certificates are expired now but valid upon submission.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
659.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore. Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6358 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 4222019594)
	Brand Name +Dosage Form + Strength	Amoxycillin 50 Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…500mg
	Finished Product Specification	
	Pharmacological Group	Antibiotic
	Shelf life	3 years

	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Saudi Arabia, Dubai
	Me-too status	Amoxinal 50% Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 069626)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003617 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Copy of GMP certificate No. 5/5/10/003095 dated 11-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. (**Original in Colistin 6M Oral Powder**) ➢ Scanned copy of legalized letter of authorization (LOA) dated 01-04-2018, issued in the name of applicant by PLH (**Original in Colistin 6M Oral Powder**)
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry, Sheep, goats, calves, foals **Shortcomings:** • Form 5A is not attached in the dossier. • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and relevant GMP certificate, since already submitted certificates are expired now but valid upon submission. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise
	Decision: Deferred for submission of following: • **Original signed Form 5A** • **Copy of valid DSL** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.** • **Original legalized valid FSC and relevant GMP certificate, since already submitted certificates are expired now but valid upon submission.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise**	
660.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022

		Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s S.P. Veterinaria. S.A. Crta. Reus-Vinyols, 4.1 km, P.O.Box. 60, 43330 Riudmos Tarragona, Spain.
	Name and address of marketing authorization holder	M/s Cenavisa S.L. Cami Pedra Estela, s/n 43205 Reus, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 9815 Dated 12-04-2023
	Fee including differential fee	Rs : 1,50,000 Dated 27-03-2023 (slip No. 5452228428)
	Brand Name +Dosage Form + Strength	Amoxal 150mg/ml Injectable Suspension
	Composition	Each ml contains: Amoxicillin (Trihydrate)…150mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	Taiwan
	Me-too status	Amoxizon 15% LA Injection of M/s. Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. (Reg. No. 119713)
	Detail of certificates attached	➢ Original legalized Certificate No. 2022/21 Issued on 14-01-2022, Certified by Spanish agency of Medicines and Medical Devices, Spain confirms Authorization to manufacture and sell in Spain and to export. (**Non-commercialized, administrative status: Suspended**) ➢ Original legalized GMP Certificate No. ES/121HV/21 Issued on 13-08-2021, Certified by Spanish agency of Medicines and Medical Devices, Spain confirms GMP status of the manufacturer (**scope of submitted GMP certificate covers beta lactam production line**). Valid till 17-06-2023 ➢ Original legalized agency agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Cows, Sheep, dogs, cats **Shortcomings:** • Choice of only one pack size • Original legalized valid GMP certificate, since already submitted certificate is **expired now but valid upon submission.** • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are

		manufactured in same section or otherwise
	Decision: Deferred for submission of following: • **Choice of only one pack size** • **Original legalized valid GMP certificate, since already submitted certificate is expired now but valid upon submission.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise**	
661.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s FM Pharma d.o.o.Beli golub 20, Palic, Republic of Serbia
	Name and address of marketing authorization holder	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name of exporting country	Republic of Serbia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17320 Dated 11-07-2023
	Fee including differential fee	Rs : 1,50,000 Dated 26-05-2023 (slip No. 935722059672)
	Brand Name +Dosage Form + Strength	Nepstrep L.A Injectable Suspension
	Composition	Each ml contains: Benzathine-Benzyl Penicillin…80,000 i.j Benzyl Penicillin-Procaine…120,000 i.j Dihydrostreptomycin Sulphate…200mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Republic of Bosnia and Herzegovina, Republic of Bulgaria, Republic of North Macedonia.
	Me-too status	Combicillin-LA Injection of M/s. Atzan Pharmaceuticals, Sargodha (Reg. No. 049534) Long Acting PPS. Injection of M/s Selmore Agencies Lahore (Reg. No. 016291) **Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original legalized COPP Certificate No. 323-00-00273-2022-6-005/1 dated 22-09-2022, Certified by Republic of Serbia Medicines and Medical Devices, agency of Serbia confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Original legalized GMP Certificate No. 46 issued on 21-01-2021, by authorization of the minister responsible for veterinary affairs Ministry of the republic of Serbia confirms GMP status of the manufacturer (**scope of submitted GMP certificate does not cover beta lactam**

		production line). ➢ Original legalized agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Horse, cattle, Sheep **Shortcomings:** • Original legalized valid GMP certificate having scope of penicillin production line • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise • Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.
	Decision: Deferred for submission of following: • **Original legalized valid GMP certificate having scope of penicillin production line** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise** • **Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.**	
662.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s FM Pharma d.o.o.Beli golub 20, Palic, Republic of Serbia
	Name and address of marketing authorization holder	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name of exporting country	Republic of Serbia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17317 Dated 11-07-2023
	Fee including differential fee	Rs : 1,50,000 Dated 26-05-2023 (slip No. 1935718880)
	Brand Name +Dosage Form + Strength	Neoceftiofur HCl 5% Solution for Injection
	Composition	Each ml contains: Ceftiofur HCl…50mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic

	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Republic of Bosnia and Herzegovina, Republic of Bulgaria, Republic of North Macedonia, Republic of Albania.
	Me-too status	Cef 5.0 Injection of M/s Atzan Pharmaceuticals, Sargodha. (Reg. No. 118470)
	Detail of certificates attached	➢ Original legalized COPP Certificate No. 323-00-00272-2022-6-005/1 dated 22-09-2022, Certified by Republic of Serbia Medicines and Medical Devices, agency of Serbia confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Scanned copy of legalized GMP Certificate No. 46 issued on 21-01-2021, by authorization of the minister responsible for veterinary affairs Ministry of the republic of Serbia confirms GMP status of the manufacturer (**scope of submitted GMP certificate does not cover beta lactam production line**). ➢ Scanned copy of legalized agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-months real time stability studies data of three batches as per zone IV-A refrigerated condition. **Target species:** cattle **Shortcomings:** • Original legalized valid GMP certificate having scope of cephalosporin production line • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise • Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.
	Decision: Deferred for submission of following: • **Original legalized valid GMP certificate having scope of cephalosporin production line** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise** • **Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.**	
663.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s FM Pharma d.o.o.Beli golub 20, Palic, Republic of Serbia

	Name and address of marketing authorization holder	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name of exporting country	Republic of Serbia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17321 Dated 11-07-2023
	Fee including differential fee	Rs : 1,50,000 Dated 26-05-2023 (slip No. 818571981)
	Brand Name +Dosage Form + Strength	Neoprost 250µg/ml Solution for Injection
	Composition	Each ml contains: Cloprostenol as sodium…250µg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	Republic of Bosnia and Herzegovina, Republic of Bulgaria, Republic of North Macedonia.
	Me-too status	Cyclomate Injection of M/s. Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 118430)
	Detail of certificates attached	➢ Original legalized COPP Certificate No. 323-00-00271-2022-6-005/1 dated 22-09-2022, Certified by Republic of Serbia Medicines and Medical Devices, agency of Serbia confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Scanned copy of legalized GMP Certificate No. 46 issued on 21-01-2021, by authorization of the minister responsible for veterinary affairs Ministry of the republic of Serbia confirms GMP status of the manufacturer (**scope of submitted GMP certificate does not cover hormone production line**). ➢ Scanned copy of legalized agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Cow, Sheep, goats, mares **Shortcomings:** • Original legalized valid GMP certificate having scope of hormone production line • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.
	Decision: Deferred for submission of following: • **Original legalized valid GMP certificate having scope of hormone production line** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.**	

664.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name and address of marketing authorization holder	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name of exporting country	Republic of Serbia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17319 Dated 11-07-2023
	Fee including differential fee	Rs : 1,50,000 Dated 26-05-2023 (slip No. 81269012205)
	Brand Name +Dosage Form + Strength	Neorelin Solution for Injection
	Composition	Each ml contains: Buserelin…4µg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	Republic of Bosnia and Herzegovina, Republic of Bulgaria, Republic of North Macedonia.
	Me-too status	Bosol Injection of M/s. Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101516)
	Detail of certificates attached	➢ Original legalized COPP Certificate No. 323-00-00270-2022-6-005/1 dated 22-09-2022, Certified by Republic of Serbia Medicines and Medical Devices, agency of Serbia confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Scanned copy of legalized agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-months real time stability studies data of three batches as per zone IV-A refrigerated condition. **Target species:** Cow, Sheep, goats, mares, rabbits **Shortcomings:** • Original legalized valid GMP certificate having scope of hormone production line • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **Original legalized valid GMP certificate having scope of hormone production line** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
665.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad

	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s FM Pharma d.o.o.Beli golub 20, Palic, Republic of Serbia
	Name and address of marketing authorization holder	M/s FM Pharma d.o.o.Vuka Mandusica 39a, Subotica, Republic of Serbia
	Name of exporting country	Republic of Serbia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17318 Dated 11-07-2023
	Fee including differential fee	Rs : 1,50,000 Dated 26-05-2023 (slip No. 5788681745)
	Brand Name +Dosage Form + Strength	Neomectin 10mg/ml Solution for Injection
	Composition	Each ml Contains: Ivermectin…10mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Anthelmintic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Republic of Bosnia and Herzegovina, Republic of Bulgaria, Republic of North Macedonia.
	Me-too status	Ivozon 1% Injection of M/s. Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK (Reg. No. 119702)
	Detail of certificates attached	➢ Original legalized COPP Certificate No. 323-00-00274-2022-6-005/1 dated 22-09-2022, Certified by Republic of Serbia Medicines and Medical Devices, agency of Serbia confirms GMP status of the manufacturer as well as free sale status of the product in the exporting country. ➢ Scanned copy of legalized agreement dated 07-2021 between MAH and the applicant.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** cattle, Sheep **Shortcomings:** • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage and (iii) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.
	Decision: Deferred for submission of following: • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Clarification regarding manufacturing site, since the address mentioned on form 5A is different from that mentioned on CoPP.**	
666.	Name and address of Applicant	M/s Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore

	Detail of Drug Sale License	Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity: 13/11/2028 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/S. Alfasan International B.V., Kuipersweg 9, 3449 JA Woerden The Netherland
	Name and address of marketing authorization holder	M/S. Alfasan Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland
	Name of exporting country	The Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18514 Dated 24-07-2023
	Fee including differential fee	Rs : 150,000 Dated 12-07-2023(Slip No. 48778211280)
	Brand Name +Dosage Form + Strength	Ketamine 10% Solution for Injection
	Composition	Each ml Contains: **Ketamine as HCl**…100mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Anaesthetics
	Shelf life	4 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	Ketexx 100 mg/ml solution for injection (**Approved in Netherlands**)
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Original legalized COPP BD/2022/No. of Certificate 257951 dated 04-08-2022 certified by Medicines Evaluation Board Agency- Veterinary Medicinal Products Unit, Ministry of Economic Affairs, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Original legalized letter of exclusive sole distributor/ authorization dated: 05-05-2017
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 48-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Dogs, cats, horses, cattle, sheep, goats, laboratory animals • Ketamine and its salts have been declared as **"Psychotropic"** vide SRO No. 1350(I)/2021 dated 15-10-2021.
	Decision: Deferred for the submission of NOC from the Narcotic Control Division / relevant controlling authority.	
667.	Name and address of Applicant	M/s Lucky Core Industries Limited, 5 West Wharf Road Karachi.
	Detail of Drug Sale License	Name: M/s Lucky Core Industries Limited Address: 5 West Wharf Road, Karachi. Validity: **10-03-2026** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Intervet International GmbH, FeldstraBe 1a 85716 UnterschleiBheim, Germany

	Name and address of marketing authorization holder	M/s Intervet Deutschland GmbH FeldstraBe 1a 85716 UnterschleiBheim, Germany
	Name of exporting country	Germany
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 10031 Dated 14-04-2023
	Fee including differential fee	Rs: 75,000 Dated 14-04-2023 (slip N0. 5307617390)
	Brand Name +Dosage Form + Strength	Shutout 2.6gm Intramammary Suspension for Dry Cows (single dose LDPE intramammary syringe)
	Composition	Each 4gram intramammary syringe contains: Bismuth Subnitrate 2.6gm eq. to Bismuth.....1.858gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Various products for teat and udder. ATC vet code: QG52X
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	4 gram
	International availability	Fatroseal 2.6 g suspension for intramammary use for dry cows (Composition corresponding to Bismuthum .....1.858 g/piece) Approved in Netherland
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Originally legalized COPP No. 2678.Ph._12-66-99 dated 27-05-2022 certified by Regierung Von Oberbayern maximilianstraße 39 80538 München confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of power of attorney dated 12-04-2022 (not notarized from country of origin) from *M/s Intervet International B.V. Boxmeer The Netherlands* and M/s ***ICI Pakistan Limited, ICI house, 63- Mozang Road, Lahore.***
	Remarks of the Evaluator [XXV]	➢ Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle (dairy cows at drying-off) **Shortcomings:** • Provide valid notarized original Power of attorney/ distribution agreement between the applicant and PLH. • Clarification regarding PLH is required since M/s Intervet International B.V. Wim de Korverstraat 35 5831 AN Boxmeer The Netherlands is mentioned on form 5A and power of attorney while M/s Intervet Deutschland GmbH FeldstraBe 1a 85716 UnterschleiBheim, Germany is mentioned on CoPP. • Clarification regarding label claim is required since the quantity of Bismuth mentioned in CoPP is 1.9g/4g while on form 5A it is written as 1.858g/4g. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **valid notarized original Power of attorney/ distribution agreement between the applicant and PLH.** • **Clarification regarding PLH since M/s Intervet International B.V. Wim de Korverstraat 35**	

	5831 AN Boxmeer The Netherlands is mentioned on form 5A and power of attorney while M/s Intervet Deutschland GmbH FeldstraBe 1a 85716 UnterschleiBheim, Germany is mentioned on CoPP. • **Clarification regarding label claim is required since the quantity of Bismuth mentioned in CoPP is 1.9g/4g while on form 5A it is written as 1.858g/4g.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
668.	Name and address of Applicant	M/s Lucky Core Industries Limited, 5 West Wharf Road Karachi (Formerly M/s ICI Pakistan Limited)
	Detail of Drug Sale License	Name: M/s Lucky Core Industries Limited Address: 5 West Wharf Road, Karachi. Validity: **10-03-2026** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Intervet GesmbH, SiemensstraBe 107, 1210 Wien, Austria
	Name and address of marketing authorization holder	M/s Intervet GesmbH, SiemensstraBe 107, 1210 Wien, Austria
	Name of exporting country	Austria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 14085 Dated 06-06-2023
	Fee including differential fee	Rs: 150,000 Dated 05-06-2023 (slip N0. 47152608)
	Brand Name +Dosage Form + Strength	Revalor H 200/20 Implant
	Composition	Each Implant Contains: Trenbolone Acetate…200mg Estradiol…20mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Sex hormones and modulator of the genital system
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	-
	International availability	Revalor-200 (Health Canada approved)
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Originally legalized COPP No. 101573737 dated 29-12-2022 certified by Bundesamt für Sicherheit im Gesundheitswesen traisengasse 5 1200 Wien, Austria confirms GMP status of the manufacturer but **DOES NOT CONFIRM** free sale status of the product in the exporting country. ➢ Original legalized letter of authorization dated 06-10-2022 from *Intervet GesmbH, SiemensstraBe 107, 1210 Wien, Austria* and M/s ***ICI Pakistan Limited, ICI house, 63-Mozang Road, Lahore.***
	Remarks of the Evaluator [XXV]	**Target species:** Steers, heifers **Shortcomings:** • Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country • Provide valid legalized original GMP certificate, since the already submitted **copy is expired now but valid upon submission.** • Provide valid legalized original letter of authorization

		(LOA)/ distribution agreement. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • 06-month accelerated and real time stability studies data of three batches upto claimed shelf life at zone IV-A conditions. • Demanded pack size
	Decision: Deferred for submission of following: • **Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country** • **valid legalized original GMP certificate, since the already submitted copy is expired now but valid upon submission.** • **valid legalized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **06-month accelerated and real time stability studies data of three batches upto claimed shelf life at zone IV-A conditions.** • **Demanded pack size**	
669.	Name and address of Applicant	M/s Fair International Trading Co., A-129, Block 15, Gulistan e Johar Karachi, Pakistan.
	Detail of Drug Sale License	Name: M/s Fair International Address: 11, Al-Syed Arcade, 2nd Floor, Block 5, Gulshan-e-Iqbal, Karachi. Validity: **24-05-2024** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Cenavisa, S.L. Cami Pedra Estela, 43205-REUS, Spain
	Name and address of marketing authorization holder	M/s Cenavisa, S.L. Cami Pedra Estela, 43205-REUS, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18372 Dated 20-07-2023
	Fee including differential fee	Rs: 150,000 Dated 17-07-2023 (slip N0. 2801381030)
	Brand Name +Dosage Form + Strength	Cencoli 4,000,000 IU Oral Solution
	Composition	Each ml Contains: Colistin (as Sulphate)…4,000,000 IU
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1L, 5L
	International availability	Colicen 4,000,000 IU/ml Solution for drinking water (**Cimavet Spain approved**)
	Me-too status	**Could not be confirmed.**
	Detail of certificates attached	➢ Originally legalized COPP No. 2021/271 dated 25-03-2021 certified by Spanish agency of Medicines and Medical Devices, Spain confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate No. ES/002HV/21 dated 20.01.2021 certified by Certified by Spanish agency of Medicines and Medical Devices, Spain

		➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle (calves), sheep (lambs), chicken, and turkeys **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Clarification regarding address of the applicant, since two different addresses are mentioned on form 5A and DSL.
	Decision: Deferred for submission of following: • **valid notarized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Clarification regarding address of the applicant, since two different addresses are mentioned on form 5A and DSL.**	
670.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd., Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan.
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi Validity: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18907 Dated 27-07-2023
	Fee including differential fee	Rs: 150,000 Dated 20-06-2023 (slip N0. 4693817453)
	Brand Name +Dosage Form + Strength	Terrixine DC 250mg Intramammary Suspension For Dry Cows
	Composition	Each Unit contains: Cefalonium dihydrate as Cefalonium Base…250mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	3gm
	International availability	Terrixine DC 250mg Intramammary Suspension For Dry Cows (**Ireland approved**)
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Scanned copy of legalized COPP dated 15-05-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in

		country of origin. ➢ Scanned copy of legalized GMP certificate No. 29062/V10864 dated 01.02.2021 certified by HPRA Ireland having the scope of Beta lactam production lines. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise.
	Decision: Deferred for submission of following: • **valid notarized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise.**	
671.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd., Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan.
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi Validity: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18908 Dated 27-07-2023
	Fee including differential fee	Rs: 150,000 Dated 20-06-2023 (slip N0. 6264313062)
	Brand Name +Dosage Form + Strength	Terrixine LC 250mg Intramammary Suspension For Lactating Cows
	Composition	Each gram contains: Cephalexin Monohydrate…20mg Kanamycin Sulphate…13.33mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10gm
	International availability	Terrixine LC 250mg Intramammary Suspension for Lactating Cows (**Ireland approved**)

		Cephalexin Monohydrate…200mg/syringe Kanamycin Sulphate…100,000IU / syringe
	Me-too status	**Terrexine Intramammary Suspension of M/s Orient Animal Health (Pvt) Ltd., Karachi (Reg. No. 048128)**
	Detail of certificates attached	➢ Scanned copy of legalized COPP dated 15-05-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. 29062/V10864 dated 01.02.2021 certified by HPRA Ireland having the scope of Beta lactam production lines. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise. • Provide conversion of Kanamycin sulphate from IU to grams.
	Decision: Deferred for submission of following: • **valid notarized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise.** • **conversion of Kanamycin sulphate from IU to grams.**	
672.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zhummadian Huazhong Chia Tai. Jainshe Road 66, High Technology Development Zone, Zhumadian, Henan, China
	Name and address of marketing authorization holder	M/s Zhummadian Huazhong Chia Tai. Jainshe Road 66, High Technology Development Zone, Zhumadian, Henan, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17459 Dated 12-07-2023
	Fee including differential fee	**Rs : 75,000** Dated 05-07-2023(slip no. 7501895444)
	Brand Name +Dosage Form + Strength	Lincofit 11% Premix

	Composition	Each Kg Contains: Lincomycin as HCl…110gm
	Finished Product Specification	USP
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg, 5Kg, 10Kg, 25Kg, 50Kg
	International availability	Canada
	Me-too status	Linco-Mix 11 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113523)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate dated 17-02-2023 issued by Agriculture and rural affairs Bureau of Zhumadian city China Validity: 16-02-2027 ➢ Copy of legalized GMP Certificate No. (2022) SHOUYAO GMP16023 issued by Department of Agriculture and rural affairs of Henan Province China Date of issuance: 08-06-2022 Validity: 07-06-2027 ➢ Photocopy of Power of Attorney dated 23-02-2023 for the applied product (**Original in Lincofit 4.4 % Premix dossier**)
	Remarks of the Evaluator [XXV]	06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee for registration of generic drug product.
	Decision: Approved subject to compliance with current import policy. Firm shall submit differential fee for registration of generic drug product before issuance of registration letter.	
673.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zhummadian Huazhong Chia Tai. Jainshe Road 66, High Technology Development Zone, Zhumadian, Henan, China
	Name and address of marketing authorization holder	M/s Zhummadian Huazhong Chia Tai. Jainshe Road 66, High Technology Development Zone, Zhumadian, Henan, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17458 Dated 12-07-2023
	Fee including differential fee	**Rs : 75,000** Dated 05-07-2023 (slip no. 36261424864)
	Brand Name +Dosage Form + Strength	Lincofit 4.4 % Premix
	Composition	Each Kg Contains: Lincomycin as HCl…44gm
	Finished Product Specification	USP
	Pharmacological Group	Antibiotic
	Shelf life	3 years

	Demanded Price	Decontrolled
	Pack size	1Kg, 5Kg, 10Kg, 25Kg, 50Kg
	International availability	Canada
	Me-too status	Lincobar-44 Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No.088636)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate dated 17-02-2023 issued by Agriculture and rural affairs Bureau of Zhumadian city China Validity: 16-02-2027 ➢ Copy of legalized GMP Certificate No. (2022) SHOUYAO GMP16023 issued by Department of Agriculture and rural affairs of Henan Province China Date of issuance: 08-06-2022 Validity: 07-06-2027 ➢ Original Power of Attorney dated 23-02-2023 for the applied product
	Remarks of the Evaluator [XXV]	06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee for registration of generic drug product.
	Decision: Approved subject to compliance with current import policy. Firm shall submit differential fee for registration of generic drug product before issuance of registration letter.	
674.	Name and address of Applicant	M/s Hi-Tech Pharmaceuticals Pvt. Ltd., 1C Shadman Chowk Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Hi-Tech Pharmaceuticals Pvt. Ltd Address: 1C Shadman Chowk Jail Road, Lahore. Validity: 03-03-2028. Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name and address of marketing authorization holder	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name of exporting country	UK
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12376 Dated 10-05-2023
	Fee including differential fee	**Rs : 75,000** Dated 13-04-2023 (slip no. 31852794)
	Brand Name +Dosage Form + Strength	Fam 30 Dark Brown Liquid
	Composition	Each ml contains: Iodine Ph. Eur. …2.840%
	Finished Product Specification	Inhouse
	Pharmacological Group	Liquid idophor based disinfectant
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	25 L
	International availability	Denmark, Ireland, UK
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Apostille Free Sale Certificate dated 16-06-2022 issued by Health and Safety Executive (for an authorized biocidal product)

		➢ Copy of Apostille GMP Certificate No. VMDGMP/M075/2019 issued by Veterinary Medicines Directorate Date of issuance: 08-10-2019 ➢ Copy of distribution agreement dated April-2021 between the applicant and PLH.
	Remarks of the Evaluator [XXV]	**Indications for use:** General cleaning and disinfection, Livestock housing and fisheries, wheels and footbaths, aerial disinfection and disease control 06 months accelerated and 36 months long term stability studies data **has not been** submitted as per zone-IV-A conditions. **Shortcomings:** • The provided distribution agreement is copy**,** Provide notarized valid original agreement from product license holder. • 06 months accelerated and long term stability studies data upto complete shelf life as per zone-IV-A conditions.
	Decision: Approved for the usage as per the country of origin. **The firm will provide the notarised original agreement with product licence holder**	
675.	Name and address of Applicant	M/s Hi-Tech Pharmaceuticals Pvt. Ltd., 1C Shadman Chowk Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Hi-Tech Pharmaceuticals Pvt. Ltd Address: 1C Shadman Chowk Jail Road, Lahore. Validity: 03-03-2028. Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name and address of marketing authorization holder	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name of exporting country	UK
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12375 Dated 10-05-2023
	Fee including differential fee	**Rs : 75,000** Dated 13-04-2023 (slip no. 299783884)
	Brand Name +Dosage Form + Strength	Masofilm Liquid
	Composition	Each ml contains: Iodine Ph. Eur. …2.346%
	Finished Product Specification	Inhouse
	Pharmacological Group	Liquid idophor based teat dip disinfectant
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25L
	International availability	Germany, Ireland, Spain, UK
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Apostille Free Sale Certificate dated 16-06-2022 issued by Health and Safety Executive (for an authorized biocidal product)

		➢ Copy of Apostille GMP Certificate No. VMDGMP/M075/2019 issued by Veterinary Medicines Directorate Date of issuance: 08-10-2019 ➢ Copy of distribution agreement dated April-2021 between the applicant and PLH.
	Remarks of the Evaluator [XXV]	**Indications for use:** As a teat disinfectant for lactating dairy cows and in prevention and healing of cracked and chapped teats • accelerated and long term stability studies data **has not been** submitted as per zone-IV-A conditions. **Shortcomings:** • The provided distribution agreement is copy**,** Provide notarized valid original agreement from product license holder. • 06 months accelerated and long term stability studies data upto complete shelf life as per zone-IV-A conditions.
	Decision: Approved for the usage as per the country of origin. • **The firm will provide the notarised original agreement with product licence holder**	
676.	Name and address of Applicant	M/s Hi-Tech Pharmaceuticals Pvt. Ltd., 1C Shadman Chowk Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Hi-Tech Pharmaceuticals Pvt. Ltd Address: 1C Shadman Chowk Jail Road, Lahore. Validity: 03-03-2028. Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name and address of marketing authorization holder	M/s Evans Vanodine International Plc. Brierley Road, Walton Summit, Preston Lancashire, PR5 8AH, UK
	Name of exporting country	UK
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12377 Dated 10-05-2023
	Fee including differential fee	**Rs : 75,000** Dated 13-04-2023 (slip no. 0487622474)
	Brand Name +Dosage Form + Strength	Masocare 1:4 Liquid
	Composition	Each ml contains: Iodine Ph. Eur. …2.346%
	Finished Product Specification	inhouse
	Pharmacological Group	Concentrated Iodophor Based Teat dip & spray with 45% Glycerin & Sorbitol
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25L
	International availability	Germany, Ireland, Spain, UK
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Apostille Free Sale Certificate dated 09-12-2021 issued by Health and Safety Executive (for an authorized biocidal product)

		➢ Copy of Apostille GMP Certificate No. VMDGMP/M075/2019 issued by Veterinary Medicines Directorate Date of issuance: 08-10-2019 ➢ Copy of distribution agreement dated April-2021 between the applicant and PLH.
	Remarks of the Evaluator [XXV]	Accelerated and long term stability studies data **has not been** submitted as per zone-IV-A conditions. **Shortcomings:** • The provided distribution agreement is copy**,** Provide notarized valid original agreement from product license holder. • 06 months accelerated and long term stability studies data upto complete shelf life as per zone-IV-A conditions.
	Decision: Approved for the usage as per the country of origin. • **The firm will provide the notarised original agreement with product licence holder**	

b. Deferred cases (Import-Veterinary)

677.	Name and address of Applicant	M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Valid copy required
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550, Bulgaria (Manufacture)
	Name and address of marketing authorization holder	M/s Huvepharma NV. Uitbreidingstraat 80, 2600 Antwerpen, Belgium
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 4476 Dated 24-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 24-04-2019
	Brand Name +Dosage Form + Strength	Gallifen 200mg/ml Suspension for use in drinking water
	Composition	Each ml Contains: Fenbendazole…200mg
	Finished Product Specification	Not provided
	Pharmacological Group	Anthelmintic
	Shelf life	30 months
	Demanded Price	Decontrolled
	Pack size	1Liter, 2.5Liter and 5 Liter
	International availability	Gallifen 200 mg/ml suspension for use in drinking water (Federal Agency for Medicines and Health Products, **Belgium approved**)
	Me-too status	Not provided
	Detail of certificates attached	• Original legalized Certificate of Pharmaceutical Product Certificate No: BG 34/2018 Issued on: 10/07/2018, Certified by: Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria

		• Free sale of the product in exporting country: Yes, confirm from COPP • GMP status: conform to GMP as recommended by the WHO Periodicity of routine inspections: 2 years • Certificate of agreement dated between M/s HuvePharma EOOD, 3a Nikolay Haytov street 1113 Sofia, Bulgaria and M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan. **(Original legalized attached in Pharmasin WSG dossier)**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL since the already submitted copy is expired. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions. Only 24-months real time stability studies data has been submitted while the claimed shelf life is 30 months. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 322nd meeting: Deferred for following: a. Valid copy of DSL b. Finished product specifications in the light of decision taken in 267th meeting of Registration Board. c. Real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions. d. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 24-02-2028 • FPP specifications: Manufacturer's specifications • 06 months accelerated and 36 months real time stability studies data as per zone IV-B conditions. • Metoo status: Fenzole 20% Granules of M/s Star Laboratories (Pvt) Ltd., Lahore. 043211 • Curazole 10% Oral Drench of M/s Orient Animal Health (Pvt) Ltd., Karachi (Reg. No. 048125) **Shortcomings:** The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved subject to compliance with current import policy. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
678.	Name and address of Applicant	M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Valid copy required
	Name and address of manufacturer	Biovet Joint Stock Company

		39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550, Bulgaria (Manufacture)
	Name and address of marketing authorization holder	M/s Huvepharma NV. Uitbreidingstraat 80, 2600 Antwerpen, Belgium
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 7570 Dated 29-05-2019
	Fee including differential fee	Rs : 1,00,000 Dated 29-05-2019
	Brand Name +Dosage Form + Strength	Pharmasin 100% w/w Water Soluble Granules
	Composition	Each 1.1 gram granules contain: Tylosin Tartrate 110gm Eq. To Tylosin Activity…100gm
	Finished Product Specification	Not mentioned
	Pharmacological Group	Macrolide antibiotics
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	HDPE bottle 125gm, PE/Al/PET bag 125gm
	International availability	Pharmasin 100% w/w Water Soluble Granules (Federal Agency for Medicines and Health Products, **Belgium approved)**
	Me-too status	Not provided
	Detail of certificates attached	• Original legalized Certificate of Pharmaceutical Product Certificate No: BG 9/2019 Issued on: 29/01/2019, Certified by: Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria • Free sale of the product in exporting country: Yes, confirm from COPP • GMP status: conform to GMP as recommended by the WHO Periodicity of routine inspections: 2 years • Original legalized Certificate of agreement dated between M/s HuvePharma EOOD, 3a Nikolay Haytov street 1113 Sofia, Bulgaria and M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan.
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL since the already submitted copy is expired. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions; since the already submitted 36-months real

		time stability studies data is not as per zone IV-A/ IV-B conditions. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • "Demanded Pack size" is not mentioned in form-5A.
	Decision of 322nd meeting: Deferred for following: • Valid copy of DSL • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Demanded Pack size	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 24-02-2028 • FPP specifications: Manufacturer's specifications • 36 months real time stability studies data as per zone IV-A conditions. • **Metoo status:** Pri-Macrocid Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 080925) • I-Tosin Oral Solution of M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 069633) **Pack size**: 1.1Kg and 110g **Shortcomings:** The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved subject to compliance with current import policy. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
679.	Name and address of Applicant	M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan
	Detail of Drug Sale License	Valid copy required
	Name and address of manufacturer	Biovet Joint Stock Company 39, Petar Rakov St. 4500 Peshtera, Bulgaria (QC and Batch Release) 48 Vasil Petleshkov Str Peshtera 4550, Bulgaria (Manufacture)
	Name and address of marketing authorization holder	M/s Huvepharma NV. Uitbreidingstraat 80, 2600 Antwerpen, Belgium
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 7569 Dated 29-05-2019
	Fee including differential fee	Rs : 1,00,000 Dated 29-05-2019
	Brand Name +Dosage Form + Strength	Pharmasin 200mg/ml Solution for Injection
	Composition	Each 50ml Contains: Tylosin…10gm
	Finished Product Specification	Not mentioned
	Pharmacological Group	Macrolide antibiotics

	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Pharmasin 200mg/ml Solution for Injection (Federal Agency for Medicines and Health Products, **Belgium approved**)
	Me-too status	Not provided
	Detail of certificates attached	• Original legalized Certificate of Pharmaceutical Product Certificate No: BG 8/2019 Issued on: 29/01/2019, Certified by: Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry 15 Pencho Slaveikov Blvd. Sofia 1606, Bulgaria • Free sale of the product in exporting country: Yes, confirm from COPP • GMP status: conform to GMP as recommended by the WHO Periodicity of routine inspections: 2 years • Certificate of agreement dated between M/s HuvePharma EOOD, 3a Nikolay Haytov street 1113 Sofia, Bulgaria and M/s Saadat International, 117 Habitat Flat, Shadman II, Jail Road, Lahore, Pakistan. **(Original legalized attached in Pharmasin WSG dossier)**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL since the already submitted copy is expired. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions; since the already submitted 36-months real time stability studies data is not as per zone IV-A/ IV-B conditions. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • "Demanded Pack size" is not mentioned in form-5A.
	Decision of 322nd meeting: Deferred for following: • Valid copy of DSL • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Real time stability studies data upto claimed shelf life of three batches at zone IV-A/ IV-B conditions. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Demanded Pack size	
	Updated status: Updated status: The firm has submitted the following:	

	• Copy of DSL valid till 24-02-2028 • FPP specifications: **BP specifications** • 06 months accelerated and 36 months real time stability studies data as per zone II conditions and **12 months at intermediate conditions**. • Metoo status: Tylosin 20% Injection of M/s International Champharma Lahore • (Reg. No. 014200) **Shortcomings:** • Demanded pack size • The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved with 12 months shelf life subject to compliance with current import policy. The firm shall submit following before issuance of registration letter: • **fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Demanded pack size**	
680.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name and address of marketing authorization holder	M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea
	Name of exporting country	Korea
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 12863 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Melen-Pro Oral Powder
	Composition	Each gram contains: Melengestrol Acetate…0.22mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm, 5000gm, 10000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Originally legalized COPP No. M2015795 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea.

<table>
<tr><td></td><td></td><td>➢ Original legalized letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product.</td></tr>
<tr><td></td><td>Remarks of the Evaluator [X]</td><td>Firm has provided 24-month real time stability studies data of three batches at conditions 30ºC, 60% RH.
Target species:
Heifer
Shortcomings:
• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
• Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.</td></tr>
<tr><td></td><td colspan="2">Decision 334:
Deferred for following:
• Choice of only one pack size/ fill volume
• evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
• Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.
Firm reply is as under:
<table>
<tr><td>Decision of 334th meeting of RB</td><td>Firm Reply</td></tr>
<tr><td>Choice of only one pack size/ fill volume</td><td>Since product is oral powder hence the one pack size policy is not applicable here.</td></tr>
<tr><td>Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm</td><td>Not available</td></tr>
<tr><td>Both 06-month accelerated and real time stability studies data upto claimed shelf life, of three batches at zone IV-A conditions.</td><td>Firm has submitted Real time 24 months and accelerated 6 months stability data as per zone-iva.</td></tr>
</table>
• Submitted for consideration of the Board</td></tr>
<tr><td></td><td colspan="2">Decision of 336th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.</td></tr>
<tr><td></td><td colspan="2">Updated status: The applied formulation is approved in Health Canada with brand name MGA 100 premix</td></tr>
<tr><td></td><td colspan="2">Decision: Approved subject to compliance with current import policy.</td></tr>
<tr><td>681.</td><td>Name and address of Applicant</td><td>M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.</td></tr>
<tr><td></td><td>Detail of Drug Sale License</td><td>Name: M/s Ghazi Brothers
Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi
Validity: 29-06-2028.
Status: Drug License by way of Wholesale (Form No.7).</td></tr>
<tr><td></td><td>Name and address of manufacturer</td><td>M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea</td></tr>
<tr><td></td><td>Name and address of marketing authorization holder</td><td>M/s Dong Bang Co., Ltd., 22-75, Gunnae-Gil, Gosam-Myeon, Anseong-si, Gyeonggi-do, Korea</td></tr>
<tr><td></td><td>Name of exporting country</td><td>Korea</td></tr>
<tr><td></td><td>Type of Form</td><td>Form-5A</td></tr>
</table>

	Diary No. & Date of R& I	Dy.No 12864 Dated 03-05-2021
	Fee including differential fee	Rs: 50,000 Dated 03-05-2021
	Brand Name +Dosage Form + Strength	Prolin Injection
	Composition	Each ml contains: Dinoprost as Dinoprost Tromethamine…5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Hormone
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	10ml, 30ml
	International availability	N/A
	Me-too status	Dprost Liquid Injection (**5mL**) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088647) Heatafas Injection **(50mL**) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 087174)
	Detail of certificates attached	➢ Originally legalized COPP No. M2015798 dated 08-12-2020 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea confirms free sale status of the applied product in country of origin. ➢ Copy of GMP certificate dated 05.11.2019 certified by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea. (Original legalized in **Melen-Pro Oral Powder** dossier) ➢ Copy of letter of authorization (LOA) dated 10-11-2020 to M/s Ghazi Brothers Karachi from PLH for the applied product. (Original legalized in **Melen-Pro Oral Powder** dossier)
	Remarks of the Evaluator [X]	Firm has provided 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 10ml and 30ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • 06-month accelerated stability studies data of three batches at zone IV-A conditions.
	Decision of 334th meeting: Deferred for following: • Choice of only one pack size/ fill volume • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

	• 06-month accelerated stability studies data of three batches at zone IV-A conditions.	
	Updated status: The firm has submitted 06-month accelerated stability studies data of three batches at zone IV-A conditions **Shortcomings:** • Choice of only one pack size/ fill volume	
	Decision: Approved subject to compliance with current import policy. Firm shall choose only one pack size/fill volume before issuance of registration letter.	
682.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5863 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.1324799623)
	Brand Name +Dosage Form + Strength	Tilmi 250 Oral Solution
	Composition	Each ml contains: Tilmicosin…250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 500ml, 1000ml, 2000ml, 5000ml, 10000ml, 20000ml
	International availability	N/A
	Me-too status	Kptil Oral 25% Oral Liquid of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113415)
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 235/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**
	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL

		▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ The firm shall submit fee Rs. 150,000/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • fee Rs. 150,000/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 26-01-2029 • Original legalized Certificate of Pharmaceutical Product Certificate No. 244/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Shortcomings:** • fee Rs. 150,000/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 • 06 months accelerated stability studies data	
	Decision: Approved subject to compliance with current import policy. Firm shall submit following before issuance of registration letter: • **fee Rs. 150,000/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **06 months accelerated stability studies data**	
683.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam

	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5864 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.43570500736)
	Brand Name +Dosage Form + Strength	Amoxicol Water Soluble Powder
	Composition	Each gram contains: Amoxicillin as Trihydrate…200mg Colistin as Sulphate…2,000,000 IU
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	5gm, 10gm, 20gm, 50gm, 100gm, 200gm, 500gm, 1000gm, 5000gm, 10000gm, 20000gm, 25000gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 226/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**
	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL ▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Confirmation of dedicated manufacturing facility. ▪ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • Confirmation of dedicated manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

	• label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 26-01-2029 • Original legalized Certificate of Pharmaceutical Product Certificate No. 239/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Shortcomings:** • Confirmation of **dedicated manufacturing facility**. • 06 months accelerated stability studies data • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of following: • **Confirmation of dedicated manufacturing facility.** • **06 months accelerated stability studies data** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.**	
684.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5866 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.883803427499)
	Brand Name +Dosage Form + Strength	Doxiclin W.S.P
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100gm, 250gm, 500gm, 1000gm, 2000gm, 5000gm, 10000gm, 20000gm, 25000gm
	International availability	N/A

	Me-too status	Bio Doxine-50 Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 112173)
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 230/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**
	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL ▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 26-01-2029 • Original legalized Certificate of Pharmaceutical Product Certificate No. 241/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Shortcomings:** • 06 months accelerated stability studies data	
	Decision: Approved subject to compliance with current import policy. Firm shall submit 06 months accelerated stability studies data before issuance of registration letter.	
685.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company.

		Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5865 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.66579145768)
	Brand Name +Dosage Form + Strength	Enrovet Oral Solution
	Composition	Each ml contains: Enrofloxacin…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 500ml, 1000ml, 2000ml, 5000ml, 10000ml, 20000ml, 25000ml
	International availability	N/A
	Me-too status	Bovicin-20 Oral Solution of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 112149)
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 231/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**
	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL ▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following:	

	• Copy of DSL valid till 26-01-2029 • Original legalized Certificate of Pharmaceutical Product Certificate No. 242/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Shortcomings:** • 06 months accelerated stability studies data	
	Decision: Approved subject to compliance with current import policy. Firm shall submit 06 months accelerated stability studies data before issuance of registration letter.	
686.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5862 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.421999261884)
	Brand Name +Dosage Form + Strength	Flovet Oral Solution
	Composition	Each ml contains: Florfenicol…250mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 500ml, 1000ml, 2000ml, 5000ml, 10000ml, 20000ml, 25000ml
	International availability	N/A
	Me-too status	Floskill-25% Liquid of M/s Bioskils Pharmaceuticals, District Gujranwala. (Reg. No. 113511)
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 232/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**

	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL ▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 26-01-2029 • Original legalized Certificate of Pharmaceutical Product Certificate No. 243/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Shortcomings:** • 06 months accelerated stability studies data	
	Decision: Approved subject to compliance with current import policy. Firm shall submit 06 months accelerated stability studies data before issuance of registration letter.	
687.	Name and address of Applicant	M/s Ichhra Vety Medicine, Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore.
	Detail of Drug Sale License	Name: M/s Ichhra Vety Medicine Address: Shami Park No.177, Main Stop Chungi Amir Sidhu, Ferozpur Road, Lahore Validity: **19-12-2018** Status: License to sell, stock, exhibit for sale and distribute Drugs By Way of Wholesale (Form No.10).
	Name and address of manufacturer	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s Vietvet Pharmaceutical Joint Stock Company. Plot B103, Road 4, Thai Hoa Industrial Zone, Duc Lap Ha Commune, Duc Hoa District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 5861 Dated 03-03-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 02-03-2022 (slip No.79196980439)
	Brand Name +Dosage Form + Strength	Amoxivet L.A Suspension for Injection

	Composition	Each ml contains: Amoxicillin as Trihydrate…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-bacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml, 100ml, 250ml, 500ml, 1000ml
	International availability	N/A
	Me-too status	
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 227/20/QLT-CPP issued on 26/11/2020, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. Validity: 2 years ▪ Original notarized letter of authorization (LOA) is **Not provided.**
	Remarks of the Evaluator [X]	▪ 06 months accelerated and 24 months long term stability studies data **has NOT been** submitted as per zone-IV-A conditions. **Shortcomings:** ▪ Copy of valid DSL ▪ Original legalized valid COPP since the already submitted is expired now but valid upon submission. ▪ Original notarized valid letter of authorization (LOA) ▪ Provide accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. ▪ Confirmation of dedicated manufacturing facility. ▪ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ▪ Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. ▪ Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 331st meeting: Deferred for following: • Copy of valid DSL • Original notarized valid letter of authorization (LOA) • Both accelerated and long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • Confirmation of dedicated manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Choice of only one pack size • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 26-01-2029	

	• Original legalized Certificate of Pharmaceutical Product Certificate No. 240/23/QLT-CPP issued on 16/10/2023, certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site. • Original power of attorney dated 15-02-2024 • 24 months real time stability studies data as per zone IV-B conditions • Label for **100ml** pack in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Demanded pack size: 100ml **Shortcomings:** • Confirmation of **dedicated manufacturing facility**. • 06 months accelerated stability studies data • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of following: • **Confirmation of dedicated manufacturing facility.** • **06 months accelerated stability studies data** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.**	
688.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name and address of marketing authorization holder	M/s Zoopan-Produtos Pecuarios S.A. Rua Da Liberdade, 77, 2050-023 Aveiras De Baixo, Portugal
	Name of exporting country	Portugal
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 29610 Dated 18-10-2022
	Fee including differential fee	Rs : 150,000 Dated 03-10-2022 (slip No.66048168287)
	Brand Name +Dosage Form + Strength	Tilfur WS 1000 Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…1000mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100gm, 500gm and 1000gm
	International availability	N/A
	Me-too status	Tylokam-100 Soluble Powder of M/s M. A. Kamil Farma (Pvt) Ltd., Karachi. (Reg. No. 119729)

	Detail of certificates attached	➢ **Unattested photocopy** of CoPP No. 602/CMVPT/2022 certified by The General Directorate of Food and Veterinary for Importing country **EGYPT** ➢ Photocopy of declaration **(not legalized)** dated 10-08-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [X]	The firm **has not provided** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even legalized. • Provide legalized original valid CoPP since already submitted is unattested copy not issued for Pakistan. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.
	Decision of 336th meeting: Deferred for submission of following: • copy of valid DSL • Notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even notarized. • Legalized original valid CoPP since already submitted is unattested copy not issued for Pakistan. • 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions.	
	Updated status: The firm has submitted the following: • Copy of DSL valid till 14-10-2024 • Original legalized copy of CoPP No. 625/CMVPT/2022 certified by The General Directorate of Food and Veterinary confirms free sale status as well as GMP status of the manufacturer. • 06 months accelerated and 36 months real time stability studies data as per zone IV-A conditions **Shortcoming:** • Notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy not even notarized.	
	Decision: Deferred for submission of notarized original valid Letter of Authorization/ Sole agency certificate.	

Agenda of Mr. Salateen Waseem Philip

Mr. Salateen Waseem Philip

Item No. 01: Routine Cases.

689.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals. (DML # 000597)** **Plot No. 224 Sector 23 Korangi Industrial Area Karachi**
	Name, address of Manufacturing site.	**M/s High-Q Pharmaceuticals. (DML # 000597)** **Plot No. 224 Sector 23 Korangi Industrial Area Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11976 Dated: 16-05-2023
	Details of fee submitted	PKR 30,000/-: 17-04-2023 (Slip # 1648515765)
	The proposed proprietary name / brand name	Tablet BARITIB 2 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 2 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	Eli lily's peoduct
	Proposed Pack size	10's, 14's, 20's, 28's, 30's, 56's & 60's.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation
3.2.S.3	• Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) i. Enantiomeric separation. ii. Final crystallization. iii. Micronisation of the active substance.
3.2.S.4	• Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product?
	As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. i. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). ii. Malvern master sizer for determination of particle size. iii. Chromatographic column, Chiralpak ID for determination of R-isomer. iv. Chromatograms of related substance & residual solvents.
3.2.P.2	• Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.
3.2.P.8	• Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.

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

690.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals. (DML # 000597)** **Plot No. 224 Sector 23 Korangi Industrial Area Karachi**
	Name, address of Manufacturing site.	**M/s High-Q Pharmaceuticals. (DML # 000597)** **Plot No. 224 Sector 23 Korangi Industrial Area Karachi**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15114 Dated: 15-06-2023
	Details of fee submitted	PKR 30,000/-: 17-04-2023 (Slip # 6106407007)
	The proposed proprietary name / brand name	**Tablet BARITIB 4 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 4 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	Baritib 4 mg tablet by Jenner Pharma
	Proposed Pack size	10's, 14's, 20's, 28's, 30's, 56's & 60's.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation
3.2.S.3	• Please submit documented evidence for control on following critical process steps of manufacturing of API based on their impact on critical quality attributes (CQAs) i. Enantiomeric separation. ii. Final crystallization. iii. Micronisation of the active substance.
3.2.S.4	• Please justify that why water content test has not been made part of specifications for certificate of analysis by API manufacturer while it is a critical process parameter in drug substance profile of innovator product?
	As per the certificate of analysis of API submitted and performed by drug product manufacturer (High-Q Pharma) which shows that firm has performed all the required tests, please submit inspection report of your firm mentioning following QC instruments, required for the following tests. v. X-Ray Powder Diffraction (XPRD) for identity of polymorphic form (Modification I). vi. Malvern master sizer for determination of particle size. vii. Chromatographic column, Chiralpak ID for determination of R-isomer. viii. Chromatograms of related substance & residual solvents.
3.2.P.2	• Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.
3.2.P.8	• Please justify that why test of uniformity of dosage form has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.

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

691.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13936 Dated: 05-06-2023
	Details of fee submitted	PKR 75,000/-: 19-04-2023 (Slip # 91959122)
	The proposed proprietary name / brand name	**Tablet BARNIB 2 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 2 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation	Reply of the firm
1.6.5	Please submit GMP certificate of API supplier which should be valid till date and issued by regulatory authority of country of origin.	Submitted (valid till 01-03-2025)
3.2.S.3	Please submit stability data of API as per climatic condition of Pakistan (Temperature: 30°C ± 2°C & Humidity: 65% ± 5% RH).	As per decision of 297th DRB meeting, the firm has performed degradation studies conducted during stability program of Finished product. Firm has also provided record of data logger of API throughout transportation.
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Submitted

Decision: Approved.

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

692.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13935 Dated: 05-06-2023
	Details of fee submitted	PKR 30,000/-: 19-04-2023 (Slip # 07772371784)
	The proposed proprietary name / brand name	**Tablet BARNIB 4 mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 4 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation	Reply of the firm
1.6.5	Please submit GMP certificate of API supplier which should be valid till date and issued by regulatory authority of country of origin.	Submitted (valid till 01-03-2025)
3.2.S.3	Please submit stability data of API as per climatic condition of Pakistan (Temperature: 30°C ± 2°C & Humidity: 65% ± 5% RH).	As per decision of 297th DRB meeting, the firm has performed degradation studies conducted during stability program of Finished product. Firm has also provided record of data logger of API throughout transportation.
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Submitted

Decision: Approved.

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

693.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Private) Limited. (DML # 000782) Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Private) Limited. (DML # 000782) Plot No. 33, Sundar Industrial Estate, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6029 Dated: 03-03-2023
	Details of fee submitted	PKR 75,000/-: 21-02-2023 (Slip # 0291746621)
	The proposed proprietary name / brand name	**Tablet BARCINI 2 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 2 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)

	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	10's, 14's, 20's, 28's, 30's. *(Aluminum foil /ALU-ALU Blister)*
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation	Status
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Submitted
3.2.P.8	Submit Stability data of 06th month interval and re-submit stability data summary sheets for comparison of 0,3 & 6 month analytical results.	Submitted

Decision: Approved.

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

694.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Private) Limited. (DML # 000782) Plot No. 33, Sundar Industrial Estate, Lahore .**
	Name, address of Manufacturing site.	**M/s Horizon Healthcare (Private) Limited. (DML # 000782) Plot No. 33, Sundar Industrial Estate, Lahore .**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6030 Dated: 03-03-2023
	Details of fee submitted	PKR 75,000/-: 21-02-2023 (Slip # 660972336)
	The proposed proprietary name / brand name	**Tablet BARCINI 4 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Baricitinib …… 4 mg
	Pharmacotherapeutic Group of (API)	Janus Kinase Inhibitor (JAK)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Olumiant® USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO *(Aluminum foil /ALU-ALU Blister)*
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observation	Status
3.2.P.2	Please submit evidence for procurement of Tablet Olumiant, manufacturer's details and the quantity procured.	Submitted

3.2.P.8	Submit Stability data of 06th month interval and re-submit stability data summary sheets for comparison of 0,3 & 6 month analytical results.	Submitted

Decision: Approved.

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

695.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11240 Dated: 05-05-2023
	Details of fee submitted	PKR 30,000/-: 26-04-2023 (Slip # 15296248)
	The proposed proprietary name / brand name	**Tablet Eppra XR 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Levetiracetam …… 500 mg
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Lerace XR by Hilton Pharma
	Proposed Pack size	10's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Decision: Approved.

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

696.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)**

		Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11241 Dated: 05-05-2023
	Details of fee submitted	PKR 30,000/-: 26-04-2023 (Slip # 6651799687)
	The proposed proprietary name / brand name	**Tablet Eppra 750 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levetiracetam …… 750 mg
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Epicetam 750 mg Tablet by CCL
	Proposed Pack size	10's
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
697.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14392 Dated: 08-06-2023
	Details of fee submitted	PKR 30,000/-: 22-05-2023 (Slip # 68724714)
	The proposed proprietary name / brand name	**Tablet Odisar-V 10/320/25**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine Besylate equivalent to Amlodipine ……. 10 mg

		Valsartan ……. 320 mg Hydrochlorothiazide ……... 25 mg
	Pharmacotherapeutic Group of (API)	Combination of Calcium antagonist + ARB +Diuretic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	Exfore HCT® USFDA approved formulation
	For generic drugs (me-too status)	Exfore HCT® Novartis
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Submit GMP certificate of API manufacturers from Amlodipine, Valsartan & Hydrochlorthiazide issued by regulatory body of country of origin & should be valid till date.	Submitted
3.2.P.8	Submit Stability data of 06th month interval for the stability batches along with resubmission of stability data sheets summary for 0,3& 6 month intervals.	Submitted
	Submit material loan agreement for Amlodipine & Valsartan from Vision Pharma which should mention quantity of API used by vision Pharma, remaining quantity with vision pharma, quantity procured by Global Pharma, COA issued by Vision Pharma for APIs at the time of loan agreement.	Submitted

Decision: Approved.

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

698.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14390 Dated: 08-06-2023
	Details of fee submitted	PKR 30,000/-: 22-05-2023 (Slip # 239286746)
	The proposed proprietary name / brand name	**Tablet Odisar-V 10/160/12.5**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine Besylate equivalent to Amlodipine ……. 10 mg Valsartan ……. 160 mg Hydrochlorothiazide ……... 12.5 mg

	Pharmacotherapeutic Group of (API)	Combination of Calcium antagonist + ARB +Diuretic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	Exfore HCT® USFDA approved formulation
	For generic drugs (me-too status)	Exfore HCT® Novartis
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Submit GMP certificate of API manufacturers from Amlodipine, Valsartan & Hydrochlorthiazide issued by regulatory body of country of origin & should be valid till date.	Submitted
3.2.P.8	Submit Stability data of 06th month interval for the stability batches along with resubmission of stability data sheets summary for 0,3& 6 month intervals.	Submitted
	Submit material loan agreement for Amlodipine & Valsartan from Vision Pharma which should mention quantity of API used by vision Pharma, remaining quantity with vision pharma, quantity procured by Global Pharma, COA issued by Vision Pharma for APIs at the time of loan agreement.	Submitted

Decision: Approved.

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

699.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14391 Dated: 08-06-2023
	Details of fee submitted	PKR 30,000/-: 22-05-2023 (Slip # 179217469)
	The proposed proprietary name / brand name	**Tablet Odisar-V 10/160/25**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine Besylate equivalent to Amlodipine ……. 10 mg Valsartan ……. 160 mg Hydrochlorothiazide ……... 25 mg
	Pharmacotherapeutic Group of (API)	Combination of Calcium antagonist + ARB +Diuretic

	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	Exfore HCT® USFDA approved formulation
	For generic drugs (me-too status)	Exfore HCT® Novartis
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Submit GMP certificate of API manufacturers from Amlodipine, Valsartan & Hydrochlorthiazide issued by regulatory body of country of origin & should be valid till date.	Submitted
3.2.P.8	Submit Stability data of 06th month interval for the stability batches along with resubmission of stability data sheets summary for 0,3& 6 month intervals.	Submitted
	Submit material loan agreement for Amlodipine & Valsartan from Vision Pharma which should mention quantity of API used by vision Pharma, remaining quantity with vision pharma, quantity procured by Global Pharma, COA issued by Vision Pharma for APIs at the time of loan agreement.	Submitted

Decision: Approved.

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

700.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14389 Dated: 08-06-2023
	Details of fee submitted	PKR 30,000/-: 22-05-2023 (Slip # 9791048078)
	The proposed proprietary name / brand name	**Tablet Odisar-V 5/160/12.5**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine Besylate equivalent to Amlodipine ……. 5 mg Valsartan ……. 160 mg Hydrochlorothiazide ……... 12.5 mg
	Pharmacotherapeutic Group of (API)	Combination of Calcium antagonist + ARB +Diuretic
	Reference to Finished product specifications	USP Specification

	The status in reference regulatory authorities	Exfore HCT® USFDA approved formulation
	For generic drugs (me-too status)	Exfore HCT® Novartis
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Submit GMP certificate of API manufacturers from Amlodipine, Valsartan & Hydrochlorthiazide issued by regulatory body of country of origin & should be valid till date.	Submitted
3.2.P.8	Submit Stability data of 06th month interval for the stability batches along with resubmission of stability data sheets summary for 0,3& 6 month intervals.	Submitted
	Submit material loan agreement for Amlodipine & Valsartan from Vision Pharma which should mention quantity of API used by vision Pharma, remaining quantity with vision pharma, quantity procured by Global Pharma, COA issued by Vision Pharma for APIs at the time of loan agreement.	Submitted

Decision: Approved.

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

701.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Name, address of Manufacturing site.	**M/s Global Pharmaceuticals (Private) Limited. (DML # 000417)** **Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14529 Dated: 09-06-2023
	Details of fee submitted	PKR 30,000/-: 22-05-2023 (Slip # 6531263166)
	The proposed proprietary name / brand name	**Tablet Odisar-V 5/160/25**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine Besylate equivalent to Amlodipine ……. 5 mg Valsartan ……. 160 mg Hydrochlorothiazide …….. 25 mg
	Pharmacotherapeutic Group of (API)	Combination of Calcium antagonist + ARB +Diuretic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	Exfore HCT® USFDA approved formulation
	For generic drugs (me-too status)	Exfore HCT® Novartis

	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.6.5	Submit GMP certificate of API manufacturers from Amlodipine, Valsartan & Hydrochlorthiazide issued by regulatory body of country of origin & should be valid till date.	Submitted
3.2.P.8	Submit Stability data of 06th month interval for the stability batches along with resubmission of stability data sheets summary for 0,3& 6 month intervals.	Submitted
	Submit material loan agreement for Amlodipine & Valsartan from Vision Pharma which should mention quantity of API used by vision Pharma, remaining quantity with vision pharma, quantity procured by Global Pharma, COA issued by Vision Pharma for APIs at the time of loan agreement.	Submitted

Decision: Approved.

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

702.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Nabi Qasim Industries (Pvt) Ltd. (DML # 000105) 17/24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10834 Dated: 02-05-2023
	Details of fee submitted	PKR 30,000/-: 04-04-2023 (Slip # 4676090887)
	The proposed proprietary name / brand name	**Tablet Keptiron XR 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Levetiracetam …… 500 mg
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Lerace XR by Hilton Pharma
	Proposed Pack size	10's
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Decision: Approved.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
703.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt) Ltd. (DML # 000504)** **A-29 North West Industrial Zone Light Industrial Zone Port Qasim, Karachi.**
	Name, address of Manufacturing site.	**M/s PharmEvo (Pvt) Ltd. (DML # 000504)** **A-29 North West Industrial Zone Light Industrial Zone Port Qasim, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12099 Dated: 17-05-2023
	Details of fee submitted	PKR 75,000/-: 01-03-2023 (Slip # 88186724308)
	The proposed proprietary name / brand name	**Tablet Syntadol 50 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol HCl 58.24 mg equivalent to Tapentadol …… 50 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Locally registered for Dyson Pharma
	Proposed Pack size	7s,10s, 14s, 20s, 21s,28s,30s,56s,84s,100s,122s
	Proposed unit price	As per SRO
Evaluation by DD-PE&R: Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.		
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
704.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. (DML # 000267)** **Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Martin Dow Limited. (DML # 000267)** **Plot # 37, Sector 19, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14904 Dated: 13-06-2023
	Details of fee submitted	PKR 75,000/-: 02-06-2023 (Slip # 832585742224)

	The proposed proprietary name / brand name	**Tablet Dowtap 75 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol HCl equivalent to Tapentadol …… 75 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Tapento 75 mg Tablet by Sami Pharma
	Proposed Pack size	10 x 1s
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Section	Observations	Status
3.2.P.8	Submit Stability studies data for the 06th month interval along with relevant record/data.	Submitted

Decision: Approved with Innovator's specifications.

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

705.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo (Pvt) Ltd. (DML # 000504)** **A-29 North West Industrial Zone Light Industrial Zone Port Qasim, Karachi.**
	Name, address of Manufacturing site.	**M/s PharmEvo (Pvt) Ltd. (DML # 000504)** **A-29 North West Industrial Zone Light Industrial Zone Port Qasim, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11786 Dated: 15-05-2023
	Details of fee submitted	PKR 75,000/-: 01-03-2023 (Slip # 17077323)
	The proposed proprietary name / brand name	**Tablet Syntadol 100 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol HCl equivalent to Tapentadol …… 100 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification

	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Locally registered for Dyson Pharma
	Proposed Pack size	7s,10s, 14s, 20s, 21s,28s,30s,56s,84s,100s,122s
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:
Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Decision: Approved.

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

706.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Name, address of Manufacturing site.	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15390 Dated: 19-06-2023
	Details of fee submitted	PKR 75,000/-: 05-04-2023 (Slip # 215347702682)
	The proposed proprietary name / brand name	**Comfortol Absorba Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol …… 500 mg
	Pharmaco-therapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	10s,20s,2x7s, 4x7s,30s.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:
The applicant has applied formulation of Paracetamol with reference to innovator product **Panadol Advance.**
Panadol Advance 500 mg Tablets contain a disintegrant system which accelerates tablet dissolution compared to standard paracetamol tablets. Panadol Advance 500 mg Tablets generally start to disintegrate by 5 minutes' post dose in the stomach. (15 minutes' relief from pain by Panadol Advance by Optizorb formulation)
The applicant has performed Pharmaceutical equivalence of their drug product with **Panadol Optizorb (Haleon Italy).** Optizorb technology contains three main ingredients which are: alginic acid that draws fluid from the stomach into the tablet causing it to swell and break apart; calcium carbonate that works together with alginic acid to boost the disintegration of the tablet and, crospovidone which acts as a super-disintegrant due to its ability to dissolve well in water. The absorption of paracetamol occurs in the small intestine and as such is dependent on the

rate of emptying of stomach contents into the small intestine. Optizorb technology increases the gastric emptying time of the drug. The comparative dissolution profile shows more than 90% dissolution in at pH 1.2 at time interval 15 minutes for both innovator and applicant's product. As per the nature of formulation, some information / documents was requested from firm as under: -

Section	Observations	Reply of the firm
3.2.P.1	• Clarify that why preservatives (Methyl & Propyl Paraben) has been part of your formulation while it is not present in the innovator brand as well as your reference product (Panadol Optizorb 500 mg)	These preservatives are part of innovator formulation with the synonyms of hydroxybenzoates. http://www.panadol.com/en-au-adult-products/panadol-optizorb-tablets/
3.2.P.5.1	• In the specification, clarify along with reference that that why disintegration time limits have been set to NMT 30 minutes while innovator product claim for rapid disintegration is by 5 minutes?	Our product formulation is in accordance with the innovator's formulation. The results of disintegration test submitted in the dossier and in stability studies are less than 5 minutes. The 30 minutes disintegration time was a typographical error.
	• As per optizorb technology used by the innovator brand for the purpose of rapid disintegration to enhance dissolution profile so that the absorption of paracetamol occurs in the small intestine and as such is dependent on the rate of emptying of stomach contents into the small intestine, clarify along with reference that why specification defines limits of 30 minutes dissolution of NLT 80% while purpose of tablet is to absorb within 15 minutes of administration of tablet?	A concern to the dissolution, in the USP general chapter ***"The Dissolution procedure: Development & Validation <1092>"*** wherein ***(6.1 immediate release dosage form)*** it is mentioned that the dissolution profile data Q value of 80% should be set at the first time point where the average dissolution is at least 85%. However, this time point should not be less than 15 minutes (copy attached). This is why we have selected the Q value of 80% in less than 30 minutes. It is evident from the dissolution test and CDP results in phosphate buffer that the results are more than 85% in 15 & 30 minutes. However we are submitting the revised method of testing and specifications.

Decision: Approved.

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

707.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. (DML # 000498) Plot No. 5-D, Sector I-10/3 Islamabad.**
	Name, address of Manufacturing site.	**M/s Scotmann Pharmaceuticals. (DML # 000498) Plot No. 5-D, Sector I-10/3 Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14726 Dated: 12-06-2023
	Details of fee submitted	PKR 30,000/-: 05-04-2023 (Slip # 6298541726)
	The proposed proprietary name / brand name	**Comfortol Forte Suspension 100mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Paracetamol …… 100 mg

	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	TGA Australia approved formulation
	For generic drugs (me-too status)	Panadol infant drop 100mg/ml
	Proposed Pack size	30ml,60ml,90ml,100ml,120ml,250ml Amber color glass bottle packed in unit carton.
	Proposed unit price	As per SRO
Evaluation by DD-PE&R		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
708.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Name, address of Manufacturing site.	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15390 Dated: 19-06-2023
	Details of fee submitted	PKR 30,000/-: 05-04-2023 (Slip # 1531377828)
	The proposed proprietary name / brand name	**Comfortol Forte Suspension 120mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Paracetamol …… 120 mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Calpol Suspension 120mg/5ml
	Proposed Pack size	30ml,60ml,90ml,100ml,120ml,250ml Amber color glass bottle packed in unit carton.
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**		

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
709.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Name, address of Manufacturing site.	**M/s Scotmann Pharmaceuticals. (DML # 000498)** **Plot No. 5-D, Sector I-10/3 Islamabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15391 Dated: 19-06-2023
	Details of fee submitted	PKR 30,000/-: 05-04-2023 (Slip # 183407672)
	The proposed proprietary name / brand name	**Comfortol Forte Suspension 250mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Paracetamol …… 250 mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Panadol Forte Suspension 250mg/5ml
	Proposed Pack size	30ml,60ml,90ml,100ml,120ml,250ml Amber color glass bottle packed in unit carton.
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
710.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s ISIS Pharmaceutical & Chemical Works. (DML # 000126)** **25/1-3 Sector 12-C North Karachi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s ISIS Pharmaceutical & Chemical Works. (DML # 000126)** **25/1-3 Sector 12-C North Karachi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12727 Dated: 23-05-2023
	Details of fee submitted	PKR 30,000/-: 06-12-2022 (Slip # 740202143)
	The proposed proprietary name / brand name	**Kanamol Infusion 1g/100ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml contains: Paracetamol …… 1 G
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Bofalgan Infusion by Bosch Pharma
	Proposed Pack size	Glass Vial USP Type-I
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.6.5	Submit GMP certificate of API manufacturer issued by regulatory body of country of origin which should be valid till date.	Submitted
3.2.S.4	Clarify about COA of ISIS Pharma is for diclofenac sodium or Paracetamol?	Typographical mistake corrected
3.2.P.3	Submit validation protocol including each and every step from dispensing, manufacturing, filling till packaging of Paracetamol infusion.	Submitted
3.2.P.7	Clarify the nature of primary container of drug product (Glass vial type I or type –II / plastic bag/ plastic bottle or any other)	Submitted
3.2.P.8	Clarify that why osmolality test has not been made part of stability studies of drug product?	Stability summary submitted

Decision: Approved.

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

711.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shrooq Pharmaceuticals (Pvt) Ltd. (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Name, address of Manufacturing site.	**M/s Shrooq Pharmaceuticals (Pvt) Ltd. (DML # 000577) 21-Km Ferozepur Road Near Masjid Ibrahim Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15968 Dated: 23-06-2023
	Details of fee submitted	PKR 30,000/-: 04-03-2022 (Slip # 7912799270)
	The proposed proprietary name / brand name	**Panono Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Palonosetron HCl equivalent to Palonosetron …… 0.25mg
	Pharmacotherapeutic Group of (API)	5HT3 Antagonist
	Reference to Finished product specifications	Innovator Specification

	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Paloxi by Himmel (Import)
	Proposed Pack size	5ml Single use Sterile vial
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations	Status
1.3.4	Submit covering letter of grant/recent renewal of DML mentioning the details of section in your licensed manufacturing facility.	Submitted
3.2.P.3	Submit validation protocol including each and every step from dispensing, manufacturing, filling till packaging of Paracetamol infusion.	Submitted
3.2.P.7	Clarify the nature of primary container of drug product is vial or ampoule?	Submitted
3.2.P.8	• Please submit stability summary sheets as per format available at Page # 37-38 of DRAP guidelines for submission of CTD at official website **Link :** https://www.dra.gov.pk/wp-content/uploads/2022/01/Guidance-Document-on-CTD-Doc-No.-PER-GL-AF-004.pdf. • The shape of the peaks of chromatograms of initial month stability studies, reflecting that tailing factor & theoretical plates are out of limit. You are hereby advised to submit chromatograms with tailing factor and theoretical plate in the table containing readings of area and height of chromatogram. • Submit DRAP clearance documents for procurement of API.	Submitted

Decision: The Board deferred the case. The firm has been advised to perform one more time the assay test and submit fresh chromatograms with the table containing values of tailing factor, theoretical plates, resolution between peaks and other system suitability parameters.

712.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited (DML # 000016) Plot # F-319, Sindh Industrial Trading Estate, Karachi.**
	Name, address of Manufacturing site.	**M/s The Searle Company Limited (DML # 000016) Plot # F-319, Sindh Industrial Trading Estate, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 9382 Dated: 06-04-2023
	Details of fee submitted	PKR 75,000/-: 04-03-2022 (Slip # 55627728794)
	The proposed proprietary name / brand name	**Tablet Bliaxten kid 10 mg Orodispersible**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orodispersible tablet contains: Bilastine …… 10 mg
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Bilastine is a non-sedating, long-acting histamine antagonist with selective peripheral H1 receptor antagonist affinity and no affinity for muscarinic receptors. Bilastine inhibited histamine-induced wheal and flare skin reactions for 24 hours following single doses.
Pharmaceutical equivalence has been performed against Bilaxten kids 10 mg Orodispersible tablet manufactured by A. Menarini GmbH Zurich.

Decision: Approved.

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

713.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488)** **Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488)** **Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14745 Dated: 12-06-2023
	Details of fee submitted	PKR 30,000/-: 08-05-2023 (Slip # 28671289)
	The proposed proprietary name / brand name	**Dorzit Sterile ophthalmic solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Dorzolamide HCl …… 20mg Timolol maleate ……5 mg
	Pharmacotherapeutic Group of (API)	Carbonic anhydrase inhibitor + beta-adrenergic receptor blocking agent
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Cosopt Eye drops by OBS (import)
	Proposed Pack size	As per SRO (LDPE Plastic bottle)
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Section	Observations
3.2.S.4.4	As per Certificates of analysis of API (timolol & dorzolamide HCl) performed by Ophth Pharma, submit chromatograms and relevant data along with calculation sheets for determination of impurities.
3.2.P.1	Submit in tabulated form the comparison of your drug product formulation against innovator brand and clarify if any difference in excipients of formulation.
3.2.P.8	• Explain that why chromatogram table in the prints submitted doesn't contain area for the retention time near about 7 and also submit names, qualification and experience of QC manager and QA Manager who counterchecked this data before submission of dossier. • Submit water loss study data along with calculation sheets, print of weights etc.

Proceedings of the case:
The Board was apprised that the applicant has submitted application without following the DRAP's guidance document for submission of CTD application. After evaluating the stability data submitted by firm, it seems that the analyst doesn't possess basic knowledge of reading chromatograms / data presentation and there is no

counterchecking of chromatograms, calculation sheets by the QC manager. The reading of areas of peak at the specific retention time in the chromatograms considered for calculation, doesn't belong to the retention time of the peak of interest in the chromatograms. The formulation of drug product for inactive ingredients of applicant is totally different from the reference product they have mentioned in the dossier.		
Decision: The Registration Board while considering the disparities in the application and submitted data, decided to reject the instant registration application.		
714.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488)** **Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	**M/s Ophth-Pharma (Pvt) Ltd. (DML # 000488)** **Plot No. 241 Sector 24 Korangi Industrial Area Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14700 Dated: 12-06-2023
	Details of fee submitted	PKR 30,000/-: 08-05-2023 (Slip # 6866477147)
	The proposed proprietary name / brand name	**Eurofenac Plus injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2 ml contains: Diclofenac Sodium …… 75 mg Lidocaine Hcl ……20 mg
	Pharmacotherapeutic Group of (API)	NSAID + Local anesthetic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	Basel, Switzerland (not verified)
	For generic drugs (me-too status)	Articure by Global Pharma *(not verified)*
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by DD-PE&R: **Section** — **Observations** 1.5.9 Submit documented evidence / official website of regulatory authority of Switzerland for the reference of approved the reference product. 1.5.8 Submit registration no. , picture of the packing & relevant record to support your claim of me too status.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
715.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfield Pharmaceuticals. (DML # 000610)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Wnsfield Pharmaceuticals. (DML # 000610)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6421 Dated: 07-03-2023
	Details of fee submitted	PKR 30,000/-: 08-05-2023 (Slip # 6866477147)

	The proposed proprietary name / brand name	**Etiroxx 120 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib ……120 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation.
	For generic drugs (me-too status)	Starcox 120 mg Tablet
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
716.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. (DML # 000614)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Welmark Pharmaceuticals. (DML # 000614)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6548 Dated: 08-03-2023
	Details of fee submitted	PKR 30,000/-: 03-03-2023 (Slip # 8394492986)
	The proposed proprietary name / brand name	**OTORN 120 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib ……120 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation.
	For generic drugs (me-too status)	Starcox 120 mg Tablet
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved.		

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
717.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals. (DML # 000614)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Name, address of Manufacturing site.	**M/s Welmark Pharmaceuticals. (DML # 000614)** **Plot No. 122 Block-A Phase-V Industrial Estate Hattar.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6547 Dated: 08-03-2023
	Details of fee submitted	PKR 30,000/-: 03-03-2023 (Slip # 5805297993)
	The proposed proprietary name / brand name	**OTORN 90 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Etoricoxib ……90 mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	MHRA UK approved formulation.
	For generic drugs (me-too status)	Starcox 90 mg Tablet
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
718.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s City Pharmaceutical Laboratories. (DML # 000723)** **Plot No. 12(A) Survey No. 1-5, Sector 5 (New Survey No. 276)** **Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s City Pharmaceutical Laboratories. (DML # 000723)** **Plot No. 12(A) Survey No. 1-5, Sector 5 (New Survey No. 276)** **Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8494 Dated: 28-03-2023
	Details of fee submitted	PKR 30,000/-: 13-02-2023 (Slip # 35393405619)

	The proposed proprietary name / brand name	**Cefobact 1G IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for reconstitution)* Cefperazone sodium equivalent to Cefoperazone ……500 mg Salbactam Sodium …… 500 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin's
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Pfizer Italy
	For generic drugs (me-too status)	Cebac 1 gm injection by Bosch
	Proposed Pack size	USP Type III 30 ml glass vial contain powder for reconstitution)
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
719.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s City Pharmaceutical Laboratories. (DML # 000723) Plot No. 12(A) Survey No. 1-5, Sector 5 (New Survey No. 276) Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s City Pharmaceutical Laboratories. (DML # 000723) Plot No. 12(A) Survey No. 1-5, Sector 5 (New Survey No. 276) Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8495 Dated: 28-03-2023
	Details of fee submitted	PKR 30,000/-: 13-02-2023 (Slip # 979378533166)
	The proposed proprietary name / brand name	**Cefobact 2G IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: *(Powder for reconstitution)* Cefperazone sodium equivalent to Cefoperazone ……1000 mg Salbactam Sodium …… 1000 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin's
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	Pfizer Italy
	For generic drugs (me-too status)	Cebac 2 gm injection by Bosch

	Proposed Pack size	USP Type III 30 ml glass vial contain powder for reconstitution)
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
720.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Himark Laboratories (Pvt) Ltd. (DML # 000909) Plot No. 37-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	**M/s Himark Laboratories (Pvt) Ltd. (DML # 000909) Plot No. 37-A, Sunder Industrial Estate, Lahore.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 12861 Dated: 24-05-2023
	Details of fee submitted	PKR 30,000/-: 11-05-2023 (Slip # 155704028158)
	The proposed proprietary name / brand name	**Paxino 500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Panadol by GSK
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by DD-PE&R:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Item No. 02: <u>Deferred cases</u>

721.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851) Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.**
	Name, address of Manufacturing site.	**M/s Maxitech Pharma (Pvt) Ltd. (DML # 000851)**

		Plot No. Z-178, S.I.T.E Phase-II, Super Highway, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33814: 23-11-2022
	Details of fee submitted	PKR 75,000/-: 02-11-2022 (Slip # 22879641)
	The proposed proprietary name / brand name	**Tablet Tedilid 200 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tedizolid phosphate …… 200 mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP Specification

Deferred in 336th meeting of Drug Registration Board:
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
3.2.P.1	• Please justify that why overage of 5% added in the formulation?	No overage has been added. It was a typographical error. Firm submitted an undertaking that no overage has been used in manufacturing of batches.
3.2.P.3	• Please mention the critical process parameters and quality attributes necessary to focus during manufacturing of tablets.	Submitted
	• Please justify that why dry granulation method has been adopted while innovator brand manufactured by wet granulation?	Firm explained that in trial batches, dry granulation technique is more reliable and economical and test results also showed that drug product is stable.
	• Please explain the procedure of manufacturing for confirmation of good flow characteristics and good uniformity of formulation.	Submitted
	• Please mention the volume of coating solution, rate and temperature control by automated system?	Submitted
3.2.P.8	• Please mention the number of tablets manufactured per 0.40kg of batch size.	Submitted

Decision: Approved.

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

722.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Safe Pharmaceuticals (Pvt.) Ltd. (DML # 000349)** **Plot # C-120, Sector 6-B, North Karachi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	**M/s Safe Pharmaceuticals (Pvt.) Ltd. (DML # 000349)** **Plot # C-120, Sector 6-B, North Karachi Industrial Area, Karachi.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 31345: 02-10-2022
	Details of fee submitted	PKR 30,000/-: 26-08-2022 (Slip # 27884048499)
	The proposed proprietary name / brand name	**LIGNOCAINE HCL 1% 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Lignocaine (as HCl) … 10 mg
	Pharmacotherapeutic Group of (API)	Local anesthetic
	Reference to Finished product specifications	USP Specification

Deferred in 336th meeting of Drug Registration Board:
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by DD-PE&R:

Section	Observations	Reply of the firm
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Liquid Injection Ampoule (General) Section.	Submitted
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.	Submitted
3.2.P.2	Please submit the comparison of the results of the testing parameters of your drug product vs comparator product for confirmation of Pharmaceutical equivalence.	Submitted
3.2.P.5	It has been observed that BP specification has been claimed at Section 1.5.6 of Module I while analytical method and specification reflect USP pharmacopeia. It is therefore requested to submit stability data and testing parameters as per BP specification **OR** correct the mistake in section 1.5.6 of Module I along with submission of prescribed fee of PKR 7500/- for correction.	Submitted Slip # 47954736381
3.2.P.8	• Please submit complete six-month stability data of three batches for both accelerated and real time climatic conditions along with stability sheets / calculation sheets and raw data. • Please submit COA of API used in manufacturing of the stability batches.	Submitted

Decision: Approved.

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

723.	**Contract Giver Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Ltd. (DML # 000641) E-40 SITE Karachi.**

	Contract Acceptor Name, address of Manufacturing site.	**M/s Saffron Pharmaceuticals (Pvt.) Ltd (DML # 000616) 19-km Sheikhupura Road, Faisalabad.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34955 (dated: 02-12-2022)
	Details of fee submitted	PKR 75,000/-: dated: 18-05-2022 (Invoice # 101869042603)
	The proposed proprietary name / brand name	**Fluvista Nasal Spray 50 mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each actuation delivers: 100 mg suspension containing Fluticasone Propionate ……50 mcg
	Pharmaceutical form of applied drug	Nasal Spray
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*MHRA* approved formulation
	For generic drugs (me-too status)	Flixinase® by M/s GSK
	GMP status of the Finished product manufacturer	GMP certificate valid up to 02-01-2024 Nasal Spray (Steroid)
	Name and address of API manufacturer.	Name: M/s Aurisco Pharmaceutical Co. Ltd. Address: Badu Industrial Park Zone, Tiantai, Zheijiang China. GMP Validity: 07-09-2025
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Name: Flixonase 50 mcg Nasal Spray Manufacturer: GSK. Testing parameters: BP specifications
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA

Manufacturer of API	Name: M/s Aurisco Pharmaceutical Co. Ltd. Address: Badu Industrial Park Zone, Tiantai, Zheijiang China.		
API Lot No.	AF-B200701, AF-B-210503		
Description of Pack (Container closure system)	Spray will be filled in amber colored spray bottle with actuator, packed din card board carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	B#052	B#053	B#054
Batch Size	200 kg	200 kg	200 kg
Manufacturing Date	11/2021	01/2022	12/2021
Date of Initiation	19-11-2021	15-01-2022	26-02-2022
No. of Batches	03		

Administrative Portion

i.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
ii.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Provided
iii.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # 18885/2020-DRAP Dated: 24-12-2020 Quantity: 1.5 kg Invoice # 14797/2021-DRAP Dated: 05-10-2021 Quantity: 1.5 kg

iv.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
v.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
vi.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Deferred case of 331st meeting of Drug Registration Board:
Registration Board deferred the case for confirmation of required manufacturing facility / section (Nasal Spray - Steroid) approval letter issued by Licensing Division, DRAP.

Remarks of the Evaluator: Firm has submitted copy of letter for renewal of DML of Saffron dated 16-05-2024. The letter specifies regularization of Nasal Spray Section (Steroidal) - Regularization

Decision: Approved.

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

724.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals (DML # 000667)** **3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad.**
	Name, address of Manufacturing site.	**M/s Axis Pharmaceuticals (DML # 000667)** **3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 839: 10-01-2023
	Details of fee submitted	PKR 30,000/-: 22-12-2022 (Slip # 835612326247)
	The proposed proprietary name / brand name	**TABLET TAPONIX 75 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain-ns: Tapentadol …… 75 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator Specification

Evaluation by DD-PE&R:
Tapentadol is a mu-opioid agonist and is a Schedule II controlled substance declared by USFDA. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty.

Section	Observations	Reply of the firm
1.6.5	Please submit GMP certificate of API manufacturer issued by the regulatory authority of country of origin which should be valid till date.	Copy of valid GMP certificate & copy of valid manufacturing license (validity: 24-05-2025) submitted.

3.2.S.4	Please submit documented evidence that drug substance manufacturer has established method and facility to determine enantiomeric purity.	For the testing of Enantiomaric purity, Drug substance manufacturer has established a HPLC based method adopted from British Pharmacopoeia. Drug substance manufacturer had provided the list of instruments and Certificate of analysis confirming the performance of enantiomer purity.
3.2.P.1	• Please submit the details of excipients used in coating of the drug product ? also clarify thay why excipients used in reference product are not fully followed in your formulation ?	A detail of coating formulation is submitted Most of the excipient used in the formulation is as per reference product, only colloidal silicon dioxide is different from RLD product. The said ingredient is not novel and routinely used in development of tablet dosage form. Excipient compatibility study has been performed and already submitted. Copy of excipient compatibility study is submitted herewith. Annex-4
3.2.P.8	• Please submit stability summary sheets for the comparison of results between 0,3&6 months' stability studies as per format available on Page # 37-38 of **Guidance Document for Submission of Application On FORM 5-F (CTD) For Registration of Pharmaceutical Drug Products for Human Use available on official website of DRAP.** https://www.dra.gov.pk/wp-content/uploads/2022/01/Guidance-Document-on-CTD-Doc-No.-PER-GL-AF-004.pdf.	Stability summary is provided as per approved format. Copy of stability data up to 6 months is submitted herewith. Annex-5

Decision: Approved.

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

Item No. 03: New Licenses / Section

725.	**New Section** Central Licensing Board in its 278th meeting held on 10th & 11th December 2020 approved the grant of additional sections including Ointment / Cream / Gel (General).	
	Name, address of Applicant / Marketing Authorization Holder	**M/s Wezen Pharmaceuticals. (DML # 000882)** **Plot 23 & 24, S-1, RCCI Industrial estate, Rawat**
	Name, address of Manufacturing site.	**M/s Wezen Pharmaceuticals. (DML # 000882)** **Plot 23 & 24, S-1, RCCI Industrial estate, Rawat**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26693 Dated: 06-11-2023
	Details of fee submitted	PKR 75,000/-: 18-09-2023 (Slip # 4932186940)

	The proposed proprietary name / brand name	**REFMO 0.3% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of cream contains: Roflumilast …… 3 mg (0.3%)
	Pharmacotherapeutic Group of (API)	Phosphodiesterase 4 Inhibitor (treatment of plaque)
	Reference to Finished product specifications	Innovator Specification
	The status in reference regulatory authorities	ZORYVE ® USFDA approved formulation
	For generic drugs (me-too status)	N/A
	Proposed Pack size	60 grams' tube further packed in unit carton.
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

Source of API: **Glenmark Pharmaceutical, Plot # A-80, MIDC Area Kurkumbh, Taluk Daund, Dist. Pune, Maharashtra India.**

Section	Observation
3.2.S.4	In the COA submitted by Drug Substance manufacturer, why laser diffraction methodology to determine the PSD and its limits not mentioned?
3.2.S.7	In the material safety data sheet for powder of drug substance Roflumilast, the storage condition mentioned are <-15^{o}C while the stability data submitted is at Zone IV , please justify?
3.2.P.1	Roflumilast is light sensitive API, submit the precautionary measures taken for manufacturing facility.
3.2.P.2	Submit details of the manufacturer name & address of reference product along with document of procurement.
3.2.P.3	Submit the process validation conducted for cooling of manufacturing tank and temperature condition for maintaining viscosity of cream.
3.2.P.8	Please justify that why test of viscosity & microbial test has not been made part of your stability studies while it is major test for determination of factors impacting CQAs.

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

Agenda pattern for applications submitted on Form 5F for local manufacturing (self & contract)

726.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ferozsons Laboratories Limited, Amangarh, Nowshera, Khyber Pakhtunkhwa.**
	Name, address of Manufacturing site.	M/s. Ferozsons Laboratories Limited, Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 8327 dated 27-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 08740153 dated 16-03-2023.
	The proposed proprietary name / brand name	**Montekast Sachet 4mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast sodium eq. to Montelukast ….. 4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist (LTRAs)
	Reference to Finished productspecifications	USP Specifications.
	The status in reference regulatory authorities	Montelukast 4mg Sachet, USFDA Approved
	For generic drugs (me-too status)	Montika 4mg Sachet, M/s. SAMI Pharmaceuticals (Pvt) Ltd.
	Proposed Pack size and MRP.	5’s, 7’s, 10’s, 14k’s, 20’s, 30’s, MRP as per SRO.
Evaluation by PEC:		
Decision: Approved.		
727.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 7, Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s. Martin Dow Marker Limited 7, Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 8791 dated 30-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 79816945013 dated 21-03-2023.
	The proposed proprietary name / brand name	**Supramycin Capsule 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Doxycycline Hyclate …… 100mg
	Pharmacotherapeutic Group of (API)	Tetracycline Antibiotics.
	Reference to Finished product specifications	USP Specifications.

	The status in reference regulatory authorities	Doxycycline Capsule 100mg, MHRA-UK Approved
	For generic drugs (me-too status)	Alodox 100mg Capsule, Healthcare Pharmaceuticals (Pvt) Ltd. DRAP Registration # 104515
	Proposed Pack size and MRP.	As per SRO.
Evaluation by PEC: The submitted GMP Certificate of the API manufacturer states that it is for animal drugs.		
Decision: Deferred for submission of valid GMP / DML certificate of the API manufacturer from relevant regulatory authority of country of origin.		
728.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited 7, Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s. Martin Dow Marker Limited 7, Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 14082 dated 06-06-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 49612185 dated 26-05-2023.
	The proposed proprietary name / brand name	**Klaribact XL Tablet 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet Contains: Clarithromycin ….. 500mg
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Reference to Finished productspecifications	BP Specifications.
	The status in reference regulatory authorities	Clarithromycin 500mg Prolonged release tablet, MHRA (UK) Approved
	For generic drugs (me-too status)	Klaricid XL 500mg tablet, M/s. Abbot Laboratories (Pakistan) Ltd.
	Proposed Pack size and MRP.	As per DPC/SRO.
Evaluation by PEC:		
Decision: Approved.		
729.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Herbion Pakistan (Pvt) Ltd. Industrial Triangle, Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s. Herbion Pakistan (Pvt) Ltd. Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 13632 dated 01-06-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 569843649 dated 30-05-2023.

	The proposed proprietary name / brand name	**Tiglor 90mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ticagrelor ….. 90mg
	Pharmacotherapeutic Group of (API)	Platelets agregation inhibitor
	Reference to Finished productspecifications	BP Specifications.
	The status in reference regulatory authorities	Brilinta 90mg film coated tablet, (Astrazeneca Pharmaceuticals) US FDA Approved.
	For generic drugs (me-too status)	Anplag 90mg tablet, M/s. PharmEvo Private limited
	Proposed Pack size and MRP.	2 x 10's, MRP as per SRO.
Evaluation by PEC :		
Decision: Approved.		
730.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Focus & Rules Pharmaceuticals (Pvt) Ltd. 44-Industrial Triangle, Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s. Focus & Rules Pharmaceuticals (Pvt) Ltd. 44-Industrial Triangle, Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 5808 dated 01-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 734417422 dated 07-02-2023.
	The proposed proprietary name / brand name	**Lakas Sachet 4mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast sodium eq. to Montelukast ….. 4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist (LTRAs)
	Reference to Finished productspecifications	USP Specifications.
	The status in reference regulatory authorities	Montelukast 4mg Sachet, USFDA Approved
	For generic drugs (me-too status)	Mytika 4mg Sachet, M/s. Hilton Pharmaceuticals (Pvt) Ltd.
	Proposed Pack size and MRP.	As per SRO.
Evaluation by PEC:		
Decision: Approved.		
731.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Welmark Pharmaceuticals. Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s. Welmark Pharmaceuticals. Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 14084 dated 06-06-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 46623372 dated 29-05-2023.
	The proposed proprietary name / brand name	**Maglor 90mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ticagrelor ….. 90mg
	Pharmacotherapeutic Group of (API)	Platelets agregation inhibitor
	Reference to Finished productspecifications	BP Specifications.
	The status in reference regulatory authorities	Brilinta 90mg film coated tablet, (Astrazeneca Pharmaceuticals) US FDA Approved.
	For generic drugs (me-too status)	Anplag 90mg tablet, M/s. PharmEvo Private limited
	Proposed Pack size and MRP.	2 x 7's, MRP As per SRO.
Evaluation by PEC:		
Decision: Approved.		
732.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Welmark Pharmaceuticals.** **Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s. Welmark Pharmaceuticals. Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 15382 dated 19-06-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 504320685 dated 29-05-2023.
	The proposed proprietary name / brand name	**Maglor 60mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ticagrelor ….. 60mg
	Pharmacotherapeutic Group of (API)	Platelets agregation inhibitor
	Reference to Finished productspecifications	BP Specifications.
	The status in reference regulatory authorities	Brilinta 60mg film coated tablet, (Astrazeneca Pharmaceuticals) US FDA Approved.
	For generic drugs (me-too status)	Anplag 60mg tablet, M/s. PharmEvo Private limited
	Proposed Pack size and MRP.	2 x 7's, MRP As per SRO.

Evaluation by PEC:		
Decision: Approved.		
733.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. BJ Pharmaceuticals. Mandialai stop, Bhattianwala road, 18-km Lahore sheikhupura road, Lahore.**
	Name, address of Manufacturing site.	M/s. BJ Pharmaceuticals. Mandialai stop, Bhattianwala road, 18-km Lahore sheikhupura road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9201 dated 05-04-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 27603582 dated 21-04-2023.
	The proposed proprietary name / brand name	**Belfen DS Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension Contains: Ibuprofen ….. 200mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	Ibuprofen Twelve Plus pain relief 200mg/5ml suspension. (Manufactured by Aspire Pharma Ltd, UK) MHRA Approved.
	For generic drugs (me-too status)	Glare 200mg Susoension, M/s. Shrooq Pharmaceuticals.0
	Proposed Pack size and MRP.	60ml, 90ml, 120ml, 400ml. MRP As per SRO.

Evaluation by PEC:

Sr. No	Shortcomings / Observations
1.	• Submit Valid copy of Drug Manufacturing License (DML).
2.	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years.
3.	• Submit documents for the procurement of API with approval from DRAP, also submit valid GMP certificate of the API manufacturer.
4.	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required.

Decision: Approved. Firm shall submit valid GMP inspection certificate / inspection report before issuance of registration letter.		
734.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. AGP Limited. B-23-C, S.I.T.E, Karachi.**
	Name, address of Manufacturing site.	M/s. AGP Limited. B-23-C, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 8950 dated 03-04-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 4045848658 dated 21-02-2023.
	The proposed proprietary name / brand name	**IbuPara 200mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ibuprofen ….. 200mg Paracetamol ….. 500mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished productspecifications	AGP Specifications.
	The status in reference regulatory authorities	Nuromol Dual action pain relief 200mg/500mg film coated tablet, (Recket & Benckiser healthcare UK, Ltd) UK MHRA Approved.
	For generic drugs (me-too status)	Provas Duo 200mg/500mg tablet, M/s. Sami Pharmaceuticals Private limited.
	Proposed Pack size and MRP.	3 x 10's, MRP as per SRO.
Evaluation by PEC :		
Decision: Approved.		
735.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. AGP Limited.** **B-23-C, S.I.T.E, Karachi.**
	Name, address of Manufacturing site.	M/s. AGP Limited. B-23-C, S.I.T.E, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 9092 dated 04-04-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 2649143399 dated 21-02-2023.
	The proposed proprietary name / brand name	**IbuPara 150mg/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ibuprofen ….. 150mg Paracetamol ….. 500mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished productspecifications	AGP Specifications.
	The status in reference regulatory authorities	UK MHRA / EMA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size and MRP.	3 x 10's, 14's, 28's, MRP as per SRO.
Evaluation by PEC:		
Decision: Approved.		

736.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Citi Pharma (Pvt) Ltd. 3-km, Head Balloki Road, Phool Nagar, Kasur.**
	Name, address of Manufacturing site.	M/s. Citi Pharma (Pvt) Ltd. 3-km, Head Balloki Road, Phool Nagar, Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 5906 dated 02-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7508552417 dated 27-12-2022.
	The proposed proprietary name / brand name	**ASKPROL-IB TABLETS**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ibuprofen ….. 200mg Paracetamol ….. 500mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished productspecifications	Innovator's specificationsk
	The status in reference regulatory authorities	Nuromol Dual action pain relief 200mg/500mg film coated tablet, (Recket & Benckiser healthcare UK, Ltd) UK MHRA Approved.
	For generic drugs (me-too status)	Provas Duo 200mg/500mg tablet, M/s. Sami Pharmaceuticals Private limited.
	Proposed Pack size and MRP.	3 x 10's, MRP as per SRO.
Evaluation by PEC:		
Decision: Approved.		

Agenda of Mr. Adil Saeed

Routine Form 5F Cases PEC-IX

737.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8072: 22.03.2023
	Details of fee submitted	PKR 30,000/- : 8473316582
	The proposed proprietary name / brand name	**ONEC 100mg SR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each SR film coated tablet contains; Diclofenac sodium……..100mg

	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB05
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	DICLOFENAC SODIUM DEXCEL XL 100 MG PROLONGED-RELEASE TABLETS MHRA Approved.
	For generic drugs (me-too status)	Voltral 100mg SR Tablet
	Proposed Pack size	10's, 20's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
738.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15820: 22.006.2023
	Details of fee submitted	PKR 30,000/- : 08002335
	The proposed proprietary name / brand name	**BLARICID 250mg TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Clarithromycin…….250mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Clarithromycin 250 mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Claritek 250mg tablet
	Proposed Pack size	10's, 20's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
739.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15810: 22.06.2023
	Details of fee submitted	PKR 30,000/- : 2909856172
	The proposed proprietary name / brand name	**BLARICID 500mg TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Clarithromycin…….500mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Clarithromycin 500 mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Claritek 500mg tablet
	Proposed Pack size	10's, 20's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
740.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15821: 22.06.2023
	Details of fee submitted	PKR 30,000/- : 0356949311
	The proposed proprietary name / brand name	**B-Droxil 125mg/5ml** **Dry powder for suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefadroxil (as monohydrate)……125mg
	Pharmacotherapeutic Group of (API)	First-generation cephalosporins ATC Code: J01DB05
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	ORACEFAL 125 mg/ 5 ml, powder for oral suspension ANSM France
	For generic drugs (me-too status)	Duricef 125mg/5ml Suspension M/s GSK
	Proposed Pack size	60ml, 90ml, 120ml
Evaluation by PEC (No IX):		

S. No.	Observation	Reply
1	Section approval letter is required (for Cephalosporin Suspension)	The firm has stated that the section approval letter issued by

		Licensing Division dated 22.09.2019 has typographic error that Cephalosporin was not written infront of Oral Dry Powder section. They have applied in Licensing division for its correction.
2	Valid RRA reference is required.	Firm has given evidence of ORACEFAL 125 mg/ 5 ml, powder for oral suspension approved by ANSM France.

Decision: Deferred for submission of copy of required section approval letter issued by the Licensing Division.

741.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15822: 22.06.2023
	Details of fee submitted	PKR 30,000/- : 68782823
	The proposed proprietary name / brand name	**B-Droxil 250mg/5ml** **Dry powder for suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefadroxil (as monohydrate)……250mg
	Pharmacotherapeutic Group of (API)	First-generation cephalosporins ATC Code: J01DB05
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Cefadroxil 250 mg/5 ml granules for oral suspension (cefadroxil monohydrate) - UK/H/5172/002/DC; PL 34088/0033 MHRA Approved.
	For generic drugs (me-too status)	Duricef 250mg/5ml Suspension M/s GSK
	Proposed Pack size	60ml, 90ml, 120ml

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Section approval letter is required (for Cephalosporin Suspension)	The firm has stated that the section approval letter issued by Licensing Division dated 22.09.2019 has typographic error that Cephalosporin was not written infront of Oral Dry Powder section. They have applied in Licensing division for its correction.

Decision: Deferred for submission of copy of required section approval letter issued by the Licensing Division.		
742.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandiali Stop Bhattianwala Road, 18-KM Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8070: 22.03.2023
	Details of fee submitted	PKR 30,000/- : 716388072
	The proposed proprietary name / brand name	**BeMycin 250mg TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Erythromycin as Erythromycin Stearate…….250mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA01
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Erythrocin 250 Erythromycin 250mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Erythrocin 250mg Tablet
	Proposed Pack size	10’s, 20’s 30’s
Evaluation by PEC (No IX):		
Decision: Approved		
743.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13948: 05.06.2023
	Details of fee submitted	PKR 75,000/- : 37012214001
	The proposed proprietary name / brand name	**ROSCA-A 10mg/5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin (as calcium) ……10mg Amlodipine (as besyltate)……5mg
	Pharmacotherapeutic Group of (API)	HMG CoA-reductase inhibitor and Calcium channel blockers (ATC code: C10BX09)

	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Could not be verified
	For generic drugs (me-too status)	NA
	Proposed Pack size	7's 10's, 14's, 20's, 28's, 30's.

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Verifiable RRA reference is required. (Provided one is not verifiable from website of any RRA)	The firm has submitted a reference of Ireland vide letter No. RA/127/24 dated 18.07.2024 but it's not verifiable from HPRA Ireland website.
2	Copy of DML or GMP certificate of manufacturer of Rosuvastatin issued by relevant regulatory authority is required. (the GMP certificate submitted is issued by Pharmaceutical association)	Copy of DML issue by Guangdong Food and Drug Administration valid till 07.10.2026 is submitted.

Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.

1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.

2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.

3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.

4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

744.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13950: 05.06.2023
	Details of fee submitted	PKR 75,000/- : 182895854846
	The proposed proprietary name / brand name	**ROSCA-A 20mg/5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin (as calcium) ……20mg Amlodipine (as besyltate)……5mg
	Pharmacotherapeutic Group of (API)	HMG CoA-reductase inhibitor and Calcium channel blockers (ATC code: C10BX09)
	Reference to Finished product specifications	Innovator specifications

	The status in reference regulatory authorities	Could not be verified
	For generic drugs (me-too status)	NA
	Proposed Pack size	7's 10's, 14's, 20's, 28's, 30's.

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Verifiable RRA reference is required. (Provided one is not verifiable from website of any RRA)	The firm has submitted a reference of Ireland vide letter No. RA/127/24 dated 18.07.2024 but it's not verifiable from HPRA Ireland website.
2	Copy of DML or GMP certificate of manufacturer of Rosuvastatin issued by relevant regulatory authority is required. (the GMP certificate submitted is issued by Pharmaceutical association)	Copy of DML issue by Guangdong Food and Drug Administration valid till 07.10.2026 is submitted.

Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.

1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.

2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.

3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.

4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

745.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13949: 05.06.2023
	Details of fee submitted	PKR 75,000/- : 12580503946
	The proposed proprietary name / brand name	**ROSCA-A 10mg/10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin (as calcium) ……10mg Amlodipine (as besyltate)……10mg
	Pharmacotherapeutic Group of (API)	HMG CoA-reductase inhibitor and Calcium channel blockers (ATC code: C10BX09)
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Could not be verified

	For generic drugs (me-too status)	NA
	Proposed Pack size	7's 10's, 14's, 20's, 28's, 30's.

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Verifiable RRA reference is required. (Provided one is not verifiable from website of any RRA)	The firm has submitted a reference of Ireland vide letter No. RA/127/24 dated 18.07.2024 but it's not verifiable from HPRA Ireland website.
2	Copy of DML or GMP certificate of manufacturer of Rosuvastatin issued by relevant regulatory authority is required. (the GMP certificate submitted is issued by Pharmaceutical association)	Copy of DML issue by Guangdong Food and Drug Administration valid till 07.10.2026 is submitted.

Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.

1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.

2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.

3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.

4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

746.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd. Pakistan 44, 45b, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13951: 05.06.2023
	Details of fee submitted	PKR 75,000/- : 379296115083
	The proposed proprietary name / brand name	**ROSCA-A 20mg/10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin (as calcium) ……20mg Amlodipine (as besyltate)……10mg
	Pharmacotherapeutic Group of (API)	HMG CoA-reductase inhibitor and Calcium channel blockers (ATC code: C10BX09)
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Could not be verified
	For generic drugs (me-too status)	NA

	Proposed Pack size	7's 10's, 14's, 20's, 28's, 30's.

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Verifiable RRA reference is required. (Provided one is not verifiable from website of any RRA)	The firm has submitted a reference of Ireland vide letter No. RA/127/24 dated 18.07.2024 but it's not verifiable from HPRA Ireland website.
2	Copy of DML or GMP certificate of manufacturer of Rosuvastatin issued by relevant regulatory authority is required. (the GMP certificate submitted is issued by Pharmaceutical association)	Copy of DML issue by Guangdong Food and Drug Administration valid till 07.10.2026 is submitted.

Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.

1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.

2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.

3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.

4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15017: 14.06.2023
	Details of fee submitted	PKR 75,000/- : 61488360841
	The proposed proprietary name / brand name	**BREXIGLOB 0.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brexipiperazole……0.5mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics Code: N05AX16
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Rexulti 0.5mg, 1mg, 2mg & 4mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	30'S

Evaluation by PEC (No IX):		
Decision: Approved.		
748.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15018: 14.06.2023
	Details of fee submitted	PKR 75,000/- : 23859093
	The proposed proprietary name / brand name	**BREXIGLOB 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brexipiperazole……1mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics Code: N05AX16
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Rexulti 0.5mg, 1mg, 2mg & 4mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	30’S
Evaluation by PEC (No IX):		
Decision: Approved.		
749.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15019: 14.06.2023
	Details of fee submitted	PKR 75,000/- : 067767479
	The proposed proprietary name / brand name	**BREXIGLOB 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brexipiperazole……2mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics Code: N05AX16

	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Rexulti 0.5mg, 1mg, 2mg & 4mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	30'S
Evaluation by PEC (No IX):		
Decision: Approved.		
750.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15020: 14.06.2023
	Details of fee submitted	PKR 75,000/- : 0636929679
	The proposed proprietary name / brand name	**BREXIGLOB 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brexipiperazole……4mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics Code: N05AX16
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Rexulti 0.5mg, 1mg, 2mg & 4mg Tablets USFDA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	30'S
Evaluation by PEC (No IX):		
Decision: Approved.		
751.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15623: 20.06.2023
	Details of fee submitted	PKR 30,000/- : 9442420209

	The proposed proprietary name / brand name	**ESOLEX 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Escitalopram Oxalate eq to Escitalopram ……20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors Code: N06AB10
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	CIPRALEX 20MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Cipralex 20mg film coated tablets.
	Proposed Pack size	10's, 14's
Evaluation by PEC (No IX):		
Decision: Approved.		
752.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jaskan Pharmaceuticals (Pvt.) Ltd. Plot No. 50, Sunder Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceuticals (Pvt.) Ltd. Plot No. 50, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10033: 14.04.2023
	Details of fee submitted	PKR 30,000/- : 94190089
	The proposed proprietary name / brand name	**ZOSTA 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin calcium eq. Rosuvasatin….20mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	ROSUVASTATIN DAWA 20 MG FILM-COATED TABLETS - PL 30684/0333
	For generic drugs (me-too status)	Rovista 20mg Tablet
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
753.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7157: 13.03.2023
	Details of fee submitted	PKR 75,000/- : 78648830872
	The proposed proprietary name / brand name	**RECIQUAT 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vericiguat……2.5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	VERQUVO 2.5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	10's, 14's, 20's, 28's, 30's.
Evaluation by PEC (No IX):		
Decision: Approved.		
754.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8954: 03.04.2023
	Details of fee submitted	PKR 75,000/- : 725327940186
	The proposed proprietary name / brand name	**RECIQUAT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vericiguat……5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	VERQUVO 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	10's, 14's, 20's, 28's, 30's.
Evaluation by PEC (No IX):		
Decision: Approved.		
755.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.**

	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8955: 03.04.2023
	Details of fee submitted	PKR 75,000/- : 2680381717
	The proposed proprietary name / brand name	**RECIQUAT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vericiguat……10mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	VERQUVO 10MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	10's, 14's, 20's, 28's, 30's.
Evaluation by PEC (No IX):		
Decision: Approved.		
756.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech (Pvt.) ltd. Plot No. FD-49-A8, FD-50-A8, Korangi Creek Industrial Park, Karachi.**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) ltd. Plot No. FD-49-A8, FD-50-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6417: 07.03.2023
	Details of fee submitted	PKR 30,000/- : 46042669713
	The proposed proprietary name / brand name	**PINAVIL-M 50mg +500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vildagliptin……..50mg Metformin Hydrochloride…..500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD08
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet blister pack (161216) TGA Australia Approved.

	For generic drugs (me-too status)	Galvus-Met 50/500
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of AD attested invoice or clearance certificate of both drug substances is required.	Submitted vide letter No. PB/PEC/QR/Pinavil-M/072024 dated 11.07.2024
2	Copy of latest GMP inspection report/ certificate of drug product manufacturer is required.	Submitted.
3	Stability of drug product submitted is up to 3 months only. Stability data up to 6 months is required.	Submitted

Decision: Approved.

757.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pinnacle Biotech (Pvt.) ltd. Plot No. FD-49-A8, FD-50-A8, Korangi Creek Industrial Park, Karachi.**
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) ltd. Plot No. FD-49-A8, FD-50-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6418: 07.03.2023
	Details of fee submitted	PKR 30,000/- : 741953303
	The proposed proprietary name / brand name	**PINAVIL-M 50mg +1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vildagliptin……..50mg Metformin Hydrochloride…..1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD08
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	VILDAGLIPTIN/METFORMIN 50 MG/1000 MG FILM-COATED TABLETS - PL 16363/0731 MHRA Approved.
	For generic drugs (me-too status)	Galvus-Met 50/1000
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of AD attested invoice or clearance certificate of both drug substances is required.	Submitted vide letter No. PB/PEC/QR/Pinavil-M/072024 dated 11.07.2024
2	Copy of latest GMP inspection report/ certificate of drug product manufacturer is required.	Submitted.
3	Stability of drug product submitted is up to 3 months only. Stability data up to 6 months is required.	Submitted

Decision: Approved.

758.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15386: 19.06.2023
	Details of fee submitted	PKR 30,000/- : 984828694543
	The proposed proprietary name / brand name	**PROZYN Plus 3mg /25mg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Olanzapine…….3mg Fluoxetine as hydrochloride……25mg
	Pharmacotherapeutic Group of (API)	Olanzapine Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03 Fluoxetine Selective serotonin reuptake inhibitors ATC Code: N06AB03
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Symbax 25mg/3mg Capsule, Symbax 25mg/6mg Capsule, Symbax 50mg/6mg Capsule Symbax 25mg/12mg Capsule, Symbax 50mg/12mg Capsule USFDA Approved.
	For generic drugs (me-too status)	Co-depricap 3/25 capsule.
	Proposed Pack size	2x7's
Evaluation by PEC (No IX):		
Decision: Approved.		
759.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15387: 19.06.2023
	Details of fee submitted	PKR 30,000/- : 03887009788

	The proposed proprietary name / brand name	**PROZYN Plus 6mg /25mg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Olanzapine…….6mg Fluoxetine as hydrochloride……25mg
	Pharmacotherapeutic Group of (API)	Olanzapine Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03 Fluoxetine Selective serotonin reuptake inhibitors ATC Code: N06AB03
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Symbax 25mg/3mg Capsule, Symbax 25mg/6mg Capsule, Symbax 50mg/6mg Capsule Symbax 25mg/12mg Capsule, Symbax 50mg/12mg Capsule USFDA Approved.
	For generic drugs (me-too status)	Co-depricap 6/25 capsule.
	Proposed Pack size	2x7's
Evaluation by PEC (No IX):		
Decision: Approved.		
760.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (pvt.) Ltd. A-20, North Western Industrial Zone, Bin Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15385: 19.06.2023
	Details of fee submitted	PKR 30,000/- : 16566304028
	The proposed proprietary name / brand name	**PROZYN Plus 12mg /25mg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Olanzapine…….12mg Fluoxetine as hydrochloride……25mg
	Pharmacotherapeutic Group of (API)	Olanzapine Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH03 Fluoxetine Selective serotonin reuptake inhibitors ATC Code: N06AB03
	Reference to Finished product specifications	USP Specifications.

	The status in reference regulatory authorities	Symbax 25mg/3mg Capsule, Symbax 25mg/6mg Capsule, Symbax 50mg/6mg Capsule Symbax 25mg/12mg Capsule, Symbax 50mg/12mg Capsule USFDA Approved.
	For generic drugs (me-too status)	Co-depricap 12/25 capsule.
	Proposed Pack size	2x7's
Evaluation by PEC (No IX):		
Decision: Approved.		
761.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar.**
	Name, address of Manufacturing site.	M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13647: 01.06.2023
	Details of fee submitted	PKR 30,000/- : 372680590299
	The proposed proprietary name / brand name	**CEFTREX 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone as sodium…….2g
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Oxidil 2g IV Injection
	Proposed Pack size	
Evaluation by PEC (No IX):		

S. No.	Observation
1	Copy of latest GMP certificate or inspection report is required.
2	Evidence of approval of Ceph Dry powder injection section is required.
3	Copy of DML/GMP certificate of drug substance manufacturer is required.
4	Copy of AD attested invoice or clearance certificate of drug substance is required.
5	3.2.P.5: Why test of Particulate matter in injections is not made part of product specifications?
6	3.2.P.5.3: It is mentioned that system suitability will be verified by repeatability of retention time and peak area value of Ceftriaxone. USP monograph states that it should be such that The relative retention times for ceftriaxone and ceftriaxone E-isomer are 1.0 and 1.4, respectively. Why USP monograph is not followed in performing assay of the drug product?

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

762.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11787: 15.05.2023
	Details of fee submitted	PKR 75,000/- : 898469636012
	The proposed proprietary name / brand name	**VERICA 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vericiguat……2.5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	VERQUVO 2.5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA
	Proposed Pack size	10’s, 14’s, 20’s, 28’s, 30’s. 56’s, 60’s, 100’s, 150’s

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	3.2.P.2: The pharmaceutical equivalence submitted in dossier is of 10mg strength. Pharmaceutical equivalence of 2.5mg strength along with its CDP is required.	The firm has submitted their response vide letter No. nil dated 24.07.2024. The firm has submitted pharmaceutical equivalence and CDP studies against product Vericigaut 2.5mg Tablet manufactured by Bayer AG Germany.

Decision: Approved.

763.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6673: 09.03.2023
	Details of fee submitted	PKR 30,000/- : 7541734040
	The proposed proprietary name / brand name	**V-CITA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Escitalopram (as oxalate)……5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	For generic drugs (me-too status)	Cipralex 5mg tablet
	Proposed Pack size	14's

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of GMP certificate/ DML of drug substance manufacturer is required.	Firm has submitted their response vide letter No. VP/024/213 dated 22.07.2024 Copy of DML issued by Commissioner F&DCA Gujrat state India, valid till 31.12.2026 is submitted.
2	Copy of latest GMP certificate or inspection report of drug product manufacturer is required.	Copy of GMP certificate valid till 05.12.2024 is submitted.
3	3.2.P.5 Under the heading of system suitability requirement, RSD NM 1.0% Standard Solution is mentioned. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted revised method of analysis and has stated that from onwards they will perform system suitability as per USP method using Compound C.

Decision: Approved.

764.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6674: 09.03.2023
	Details of fee submitted	PKR 30,000/- : 5146851838

	The proposed proprietary name / brand name	**V-CITA 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Escitalopram (as oxalate)……10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	For generic drugs (me-too status)	Cipralex 10mg tablet
	Proposed Pack size	14's

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of GMP certificate/ DML of drug substance manufacturer is required.	Firm has submitted their response vide letter No. VP/024/213 dated 22.07.2024 Copy of DML issued by Commissioner F&DCA Gujrat state India, valid till 31.12.2026 is submitted.
2	Copy of latest GMP certificate or inspection report of drug product manufacturer is required.	Copy of GMP certificate valid till 05.12.2024 is submitted.
3	3.2.P.5 Under the heading of system suitability requirement, RSD NM 1.0% Standard Solution is mentioned. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted revised method of analysis and has stated that from onwards they will perform system suitability as per USP method using Compound C.

Decision: Approved.

765.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals (Pvt.) Ltd. Plot No. 5, M2-Pharma Zone, 26Km, Lahore Sharaqpur Road, Sheikhupura.`
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6675: 09.03.2023
	Details of fee submitted	PKR 30,000/- : 99043337
	The proposed proprietary name / brand name	**V-CITA 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Escitalopram (as oxalate)……20mg

	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	For generic drugs (me-too status)	Cipralex 20mg tablet
	Proposed Pack size	14's

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of GMP certificate/ DML of drug substance manufacturer is required.	Firm has submitted their response vide letter No. VP/024/213 dated 22.07.2024 Copy of DML issued by Commissioner F&DCA Gujrat state India, valid till 31.12.2026 is submitted.
2	Copy of latest GMP certificate or inspection report of drug product manufacturer is required.	Copy of GMP certificate valid till 05.12.2024 is submitted.
3	3.2.P.5 Under the heading of system suitability requirement, RSD NM 1.0% Standard Solution is mentioned. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted revised method of analysis and has stated that from onwards they will perform system suitability as per USP method using Compound C.

Decision: Approved.

766.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5811: 01.03.2023
	Details of fee submitted	PKR 30,000/- : 468166664
	The proposed proprietary name / brand name	**D-SODIUM 25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet Contains: Diclofenac sodium…….25mg
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB05
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	DICLOFENAC SODIUM 25 MG GASTRO-RESISTANT TABLETS

		MHRA Approved.
	For generic drugs (me-too status)	Voltral 25mg Tablet Reg No. 021524
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
767.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6365: 06.03.2023
	Details of fee submitted	PKR 30,000/- : 78185563657
	The proposed proprietary name / brand name	**D-SODIUM 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet Contains: Diclofenac sodium…….50mg
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB05
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	DICLOFENAC SODIUM 50 MG GASTRO-RESISTANT TABLETS MHRA Approved.
	For generic drugs (me-too status)	Voltral 50mg Tablet
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
768.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5812: 01.03.2023
	Details of fee submitted	PKR 30,000/- : 66366893324
	The proposed proprietary name / brand name	**D-SODIUM 75mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet Contains: Diclofenac sodium…….75mg

	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB55
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	CARLSBAD's DICLOFENAC SODIUM75mg EC, tablet USFDA Approved
	For generic drugs (me-too status)	Panslay 75mg Tablet M/s Getz
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	RRA reference is required.	The firm vide letter No. Nil dated 05.08.2024 has submitted their response. Verifiable USFDA reference is submitted.
2	Copy of clearance certificate or attested invoice of drug substance is required.	Submitted
3	The pharmaceutical equivalence and CDP performed is against product Voltral 75mg Tablets. Evidence is required that Voltral 75mg tablet is an enteric coated tablet.	The fir has stated that it was a typographic error that they couldn't write EC with Voltral 75mg tablet. Firm has also resubmitted CDP data indicating that reference product is enteric coated.

Decision: Approved.

769.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals Plot No. 122, Block B, Phase V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot No. 122, Block B, Phase V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6363: 06.03.2023
	Details of fee submitted	PKR 30,000/- : 839814723
	The proposed proprietary name / brand name	**ROSAVET 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rosuvastatin calcium eq. Rosuvasatin….20mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors ATC Code: C10AA07
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	ROSUVASTATIN DAWA 20 MG FILM-COATED TABLETS - PL 30684/0333
	For generic drugs (me-too status)	Rovista 20mg Tablet
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Observation	Reply

1	Copy of AD attested invoice or clearance certificate of API is required.	Submitted vide letter No. WM/DRAP/2024/PEC/6/2 dated 26.07.2024
2	3.2.S.4: Testing method of drug substance along with batch analysis validated and performed by the drug product manufacturer is required.	Submitted.

Decision: Approved.

770.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot No. 31, 32, Punjab Small Industrial Estate Taxila.**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot No. 31, 32, Punjab Small Industrial Estate Taxila.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13518: 31.05.2023
	Details of fee submitted	PKR 30,000/- : 7395758743
	The proposed proprietary name / brand name	**PIXAN 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….2.5mg
	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	APIXABAN ACCORD 2.5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 2.5mg Tablets, M/s Highnoon
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Decision: Approved.

771.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot No. 31, 32, Punjab Small Industrial Estate Taxila.**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot No. 31, 32, Punjab Small Industrial Estate Taxila.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 11132: 04.05.2023
	Details of fee submitted	PKR 30,000/- : 20604537
	The proposed proprietary name / brand name	**PIXAN 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Apixaban…….5mg

	Pharmacotherapeutic Group of (API)	Direct factor Xa inhibitors ATC Code: B01AF02
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	APIXABAN ACCORD 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Apiban 5mg Tablets, M/s Highnoon
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		

New DML/ New Section Cases

772.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi..
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26041: 27.10.2023
	Details of fee submitted	PKR 20,000/- : 863059859258 PKR 10,000/- : 54561062359
	The proposed proprietary name / brand name	**CLAMAF Suspension 125mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml contains; Clarithromycin…….125mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	CLARITHROMYCIN 125 MG/5ML GRANULES FOR ORAL SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	Claritek 125mg/ml Granules for suspension
	Proposed Pack size	60ml
Evaluation by PEC (No IX):		

S. No.	Observation
1	3.2.P.2, 3.2.P.3: In the description of dug product it is mentioned that its granules for oral suspension, in manufacturing method it is nowhere mentioned how granules will be manufactured. Further none of the manufacturing method indicate that final product will be in granular form. Please clarify.
2	Clearance certificate or AD attested invoice of API is required.

Decision: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Deferred Form-5F Cases

773.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13942 dated 05.06.2023 RnI Verified. Dy. No 27659 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 99142294489 dated 17.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime…….500mg With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 500mg Reg No. 076005 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 500mg Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
API Lot No.	CEIV/B2107059
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	15.09.2022	15.09.2022	15.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Cefipime HCl Sterile USP L-Arginine** Batch No.: CEIV/B2008086 Mfg date: 08.2020 Exp date: 07.2023 Quantity: 100kg Invoice No.: EXP-373 Invoice date: 17.12.2020 Cleared by AD I&E DRAP Islamabad, Material is imported by M/s Shawan Pharmaceuticals and taken loan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision of 333rd meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm has submitted response vide letter dated 19.04.2024 Product Biopime 500mg injection batch No. 113 manufactured by M/s Biorex Pharmaceuticals. As per data submitted in dossier, pharmaceutical equivalence was established against product Maxipime, now firm is claiming that they had performed pharmaceutical equivalence studies against product Biopime.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Submitted.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Submitted vide letter No. nil dated 19.04.2024. The material is taken loan from M/s Shawan Pharma. The batch No. of drug substance used for manufacturing the trial batches as per submitted dossier was CEIV/B2107059. Now the firm has submitted documents for drug substance having batch No. CEIV/B2008086.
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.	The firm has stated that in future they will use different batch Numbers.
Decision of 336th RB		**The Board deferred the case for clarification of difference in data submitted in the application dossier and their response dated 19.04.2024**	
Response of Firm:		The firm vide letter No. nil dated 24.07.2024 has submitted their response. The firm has stated that the data of pharmaceutical equivalence performed against product Maxipime was misplaced, so they have again performed pharmaceutical equivalence studies against the product Biopime 500mg Batch No. 113. Complete pharmaceutical equivalence studies are submitted by the firm. Regarding difference of batch No. of drug substance, the firm has stated that the drug substance utilized for manufacturing of Drug product was CEIV/B2008086 and was incorrectly mentioned in dossier due to human error. The firm has submitted batch analysis and clearance of drug substance having batch No. CEIV/B2008086	

Decision: Approved.

774.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. DML No. 000911
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML/Section
	Evidence of approval of manufacturing facility	Copy of grant of DML letter vide No. 1-2/2019-Lic dated 14.02.2023 is submitted. Dry Vial Section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 13943 dated 05.06.2023 RnI Verified. Dy. No 27660 dated 27.11.2023
	Details of fee submitted	PKR 30,000/- Slip No. 53358171 dated 16.05.2023
	The proposed proprietary name / brand name	**CEFEGEN 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefepime hydrochloride eq to Cefepime……1gm With L-Arginine.
	Pharmacotherapeutic Group of (API)	Fourth-generation cephalosporins ATC Code: J01DE01
	Pharmaceutical form of applied drug	White to pale yellow powder filled in glass vial with flip-off seal. Powder for solution for IM/ IV injection
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 500mg, 1gm & 2gm Injection USFDA Approved.
	For generic drugs (me-too status)	Cefstar Injection 1g Reg No. 076007 M/s Barrett and Hodgson.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. CEIV/B2107059
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is

		conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. CEIV/b1203011, CEIV/b1203012, CEIV/b1203013
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against comparator product **Maxipime 1g Injection batch no. _____ exp. _____. manufactured by _____.** Pictorial evidence is not submitted. **Tests:** Description, identification, particulate matter, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad Maharashtra, India.		
API Lot No.	CEIV/B2107059		
Description of Pack (Container closure system)	White to pale yellow powder filled in glass vial with flip-off seal.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	09.2022	09.2022	09.2022
Date of Initiation	16.09.2022	16.09.2022	16.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New section.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. NEW-WHO-GMP/CERT/KD/26116/2015/11/10947 dated 15.06.2015 valid till 14.04.2017, issued FDA Maharashtra India.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Cefipime HCl Sterile USP L-Arginine** Batch No.: CEIV/B2008086 Mfg date: 08.2020 Exp date: 07.2023 Quantity: 100kg Invoice No.: EXP-373 Invoice date: 17.12.2020 Cleared by AD I&E DRAP Islamabad, Material is imported by M/s Shawan Pharmaceuticals and taken loan.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted log for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.
2	3.2.P.8	Copy of executed BMRs of trial batches are required.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.

Decision of 333rd meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1	3.2.P.2.2	Batch No. mfg date, exp date and manufacturer of reference product (Maxipime) used in pharmaceutical equivalence are not provided. Further pictorial evidence of reference product is also required.	The firm has submitted response vide letter dated 19.04.2024 Product Walfipime 1g injection batch No. 049 manufactured by M/s Valor. As per data submitted in dossier, pharmaceutical equivalence was established against product Maxipime, now firm is claiming that they had performed pharmaceutical equivalence studies against product Walfipime
2	3.2.P.8	Copy of executed BMRs of trial batches are required.	Submitted.
3	-	Copy of purchase documents of Drug Substance are required. (AD attested invoice or clearance certificate)	Submitted vide letter No. nil dated 19.04.2024. The material is taken loan from M/s Shawan Pharma.

			The batch No. of drug substance used for manufacturing the trial batches as per submitted dossier was CEIV/B2107059. Now the firm has submitted documents for drug substance having batch No. CEIV/B2008086.
4	-	The batch numbering used for trail batches is same for all products. Batch No. should be unique for trial batches of different batches.	The firm has stated that in future they will use different batch Numbers.
Decision of 336th RB		**The Board deferred the case for clarification of difference in data submitted in the application dossier and their response dated 19.04.2024**	
Response of Firm:		The firm vide letter No. nil dated 24.07.2024 has submitted their response. The firm has stated that the data of pharmaceutical equivalence performed against product Maxipime was misplaced, so they have again performed pharmaceutical equivalence studies against the product Valfipime 1g Injection Batch No. 049 manufactured by M/s Shawan Pharma. Complete pharmaceutical equivalence studies are submitted by the firm. Regarding difference of batch No. of drug substance, the firm has stated that the drug substance utilized for manufacturing of Drug product was CEIV/B2008086 and was incorrectly mentioned in dossier due to human error. The firm has submitted batch analysis and clearance of drug substance having batch No. CEIV/B2008086	

Decision: Approved.

775.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)**
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi. (DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1856, Dt. 19.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No. 284819137127 PKR 45,000/- Slip no. 95125517
	The proposed proprietary name / brand name	**ALERNIL 2.5mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains; Bilastine……2.5mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use ATC Code: R06AX29
	Reference to Finished product specifications	**Innovators Specifications**

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	The batch size mentioned in stability data sheets is 1L. As per bill of material in BMR, volume per bottle is 100ml,	The firm vide letter No. RA/DRAP/708/2024 dated 24.05.2024 has

		It makes total batch size of 10 units each. Justify how this small batch can be used in stability studies over whole proposed shelf life.	stated that stability batch size is 10 units, One bottle was consumed in initial testing. 6 were placed on real time stability. 2 were placed on accelerated stability study.

Decision of 336th Meeting of RB: The board deferred the case for clarification of the firm that how batch of 1 litre was manufactured and in which facility. Further the firm should justify how stability of such a small batch will represent the stability of commercial scale batches.

Evaluation by PEC-IX:

The firm vide letter No. RA/DRAP/708/2024 dated 30.07.2024 has submitted their response.

The firm has stated that they had already recognized the issue of small batch size and they had manufactured 2 batches of 5 liter each again in April, 2024. (TF-04 & TF-05)

The size of new stability batches is 50 units each.

The firm has submitted stability testing data of initial testing and 3rd month time point.

Decision: Approved, Letter shall be issued on submission of 6th month time point stability data.

776.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2388, Dt. 25.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No.785717727193
	The proposed proprietary name / brand name	**ESCADEP 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram oxalate eq. to Escitalopram…..20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	10’s 20’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipralex 20mg Film coated tablet MHRA Approved.
	For generic drugs (me-too status)	Depsit 20mg Tablets M/s Genix Pharma.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5	Under the heading of system suitability tests, its mentioned that its done by calculating symmetry factor and RSD for 5 replicate injections of standard	The firm has submitted their response vide letter No. nil dated nil.

		preparations. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has stated that they have revised the method of analysis to comply with the USP monograph. But even in revised method there is no mentioning of Compound C for assessing system suitability.
2	-	Cop of clearance certificate or AD attested invoice of drug substance is required.	Firm has submitted clearance certificate of batch No. AE-084/22 cleared in 2023. Trial batches were manufactured by batch No. EO-108/20 in 2021 & 2022

Decision of 336th RB: The board deferred the case for submission of;

i. Clarification of why clearance of different batch of drug substance is submitted.

ii. Justification of deviating from official monograph of drug product.

Evaluation by PEC-IX:

The firm vide letter No nil dated 30.07.2024 has submitted their response.

- Regarding submission of different AD attested invoice, the firm has stated that they already have registration of product Escadep 10mg tablet (Reg. No. 042329) and they import API for it on regular basis. The raw material for trial batches was used from it. By mistake clearance of different batch was attached in reply. Now the firm has submitted clearance certificate of the API batch No. EO-108/20 that was used in manufacturing of trial batches.
- Regarding Deviation from USP monograph, the firm has submitted revised testing method which is in accordance with USP monograph of the applied product.

Decision: Approved.

777.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20, North Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2387, Dt. 25.01.2023
	Details of fee submitted	PKR 30,000/- : Slip No.634829387
	The proposed proprietary name / brand name	**ESCADEP 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram oxalate eq. to Escitalopram…..5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	10’s 20’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipralex 5mg Film coated tablet MHRA Approved.
	For generic drugs (me-too status)	Depsit 5mg Tablets M/s Genix Pharma.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.5	Under the heading of system suitability tests, its mentioned that its done by calculating symmetry factor and RSD for 5 replicate injections of standard preparations. As per USP monograph it is required to be assessed by using Citalopram Related Compound C. Please justify this deviation from USP monograph and clarify whether USP allow such deviations from pharmacopoeial methods or otherwise.	The firm has submitted their response vide letter No. nil dated nil. The firm has stated that they have revised the method of analysis to comply with the USP monograph. But even in revised method there is no mentioning of Compound C for assessing system suitability.
2	-	Copy of clearance certificate or AD attested invoice of drug substance is required.	Firm has submitted clearance certificate of batch No. AE-084/22 cleared in 2023. Trial batches were manufactured by batch No. EO-108/20 in 2021 & 2022

Decision of 336th RB: The board deferred the case for submission of;

i. **Clarification of why clearance of different batch of drug substance is submitted.**
ii. **Justification of deviating from official monograph of drug product.**

Evaluation by PEC-IX:

The firm vide letter No nil dated 30.07.2024 has submitted their response.

- Regarding submission of different AD attested invoice, the firm has stated that they already have registration of product Escadep 10mg tablet (Reg. No. 042329) and they import API for it on regular basis. The raw material for trial batches was used from it. By mistake clearance of different batch was attached in reply. Now the firm has submitted clearance certificate of the API batch No. EO-108/20 that was used in manufacturing of trial batches.
- Regarding Deviation from USP monograph, the firm has submitted revised testing method which is in accordance with USP monograph of the applied product.

Decision: Approved.

778.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33454, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 365771579
	The proposed proprietary name / brand name	**CIPRAM 5mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram as oxalate……..5mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 5MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 5mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	
2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	
3	3.2.P.8	Stability Studies data of 3 months is submitted. Data of 6 months is required.	

Decision of 336th RB: The board was appraised that deficiencies are communicated to the firm. Reply from the firm is awaited. The board deferred the case for submission of reply of communicated deficiencies.

Evaluation by PEC-IX:

The firm vide letter No IP/DR/037 dated 24.05.2024 has submitted their response.

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	Copy of GMP certificate valid till 07.02.2025 is submitted.
2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	Copies of relevant chromatograms are submitted.
3	3.2.P.8	Stability Studies data of 3 months is submitted. Data of 6 months is required.	6 months stability data is submitted.

Decision: Approved.

779.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals, 7KM Pasrur Road, Sialkot. (DML No. 000885)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33453, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 06734487

	The proposed proprietary name / brand name	**CIPRAM 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Escitalopram as oxalate……..10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRALEX 10MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 10mg Tablet

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	Submitted vide letter No. IP/DR/038 dated 24.05.2024.
2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	The firm has not submitted any justification of deviation from USP monograph. Chromatograms of system suitability run are submitted wherein peak of Compound C is not present. The firm has submitted partial reply.

Decision of 336th RB: The Board deferred the case for submission of complete reply with justification for deviation from official monograph in assay of drug product.

Evaluation by PEC-IX:

The firm vide letter submitted on 03.06.2024 has given following response.

S. No.	Section	Observation	Reply
1	-	Copy of latest GMP inspection report or certificate is required.	Copy of GMP certificate valid till 07.02.2025 is submitted.
2	3.2.P.5	In 7.4.3 System Suitability solution it is mentioned that 10mg of USP Citalopram related compound C RS will be used. But it's not represented in chromatograms. Chromatographs of system suitability run for assay are not submitted, please submit copies of these.	Copies of relevant chromatograms are submitted.
3	3.2.P.8	Stability Studies data of 3 months is submitted. Data of 6 months is required.	6 months stability data is submitted.

Decision: Approved.

780.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Apsis Pharmaceuticals Eminabad road Khan payara, 1.3KM GT Road, Gujranwala. (DML No. 000855)**
	Name, address of Manufacturing site.	M/s Apsis Pharmaceuticals Eminabad road Khan payara, 1.3KM GT Road, Gujranwala. (DML No. 000855)
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33449, Dt. 21.11.2022
	Details of fee submitted	PKR 30,000/- : Slip No. 565477162535
	The proposed proprietary name / brand name	**BATALASOL 5% IV Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml contains; Dextrose anhydrous……5gm
	Pharmacotherapeutic Group of (API)	Glucose Infusion
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	5% GLUCOSE INTRAVENOUS INFUSION SOLUTION MHRA Approved.
	For generic drugs (me-too status)	Dexsol 5% IV Infusion

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Water loss studies data has not been submitted.	
2	3.2.P.8	Batch sizes are given in litres, batch size in number of units is required.	

Decision of 336th RB: The board was appraised that deficiencies are communicated to the firm. Reply from the firm is awaited. The board deferred the case for submission of reply of communicated deficiencies.

Evaluation by PEC-IX

S. No.	Section	Observation	Reply
1	3.2.P.8	Water loss studies data has not been submitted.	The firm vide letter No. AP-0021 dated 27/05/2024 has submitted their response. Data of water loss studies is submitted.
2	3.2.P.8	Batch sizes are given in litres, batch size in number of units is required.	Batch size is stated as 500 units per batch.

The QA&LT Division has forwarded a letter No. 4-07/2017-QA dated 15.07.2024 wherein its mentioned that the firm M/s Apsis Pharma Gujranwala was inspected by a panel on 3rd & 4th July, 2024 and as a result of inspection, the QA&LT Division has ordered to stop production activities in all sections with immediate effect.

Decision: The Board deferred the case. The firm shall submit evidence of resumption of production activities order issued by the QA&LT Division for reconsideration of the case.

781.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Onyx Pharmaceuticals 30-A, Industrial Estate Mansehra (DML No. 000440)**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore. DML No. 000863.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26.02.2020 valid till 12.02.2022 issued by DRAP Lahore in favour of

		M/s Bio-Mark is provided. (Firm has applied for new GMP certificate)
	Evidence of approval of manufacturing facility	Not submitted
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form 5F Dy. No 6373 dated 06.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 6803447638 dated 09.02.2023
	The proposed proprietary name / brand name	**SONYX 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ondansetron (as HCl)…….8mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	A film coated pink colour round biconvex tablet, in alu alu blister with leaflet pack in unit carton.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Tablets 8 mg MHRA Approved.
	For generic drugs (me-too status)	Onden 8mg Tablet Reg. No. 055754 M/s Macter Karachi.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	1.5.2	The label applied is Ondansetron (as HCl), the innovator product uses Ondansetron as hydrochloride dihydrate. Clarify.
2.	3.2.P.2.2	The F2 factor calculations in CDP are not submitted.
3.	3.2.P.8	Copies of executed BMR of stability batches are required.

Decision of 333rd meeting of RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Remarks of Evaluator:

The firm has given their response vide letter submitted on 14.06.2024.

Sr. No.	Section	Observation	Reply
1.	1.5.2	The label applied is Ondansetron (as HCl), the innovator product uses Ondansetron as hydrochloride dihydrate. Clarify.	The firm has stated that it was a typographic mistake. The correct label is; Each film coated tablet contains; Ondansetron as hydrochloride dihydrate……..8mg

			Fee fir revision of label is not submitted
2.	3.2.P.2.2	The F2 factor calculations in CDP are not submitted.	Similarity Factor (F2) calculations at all 3 pH are now submitted. (65, 86, 67)
3.	3.2.P.8	Copies of executed BMR of stability batches are required.	Copies are submitted.

Decision: Approved. The letter shall be issued after submission of fee of Rs. 75000/- for preregistration variation.

782.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s UniMark Pharmaceuticals (Pvt.) Ltd. Plot No. 7-A, National Industrial Zone Rawat. (DML No. 000557)**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals(Pvt.) Ltd. A/159, S.I.T.E. Super Highway Karachi. DML No. 000557
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP certificate No. 52/2022-DRAP (K) dated 04.04.2022 valid till 17.03.2024 issued by DRAP Karachi in favour of M/s Swiss Pharma is provided.
	Evidence of approval of manufacturing facility	Not submitted. Copy of approval of layout plan letter is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 7171 dated 13.03.2023
	Details of fee submitted	PKR 75,000/- Slip No. 796720264 dated 08.12.2022
	The proposed proprietary name / brand name	**VOMFRAN 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Ondansetron as Hydrochloridedihydrate..8mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	Pharmaceutical form of applied drug	Clear, almost colourless solution, free from any visible particle filled in amber glass ampoule.
	Reference to Finished product specifications	**USP Specifications.**
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondansetron 8mg/4ml Injection (ondansetron hydrochloride) - PL 04543/0508 MHRA Approved.
	For generic drugs (me-too status)	Zofran 8mg/4ml Injection Reg. No. 020669 M/s GSK Karachi.

	Name and address of API manufacturer.	M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 & C-62 KSSIDC, Industrial Estate Doddaballapur India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. AOND20003
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. AOND-17002, AOND-17003 AOND-17004.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** VOMFRAN 8mg/4ml Injection Batch No. 01 **Reference product:** Zofran 8mg Injection, Batch No. TA9B. mfg.:04.2020, Exp. 05.2023 manufactured by M/s GSK Pakistan Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, pH, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Anugraha Chemicals, D-47, D-48, D-49, D-50 & C-62 KSSIDC, Industrial Estate Doddaballapur India.

API Lot No.	AOND20003		
Description of Pack (Container closure system)	Clear, almost colourless solution, free from any visible particle filled in amber glass ampoule.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	01	2	3
Batch Size	18410 ampoules	23463	22236 ampoules
Manufacturing Date	09.2020	11.2020	10.2021
Date of Initiation	10.09.2020	30.12.2020	29.10.2021
No. of Batches	3		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. DCD/SPL-1/CR-1733/2021-22 dated 31.01.2022 valid till 30.01.2023 issued by Drug Control department Karnataka state India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Ondensetron HCL Injection grade** Batch No. AOND20003 Mfg: 02.2020 Exp: 01.2025 Invoice No.: PCI/CI20/06002 Dated: 15.06.2020 Cleared by AD I&E DRAP Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation
1.	-	Layout approval letter is provided. Section Approval letter is required.
2.	3.2.P.5	The specifications claimed for the drug product are USP specifications. As per USP monograph, for system suitability and verification of chromatographic system ondansetron related compound A is required to be used. The submitted method does not indicate system suitability as per USP monograph. Justify.

Decision of 333rd Meeting of RB.: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Sr. No.	Section	Observation	Reply

1.	-	Layout approval letter is provided. Section Approval letter is required.	The firm has again submitted layout approval letter. Ampoule section is also not mentioned in GMP certificate.
2.	3.2.P.5	The specifications claimed for the drug product are USP specifications. As per USP monograph, for system suitability and verification of chromatographic system ondansetron related compound A is required to be used. The submitted method does not indicate system suitability as per USP monograph. Justify.	The firm has submitted revised analytical method that is in line with USP monograph.

Decision: Registration Board decided to reject the application since firm could not provide evidence of approval for required manufacturing facility of "Liquid Injection Ampoule (general) section" in name of M/s Swiss Pharmaceuticals(Pvt.) Ltd. A/159, S.I.T.E. Super Highway Karachi.

783.	**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: 0441 Dated: 07.06.2024 Address: M/s Otsuka Pakistan Ltd., 30-B, SMCHS Karachi. Address of Godown: NA Status: Drug License by way of Wholesale Valid till: 16.06.2029
	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	☐ Manufacturer ☒ Importer ☐ 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	**FATOLIP 250ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 250ml HDPE Bottle contains;** 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)	**CoPP:** 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 of 337th meeting of RB: The board was informed that deficiencies have been communicated to the firm. The board deferred the case for submission of reply to communicated deficiencies.

Evaluation by PEC (IX):

S. No.	Observations	Reply
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.	The Firm has requested to consider the application of 250ml fill volume for this application.
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.	Firm has not submitted any response against this observation.
3	Copy of DSL uploaded is not readable.	Readable copy is submitted.
4	Container closure system is different than the innovator product.	The firm has submitted that same product in same packaging is being exported to countries like Indonesia, Thailand etc. Similar products in similar packing are available in European market also. The firm has stated that M/s Otsuka Japan is using similar packing for other products being marketed in Japan.

5	Copy of executed BMR of trial batches are not attached.	Copy is submitted
6	Why stability of drug product is not done as per conditions of Zone IVa?	The firm has stated that when product was placed on stability on 30℃±2℃/ 35% RH±5% RH, test results of glycerol were out of specification. The stability was then conducted at 25℃±2℃/ 40% RH±5% RH, and product was stable at these conditions. Further the firm has stated that storage conditions for innovator products are to store at not more than 25℃ and do not freeze. Their product has same storage conditions, and such products only remain stable below 25℃.
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	Data is submitted.
8	COPP and letter of authorization uploaded are not legalized.	Legalized documents are submitted.

Decision: Approved as per policy for inspection abroad.
The firm shall submit full fee for registration from its DSL whose address is mentioned on the attested Letter of Authorization, submit attested Letter of authorization, legalized COPP, legalized GMP certificate before issuance of letter.
Further the firm shall write the required storage conditions (store below 25℃ and do not freeze) in both Urdu and English languages in conspicuous way on label of the product.

Deferred Cases of Form-5

784.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart Plus Tablet 40/12.5mg
	Composition	Each tablet contains: Telmisartan...40mg Hydrochlorothiazide…....12.5mg
	Dairy No. date of R &I fee	Dy. No. 13671, 28-08-2017, Rs. 20,000/- 25-08-2017
	Pharmacological Group	Antihypertensive
	Type of form	Form- 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	14's & 28's
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too-status	Velmon-H 40/12.5mg Tablet of M/s Martin Dow Ltd. Karachi (Reg.#081160)
	GMP Status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance.
	Remark of the Evaluator.	
	Decision of 283rd RB	**Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies.**

	Remark of the Evaluator.	The firm vide letter No. nil dated 25.05.2024 has submitted a copy of inspection report dated 15.02.2024 wherein there is nothing mentioned regarding stability chambers. In same report regarding double compression machine, following statement is reported by the FID; It was noted that he firm has bi-Layerd Tablets compression and co-blistering facility in all section including general tablet, penicillin section and cephalosporin section. As per minutes of 292nd meeting of RB, FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.
	Decision: Approved with USP Specifications. The firm shall submit fee of Rs. 30,000/- for preregistration variation before issuance of letter.	
785.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart HCT 80mg/25mg Tablet
	Composition	Each tablet contains: Telmisartan USP …….80mg Hydrochlorothiazid……..25mg
	Dairy No. date of R &I fee	Dy.No.13655; 28-08-2017; Rs.20,000/- (25-08-2017)
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	14’s & 28’s
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too-status	Teli-H Tabletsof M/S Wilson’s Pharmaceuticals
	GMP Status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance.
	Remark of the Evaluator.	Evidence of double compression machine not found.
	Decision of 283rd RB	**Registration board deferred the case for Evidence of double compression Machine verified by FID. Moreover, Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 25.05.2024 has submitted a copy of inspection report dated 15.02.2024 wherein there is nothing mentioned regarding stability chambers. In same report regarding double compression machine, following statement is reported by the FID; It was noted that he firm has bi-Layerd Tablets compression and co-blistering facility in all section including general tablet, penicillin section and cephalosporin section. As per minutes of 292nd meeting of RB, FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.

	Decision: Approved with USP Specifications. The firm shall submit fee of Rs. 30,000/- for preregistration variation before issuance of letter.	
786.	Name and address of manufacture / Applicant	M/s. Lisko Pakistan (Pvt.) Ltd.L-10-D, Block# 21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi.
	Brand Name + Dosage Form and Strength	Voltrex Plus tablet 75mg+200mcg
	Composition	Each enteric coated tablet contains: Diclofenac sodium….75 mg Misoprostol……0.2mg
	Dairy No. date of R &I fee	Dy. No. 7982, 07-07-2017 , Rs.20,000/- (07-07-2017)
	Pharmacological Group	NSAID/Prostaglandin
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's, 20's, 28's, Alu Alu; Rs 60/Tablet
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too-status	Registration Number: 024014 Brand Name: Cytopan-75 Tablets Manufacturer Name: M/s Getz Pharma (Pvt) Ltd, Karachi
	GMP Status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Recommendations)
	Remark of the Evaluator.	Approved in USFDA with Box Warning. □ The formulation contains misoprostol 1% HPMC dispersion and contains inner enteric coated layer surrounded by misoprostol dispersion coating and the method of manufacturing submitted is in line with the innovator product. □ Evidence of availability of requisite manufacturing equipment by area FID not provided by the firm. □ Availability of Misoprostol as 1 % HPMC could not be verified from Form 5.
	Decision of 283rd RB	**Deferred for the following reasons:** **□ Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm.** **□ Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion.** **□ Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID.**
	Remark of the Evaluator.	□ Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. Firm has not provided evidence of availability of requisite manufacturing equipment by area FID. □ Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. Firm has submitted revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. □ Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed

		that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.
	Decision of 292nd Meeting of RB	Registration Board deferred the case for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.
	Remarks of Evaluator:	The firm vide letter No. nil dated 24.05.2024 has submitted a copy of inspection report conducted by FID on 15.02.2024 wherein FID has written following statement; *"It was noted that he firm has bi-Layerd Tablets compression and co-blistering facility in all section including general tablet, penicillin section and cephalosporin section"* The inspection report is not a panel inspection report and firm has not submitted DQ, IQ & OQ report
	Decision: Approved	
787.	Name and address of manufacture / Applicant	M/s. Lisko Pakistan (Pvt.) Ltd.L-10-D, Block# 21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi.
	Brand Name + Dosage Form and Strength	Voltrex Plus tablet 50mg+200mcg
	Composition	Each enteric coated tablet contains: Diclofenac sodium….50mg Misoprostol……0.2mg
	Dairy No. date of R &I fee	Dy. No. 7975, 07-07-2017 , Rs.20,000/- (07-07-2017)
	Pharmacological Group	NSAID/Prostaglandin
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 14's, 20's, 28's, Alu Alu; Rs 60/Tablet
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too-status	Registration Number: 026839 Brand Name: Prostol Tablets Manufacturer Name: Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore
	GMP Status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Recommendations)
	Remark of the Evaluator.	Approved in USFDA with Box Warning. □ The formulation contains misoprostol 1% HPMC dispersion and contains inner enteric coated layer surrounded by misoprostol dispersion coating and the method of manufacturing submitted is in line with the innovator product. □ Evidence of availability of requisite manufacturing equipment by area FID not provided by the firm. □ Availability of Misoprostol as 1 % HPMC could not be verified from Form 5.
	Decision of 283rd RB	**Deferred for the following reasons:** □ **Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm.** □ **Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion.**

		Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID.
	Remark of the Evaluator.	Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. Firm has not provided evidence of availability of requisite manufacturing equipment by area FID. Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. Firm has submitted revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.
	Decision of 292nd Meeting of RB	Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submit DQ (Design Qualification),IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.
	Remarks of Evaluator:	The firm vide letter No. nil dated 24.05.2024 has submitted a copy of inspection report conducted by FID on 15.02.2024 wherein FID has written following statement; *"It was noted that he firm has bi-Layerd Tablets compression and co-blistering facility in all section including general tablet, penicillin section and cephalosporin section"* The inspection report is not a panel inspection report and firm has not submitted DQ, IQ & OQ report
	Decision: Approved	
788.	Name and address of manufacture / Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Injection AMIKACIN 250mg
	Composition	Each 2ml vial contains:- Amikacin (as Sulphate)……..250mg
	Dairy No. date of R &I fee	Fast Track 23/10/2013, Dy# 264 R&I dated 23/10/2013 (Rs. 60,000/-)
	Pharmacological Group	
	Type of form	Form- 5
	Finished product specifications	USP
	Pack size and Demand Price	Rs.150 per 1x2ml
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Grasil Sami
	GMP Status	
	Remark of the Evaluator.	
	Decision of 257th RB	Deferred for confirmation of approval status of dosage form (250mg per 2ml) in same strength in reference regulatory authorities.

	Remark of the Evaluator.	The firm vide letter No. nil dated 27.1.2023 has stated that RRA reference of applied formulation is not available so they want to revise the label as under; Each 1ml Ampoule contains; Amikacin (as Sulphate) ……..250mg (USP Specifications) The firm has submitted fee of Rs. 30,000/- vide slip No. 36503086. The firm has not submitted section approval letter and GMP certificate from which manufacturing facility could be verified.
	Decision: Considering the fact that firm ahs not submitted the section confirmation letter, the application is disposed off.	
789.	Name and address of manufacture / Applicant	M/s.Caraway Pharmaceuticals, Plant:Plot#12, Street#N-3, National Industrial Zone,(RCCI), Rawat, Islamabad,
	Brand Name + Dosage Form and Strength	Clopidol Tablet
	Composition	Each enteric coated Tablet contains: Clopidogrel (as bisulphate)…. 75mg Aspirin …..75mg
	Dairy No. date of R &I fee	Routine 16-07-2010/6628 20-05-2013/3153 Rs. 20,000/-
	Pharmacological Group	Antplatelet
	Type of form	Form- 5
	Finished product specifications	
	Pack size and Demand Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	
	Remark of the Evaluator.	
	Decision of 241st RB	Deferred for product specific inspection for confirmation of manufacturing and QC facility by DDG (E&M) and FID.

Remark of the Evaluator.

The PSI report of M/s Caraway Pharmaceuticals Rawat for confirmation of manufacturing & QC testing facility for Clopidol Tablets was conducted by following panel on 16.01.2024 & 02.07.2024.

1. Dr. Ghazanfar Ali Khan, Additional Director (E&M),
   Drug Regulatory Authority of Pakistan,
   Islamabad
2. Mr. Muneeb Ahmed Cheema, Deputy Director (PE&R)
   Drug Regulatory Authority of Pakistan,
   Islamabad

The detailed report was received vide letter No. Dy. No. 176-Addl. Director (QALT-Field Office) dated 10.07.2024.

The report is reproduced below;

Name of manufacturer	M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat.
DML and Section approval	DML No. 000629 Tablet Section (General) granted vide Licensing Division letter No. F.1-9/2004-Lic (Vol-II) dated 04.07.2022.

Date of inspection	16.01.2024 and 02.07.2024
Inspection panel	1. Dr. Ghazanfar Ali Khan, Additional Director (E&M), Drug Regulatory Authority of Pakistan, Islamabad 2. Mr. Muneeb Ahmed Cheema Deputy Director (PE&R) Drug Regulatory Authority of Pakistan, Islamabad
Name of firm representatives present during inspection	Mr. Umar Farooq (Managing Director) Dr. Syed Tauqeer Ali (Director Operations/ Production Incharge) Mr. Mohammad Arif (Plant Manager) Mr. Murad Ali (Head of Quality Operations/ Quality Control Incharge) Mr. Rasheedullah (Quality Control Manager)
Scope of inspection	Product specific inspection referred vide DRAP letter No. F.15-1/2022-PEC dated 28.12.2023 for confirmation of manufacturing & quality control testing facility for clopidol tablets (Clopidogrel 75mg + Aspirin 75mg) as per decision of Registration Board in its 241st meeting.

General information about the Innovator formulation:

In year 2009, the European Medicine Agency (EMA) approved the market authorization of DuoCover Tablets in name of Bristol-Myers Squibb Pharma EEIG through centralised procedure. The formulation is a fixed-dose combination of clopidogrel (75 mg) and Acetylsalicylic acid (ASA) (75 mg or 100mg) as film-coated bilayer immediate release tablet formulations. Each tablet of the first strength contains 97.875 mg of clopidogrel hydrogen sulphate (equivalent to 75 mg clopidogrel) and 75 mg of acetylsalicylic acid. Each tablet of the second strength contains 97.875 mg of clopidogrel hydrogen sulphate (equivalent to 75 mg clopidogrel) and 100 mg of acetylsalicylic acid. DuoCover is indicated for the prevention of atherothrombotic events in adult patients.

General introduction of manufacturing facility:

M/s Caraway Pharmaceuticals situated at Plot No. 12, Street No. S-4, National Industrial Zone, Rawat holds drug manufacturing license (DML) by way of formulation vide No. 000629. The firm is involved in the manufacturing of several dosage forms including oral, topical and parenteral formulations. GMP certificate was awarded to the manufacture on 13th April 2022 based on an inspection conducted on 22.02.2022. The aforesaid certificate was valid till 21.02.2024.

Brief of inspection:

Mr. Umar Farooq (Managing Director), Dr. Syed Tauqeer Ali (Director Operations/ Production Incharge) and Mr. Mohammad Arif (Plant Manager) assisted the panel during the course of inspection. As the scope of inspection was limited only for confirmation of manufacturing & quality control testing facility for clopidol tablets (Clopidogrel 75mg + Aspirin 75mg) as per decision of Registration Board in its 241st meeting, hence the panel inspected only the required areas. Details are as under:

a. Tablet Section (General):

The following equipment was installed in the tablet section at the time of inspection:

i. Ribbon Mixer.
ii. Granulator,
iii. Fluidized bed drier,
iv. Compression Machine ZP17
v. **Rotatory tablet Press/Compression Machine ZP 31**
vi. Coating Pan
vii. Blister machine
viii. blister machine

Temperature & humidity monitoring devices and monometers were available. HVAC system was operational in the tablet section area at the time of inspection. The firm informed that they had imported Rotatory Tablet Press/Compression Machine ZP 31 from china in September 2022. The aforesaid machine shall be used for the manufacturing of Clopidol Tablets (Clopidogrel 75mg + Aspirin 75mg) bilayer tablets. The machine was operational at the time of inspection. Placebo bilayer tablets manufactured by aforesaid machine were also presented to the panel. The import documents (commercial invoice, bill of lading) and IQ/OQ/PQ documents of the machine provided by the firm are attached.

b. Quality Control:

Quality Control was situated at first floor. The lab was equipped to carryout different categories of quality tests including wet chemistry and instrumental testing. Major quality control equipments include UV Visible Spectrophotometer, HPLC, Dissolution testing apparatus, pH meter. The list is of QC equipment is attached. The FTIR was not available at the time of inspection and the firm informed that they will purchase the one in near future, however till then they will contract the identification tests by FTIR with Max Pharmaceutical Rawat. The firm also presented a contract testing agreement b/w M/s Caraway Pharmaceuticals and Max Pharmaceutical Rawat and SOP's for the contract analysis. Log books for analysis of API, excipients and finished products were maintained.

Reference standard including primary and working standards were available. Retain sample room is available in the QC Lab. The firm had installed Stability chambers for accelerated long term studies.

c. Material management:

The raw material store was located at first floor. The store has sufficient capacity for storage of raw materials used for manufacturing activities. Receiving, Quarantine, Sampling, Release and Dispensing areas were seen. Temperature and humidity was appropriate. Sampling and dispensing booths were provided. Finished Goods store was available with appropriate storage area.

Conclusion:

Based on inspection of the above mentioned manufacturing, testing and storage facility, discussion with the technical staff and review of documents provided, the panel has reached to the conclusion that M/s Caraway Pharmaceuticals situated at Plot No. 12, Street No. S-4, National Industrial Zone, Rawat has requisite manufacturing and testing facilitates for Clopidol Tablets (Clopidogrel 75mg + Aspirin 75mg) bilayer tablets. **Hence the panel recommends the grant of registration of Clopidol Tablets (Clopidogrel 75mg + Aspirin 75mg) bilayer tablets in name of M/s Caraway Pharmaceuticals situated at Plot No. 12, Street No. S-4, National Industrial Zone, Rawat**.

Dr. Ghazanfar Ali Khan
Additional Director (E&M)
Drug Regulatory Authority of Pakistan
Islamabad.

Muneeb Ahmed Cheema
Deputy Director (PE&R)
Drug Regulatory Authority of Pakistan
Islamabad**.**

	Decision: Approved with innovator specifications. Letter shall be issued after submission of fee of Rs. 30,000/- for preregistration variation.

	Name and address of manufacture / Applicant	M/s. Revive Health Care, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore.					
	The firm vide letter submitted on 19.07.2024 has stated that their following 5 products deferred in 260th meeting of the Regstation board due to issue of import from India. 1. Cagin 50mg Injection Each vial contains:- Caspofungin Acetate eq. to Caspofungin…….50mg 2. Ambilip 50mg Injection Each vial contains:- Liposomal Amphotericin B USP……50mg 3. Amphotin Lip-50 Injection Each vial contains:- Amphotericin B Lipid Complex…50mg 4. Vonaz 200 Injection Each ml contains:- Voriconazole….200mg 5. Amphotin 50mg Injection (Lyophilized) Each vial contains:- Amphotericin B (Lyophilized) 50mg The firm has quoted following decision of 128th Meeting of Authority and have requested to consider their products for registration. *The Authority in its 128th meeting held on 14-12-2021, while considering the agenda item of "IMPORT OF ANTI-FUNGAL DRUGS FROM INDIA", decided as under: "The Authority noted that antimicrobials is a broader category which includes antibiotics, antifungals, antiprotozoals, and antivirals. While, antibiotics are antibacterial substance and are used to treat or prevent bacterial infections, therefore, clarified that anti-fungal products do not fall under definition of antibiotics and are importable from India as per Import Policy Order, 2016 subject to other conditions and requirements as per aforesaid order."* The extract of 5 products from minutes of 260th meeting of Registration Board is reproduced below for consideration of the Board.						
790.	M/s. Revive Health Care, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. M/s. United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District-Solan (H.P) 174101, India.	Cagin 50mg Injection Each vial contains:- Caspofungin Acetate eq. to Caspofungin…….50mg (Antifungal/Supportive cancer therapy) **New Molecule** Manufacturers Specifications. 24 months	Form 5A Dy No.26 dated 04-07-2014 Rs.50,000/- As per PRC	MHRA. Cancidas 50 powder for conc. For infusion by M/s MSD.	Free sales certificate issued dated 26-02-2016. COPP valid upto 10-5-2017. GMP valid upto 17-09-2017.	**Deferred as Anti-fungal drugs are not importable from India as per import Policy Order, 2016.**	

791.	M/s. Revive Health Care, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. M/s United Biotech (P) Ltd., Village Bagbania, Baddi-Nalagarh Road, District-Solan (H.P) 174101, India.	Ambilip 50mg Injection Each vial contains:- Liposomal Amphotericin B USP……50mg Antifungal Manufacturer's Specifications 24 months	Form 5A Dy No.29 dated 04-07-2014 Rs.100,000 /- As per SRO.	MHRA. Ambisome 50mg Powder for Infusion by M/s Gilead. Local. Anfogen 50mg, Ferozsons	COPP valid upto 10-05-2017. GMP complian t as per COPP. Free sales issued dated 26-02-2016. GMP valid upto 17-09-2017.	Defered as the product does not fall in the priority list. Moreover Anti-fungal drugs are not importable from India as per Import Policy Order, 2016
792.	M/s. Revive Health Care, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. M/s. United Biotech (P) Ltd., Village Bagbania, Baddi Nalagarh Road, District-Solan (Himachal Pradesh) 174101, India.	Amphotin Lip-50 Injection Each vial contains:- Amphotericin B Lipid Complex…50mg (Antifungal) Manufacturer's Specifications 2 years	Form 5A Dy No. 614 31-12-2015 Rs.50,000/- As per PRC	MHRA. Abelcet 5mg/ml Amphotericin B lipid complex(10ml , 20ml) Concen. For infusion by M/s Teva.	Free sale issued dated 26-02-2016. COPP valid upto 10-5-2017 Legalize d photocop y of GMP valid upto 17-09-2017.	Deferred as the product does not fall in the priority list. Moreover Anti-fungal drugs are not importable from India as per Import Policy Order, 2016
793.	M/s. Revive Health Care, Office 503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. M/s.United Biotech (P) Ltd., Village Bagbania Baddi- alagarh Road, District-Solan (Himachal Pradesh) 174101, India.	Vonaz 200 Injection Each ml contains:- Voriconazole….200mg (Antifungal) Manufacturer's Specifications 2 years	Form 5A Dy No. 615 dated 31-12-2015 Rs.50,000/- As per PRC	MHRA. Vfend 200mg powder for infusion by Pfizer.	Free sale issued dated 26-02-2016. COPP valid upto 10-5-2017. GMP valid upto 17-09-2017.	Deferred as Anti-fungal drugs are not importable from India as per Import Policy Order, 2016.

794.	M/s. Revive Health Care, Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. M/s. United Biotech (P) Limited, Bagbani, Baddi, Nalagarh Road, District, Solan, India.	Amphotin 50mg Injection (Lyophilized) Each vial contains:- Amphotericin B (Lyophilized) ..... 50 mg **(Anti-fungal)** Manufacturer's Specifications 02 years	Form-5-A Dy No.374 dated 04-05-2016 Rs.50,000/- & Rs.50,000 dated 24-06-2016. As per SRO	MHRA. Fungizone 50mg powder for solution by M/s E.R Squibb. Local. Medinet	Free sale issued dated 26-02-2016. COPP valid upto GMP valid upto 17-09-2017.	Defered as the product does not fall in the priority list. Moreover Anti-fungal drugs are not importable from India as per Import Policy Order, 2016

Decision: Registration Board approved the applications of Cagin 50mg Injection, Ambilip 50mg Injection, Amphotin Lip-50 Injection, Vonaz 200 Injection & Amphotin 50mg Injection (Lyophilized) as per Policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of Original Valid, legalized CoPP and GMP certificate along with Notarized Valid Letter of Authorisation for each product.

795.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	Chaien Syrup
	Composition	Each 5 ml of syrup contains: Pizotifen (as hydrogen maleate)…….0.25 mg Thiamine hydrochloride……0.875 Riboflavin phosphate…….1.31mg Pyridoxine hydrochloride……..0.77mg Nicotinamide……5.25mg
	Dairy No. date of R &I fee	Dy. No.7436; 08-07-2015; Rs.20,000/- (06-07-2015)
	Pharmacological Group	Vitamin
	Type of form	Form- 5
	Finished product specifications	**Manufacturer specifications**
	Pack size and Demand Price	60ml, 90 ml, 120 ml & 240 ml; As per policy of MOH
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too-status	Mosegor-V syrup of M/s Novartis Pharma
	GMP Status	Last inspection report dated 16-01-2019, with the following conclusion: Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remark of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as submitted reference is not verifiable.
	Decision of 283rd RB	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted

		by the Registration Board in its 275th meeting as submitted reference is not verifiable
	Evaluation by PEC AD(PEC-XII)	Me Too product mentioned by the firm has different composition
	Decision of 295th RB:	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
	Evaluation:	The firm has submitted reference of Cestonil Plus syrup reg No. 021843, manufactured by m/s Raazee Therapeutics Kasur, it has same formulation as the applied product. Further RRA reference is not submitted.
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. **1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
796.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	Gynezol 1.0% w/w Cream
	Composition	Each gram contains: Isoconazole Nitrate……1% w/w
	Dairy No. date of R &I fee	Dy. No. 1433: 19-10-2015 PKR 20,000/-: 16-10-2015
	Pharmacological Group	(Antifungal for topical use)
	Type of form	Form- 5
	Finished product specifications	**Firm has claimed in house specifications**
	Pack size and Demand Price	10gm, 40gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Ispgen by Shrooq
	GMP Status	Last inspection report dated 29-11-2016 do not have any conclusion and remarks regarding GMP status
	Remark of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Decision of 273rd RB	Deferred for following submissions • Comments of QA & LT Division regarding the GMP status of the firm • Evidence of approval in reference regulatory authorities
	Remark of the Evaluator.	The firm has submitted GMP certificate valid till 2023

	Decision of 320th RB:	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
	Evaluation:	The firm vide letter No. DRA/RRA/GTZ/FEB-24 dated 24.02.2024 has submitted reference of Travogen 1% crema AIFA Italy approved. The reference is verifiable.
	Decision: Approved with innovator specifications. Letter shall be issued after submission of fee of Rs. 30,000/- for preregistration variation.	
797.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	Trimax cream
	Composition	Each gram contains Flucinolone acetonide……..0.01% w/w Hydroquinone……..4.0% w/w Tretinoin……..0.05% w/w
	Dairy No. date of R &I fee	Dy No. 1807: 3-11-2015 PKR 20,000/-: 2-11-2015
	Pharmacological Group	Antiinflammatory and antipruritic drug
	Type of form	Form- 5
	Finished product specifications	**Firm has claimed in house specifications**
	Pack size and Demand Price	10g, 15g, 20g, 40g: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Trimelasin cream by Valor
	GMP Status	Last inspection report dated 29-11-2016 do not have any conclusion and remarks regarding GMP status
	Remark of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Decision of 273rd RB	Deferred for following submissions • Comments of QA & LT Division regarding the GMP status of the firm • Evidence of approval in reference regulatory authorities
	Remark of the Evaluator.	The firm has submitted GMP certificate valid till 2023
	Decision of 320th RB:	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
	Evaluation:	The firm has submitted reference of Tri-Luma Cream approved by USFDA. The reference is verifiable.
	Decision: Approved with innovator specifications. Letter shall be issued after submission of fee of Rs. 30,000/- for preregistration variation.	
798.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	Palidone XR 9mg Tablets
	Composition	Each extended release tablet contains: - Paliperidone …… 9mg
	Dairy No. date of R &I fee	13-02-2015 Dy.No.937 Rs.8000/= Rs.12,000/= 19-06-2012
	Pharmacological Group	(Psychotropic agent belonging to the chemical class of benzisoxazole derivatives.

	Type of form	Form- 5
	Finished product specifications	**Manufacturer's Specs**
	Pack size and Demand Price	1x10's 2x10's 3x10's 5x10's 10x10's 20x10's 50x10's 100x10's As Per SRO
	Approval status of product in Reference Regulatory Authorities	Invega prolong release tablets-MHRA
	Me-too-status	Invega 9mg Tablrts by M/s Johnson & Johnson Pharma, Pakistan
	GMP Status	Last inspection report of 10-02-2016 submitted with compliance remarks
	Remark of the Evaluator.	
	Decision of 263rd RB	Deferred for evidence of me-too status
	Remark of the Evaluator.	The firm has revised the strength from Paliperidone XR 9mg to Paliperidone XR 1.5mg as below: Palidone XR (Palinode XR) Each extended release tablet contains: Paliperidone…. 1.5mg The firm has submitted fee of Rs.7500 only Deposit 4805777154 dated 8 March 2022. The firm did not submit revised form5. GMP certificate valid till 2023.
	Decision of 320th RB:	**Deferred for confirmation of manufacturing requirements as per reference product.**
	Evaluation:	The firm vide letter No. DRA/RRA/GTZ/Feb-24 dated 24.02.2024 has submitted that there are no special manufacturing requirements for this product. They already have registration of same product Paligit XR 3mg Tablets. (different strength) The product applied is Osmotic-controlled release oral delivery system, it does require a small hole made in the tablet for making port for release of drug.
	Decision: Deferred for submission of evidence of facility for producing Osmotic-controlled release oral delivery dosage forms.	
799.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	Palidone XR 6mg Tablets
	Composition	Each extended release tablet contains:- Paliperidone …… 6mg
	Dairy No. date of R &I fee	13-02-2015 Dy.No.941 Rs.8000/= Rs.12,000/= 19-06-2012
	Pharmacological Group	(Psychotropic agent belonging to the chemical class of benzisoxazole derivatives.
	Type of form	Form- 5
	Finished product specifications	**Manufacturer's Specs**
	Pack size and Demand Price	1x10's 2x10's 3x10's 5x10's 10x10's 20x10's 50x10's 100x10's As Per SRO
	Approval status of product in Reference Regulatory Authorities	Invega prolong release tablets-MHRA
	Me-too-status	Invega 6mg Tablrts by M/s Johnson & Johnson Pharma, Pakistan
	GMP Status	Last inspection report of 10-02-2016 submitted with compliance remarks

	Remark of the Evaluator.	
	Decision of 263rd RB	Deferred for evidence of me-too status
	Remark of the Evaluator.	The firm vide letter No. DRA/RRA/GTZ/Feb-24 dated 24.02.2024 has submitted reference of Paliris-XR Tablets 6mg registered in name of M/s Genome Pharma. The product applied is Osmotic-controlled release oral delivery system, it require a small hole made in the tablet for making port for release of drug.
	Decision: Deferred for submission of evidence of facility for producing Osmotic-controlled release oral delivery dosage forms.	
800.	Name and address of manufacture / Applicant	**M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad**
	Brand Name + Dosage Form and Strength	G-Scab 5% Cream
	Composition	Each gram contains:- Permethrin……..5% w/w
	Dairy No. date of R &I fee	Dy No. 1431: 19-10-2015 PKR 20,000/-: 16-10-2015
	Pharmacological Group	Antiparasitic .
	Type of form	Form- 5
	Finished product specifications	**Firm has claimed in house specifications**
	Pack size and Demand Price	15g, 30g: As per SRO
	Approval status of product in Reference Regulatory Authorities	Permethrin 5% w/w cream by Sandoz (**MHRA** Approved)
	Me-too-status	Doxema cream by Tabros
	GMP Status	Last inspection report dated 29-11-2016 do not have any conclusion and remarks regarding GMP status
	Remark of the Evaluator.	The formulation is internationally available as racemic mixture containing Permethrin Medical grade 5% w/w (*cis:trans isomer* 25:75), while the firm has applied for simple permethrin API
	Decision of 273rd RB	**Deferred for following submissions** • **Update by QA & LT Division regarding the GMP status of the firm** • **Clarification regarding the Active Pharmaceutical Ingredient (API) since the formulation approved by reference regulatory authorities contains racemic mixture of medical grade permethrin 5% w/w (*cis:trans isomer 25:75*).**
	Remark of the Evaluator.	The firm has submitted that they will use drug substance of BP specifications and it does contain 23 % 27% Cis isomer and 73% to 77% trans isomer.
	Decision: Approved.	
801.	Name and address of manufacture / Applicant	**M/s Standpharm Pakistan (Pvt) Ltd. 20Km, Ferozepur Road, Lahore.**
	Brand Name + Dosage Form and Strength	VEXNIL-P TABLET
	Composition	Each film-coated tablet contains: Paracetamol……325mg Tramadol Hydrochloride….37.5mg
	Dairy No. date of R &I fee	Dy.No. dated 23-02-2015, Differential fee: Rs. 12,000 Dated 19-02-2015 vide deposit slip No.0308737 dated 19-02-2015.

		"Duplicate dossier"
	Pharmacological Group	Analgesic
	Type of form	Form- 5
	Finished product specifications	Not Mentioned
	Pack size and Demand Price	10's MRP Rs. 10.0 per tablet
	Approval status of product in Reference Regulatory Authorities	Ultracet coated tablet (Janssen Pharma) US FDA approved. In MHRA both coated and uncoated available.
	Me-too-status	Tramal plus film coated tablet of M/s The Searle Company, Lahore. Registration No. 077129
	GMP Status	cGMP compliance certificate No. 101/2020-DRAP (AD-322072-1295) dated 29-06-2020 issued based on evaluation conducted on 18-02-2020.
	Remark of the Evaluator.	• Firm was asked to submit covering letter, bearing statistical officer and DRAP R & I stamp along with fee challan copy of initial submission but did not provide the same. • Firm has revised finished drug product specifications as per USP and submitted fee Rs:7500/- vide deposit slip No.60091350. Minutes of of 321st meeting of Registration Board (20th - 22nd September, 2022) 987 • Tablet Section (General) section available as per Licensing Division letter No.F.1-51/84-Lic (Vol-II) dated 30-06-2020 for renewal of Drug Manufacturing License.
	Decision of 321st RB	**Deferred for verification of R & I record of initial submission of registration application and differential fee submission.**
	Remark of the Evaluator.	The firm vide letter No. nil dated 12.01.2024 has submitted their response. The firm has stated that they have submitted fees as under; Rs. 8000/- vide slip no. 15503054, with R&I receiving dated 07.11.2022. Rs. 12000/- vide slip No. 0308737 dated 19.02.2015 R&I 23.02.2015 Firm has submitted yellow slip (customer copy) of the differential fee submitted vide slip No. 0308737 dated 19.02.2015
	Decision of 336th RB:	**Deferred for verification of fee from concerned division.**
	Remarks of Evaluator:	The firm vide letter No. nil dated 11.07.2024 has again requested for consideration of their application. Further the firm has submitted fee of Rs. 20,000/- vide slip No. 9008973117.
	Decision: Deferred for verification of fee from concerned division.	

Registration-I Section

Case No 01: **Show Cause Notice to M/s Lisko Pakistan Ltd for Submitting Application of Zinkrol Syrup (Zinc Sulphate Monohydrate Eq To Elemental Zinc….20mg) Twice**

M/s Lisko Pakistan Ltd, L-10-D Block 21, Industrial Federal B Area, Karachi has applied two applications for registration of same product which were considered in different meetings details as under:

Extract of M-276

Name and address of manufacturer / Applicant	M/s Lisko Pakistan, Karachi
Brand Name +Dosage Form + Strength	Zinkrol Syrup 20mg/5ml
Composition	Each 5ml contains: Zinc sulphate monohydrate eq to elemental zinc….20mg
Diary No. Date of R& I & fee	**Dy. No.1226; 31-12-2015; Rs.20,000/- (29-12-2015)**
Pharmacological Group	Zinc Suplement
Type of Form	Form-5
Finished product Specification	International pharmacopoeia
Pack size & Demanded Price	60ml; Rs.80/- 90ml; Rs.100/- 100ml; Rs.110/- 120ml; Rs.130/-
Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
Me-too status	Zevro Syrup 20mg
GMP status	Last inspection report 23-1-2017 overall GMP compliance level is good.
Remarks of the Evaluator.	
Decision: Approved	

Extract of M-285						
Sr. No	**Name and address of manufacturer / Applicant**	**Brand Name** **(Proprietary name + Dosage Form + Strength)** **Composition** **Pharmacological Group** **Finished product Specification**	**Type of Form** **Initial date,** **diary** **Fee including differential fee** **Demanded Price /Pack size**	**Approval status in Reference regulatory agencies / authorities** **Me-too status/ GMP status**	**Previous Decisions**	**Evaluation by PEC**
380.	M/s Lisko Pakistan Pvt. Ltd. L- 10-D, Block no. 21, Shaheed Rashid Minhas Rd. F.B industrial area, Karachi 346	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate as Elemental Zinc ……..20 mg Zinc Supplement.	Form5 **31-12-2013** Dy.No.623 Routine Rs. 20,000/- Rs.75/60ml Rs.130/120ml	WHO recommended formulation Zincat oral solution of M/s Atco Labs Karachi (Reg # 053094) GMP inspection conducted on	Deferred in **262nd** meeting as formulation is under review. Deferred for the confirmation of valid DML status (Drug manufacturing License) from	The firm has submitted that the policy regarding formulation of said product has been decided and registration of same has been given to many companies in recent times.

		(Mfg. Specs)		27-09-2018 concluded that all relevant activities in process areas, QC and ware house were found at good level of GMP compliance. Area FID vide letter No.F.SAA.02-06/2018-FID-V dated 30-08-2018 has confirmed that firm has purchased two stability chambers with capacity of 250L (accelerated) and 800L (Real time), placed in their QC department.	Licensing Division. **(M-282)**	
Decision: Approved with USP specifications.						

Accordingly, registration letters were issued to both products as per following details:

Sr.No	Reg.No.	Brand Name & Composition	Reference Letter No & Dated
1.	092905	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate eq. to Elemental Zinc ……..20mg (USP Specifications)	No.F.3-8/2018-Reg-II (M-285) dated 08-02-2019
2.	086949	Zinkrol Syrup Each 5ml contains: Zinc Sulphate Monohydrate eq. to Elemental Zinc ……..20mg (IP Specifications)	No.F.3-13/2017-Reg-II (M-276) dated 15-03-2018

Show cause notice to to be issued to M/s Lisko Pakistan Ltd for submitting two different

applications of same formulation (same strength and same dosage form) i.e Zinkrol syrup 20mg/5ml (zinc sulphate monohydrate).

Decision 336th meeting: Registration Board deliberated the case and decided to issue show cause notice to the firm under Section 7 (11)(a) of the Drug Act, 1976 that why the registration of their product "Zinkrol Syrup (Reg. No. 092905)" may not be cancelled.

Accordingly show cause notice was issued to firm dated 09.07.2024 and firm had submitted reply dated 19.07.2024 as follows:

We submitted first dossier of Zinc sulphate syrup 20mg/5ml on 31-12-2013 via Dy. No 623 with all relevant documents and challan regarding registration of product with the brand name "ZINKROL" . Later on, we came to know that our dossier file has been missed by the clerical staff of registration department of DRAP. We gave numerous reminders to registration board as well in this regard but we got no response. After waiting for around 2 years, we submitted new dossier for Zinc sulphate syrup and we applied same product second time on 31-12-2015 via Dy. No 1226 with same brand name "ZINKROL" considering the situation that first dossier file has been missed place. After couple of years, we got registration against both submitted dossiers of Zinc sulphate syrup i.e first on 15-3-2018 and second on 8-2-2019.

We willingly submitted an application for de-registration of product "ZINKROL SYRUP with IP Specs REG NO# 086949" on 14-7-2022 but we got no reply from registration board. Our intentions were clear to keep single registration of Zinc sulphate syrup 20mg/5ml at a time with brand name "ZINKROL". We are continuously supplying product "ZINKROL having registration no# 092905 (USP specs)" in market and also in government institutions whereas we have stopped production of "ZINKROL having registration no# 086949 (IP specs)"

We request you to kindly do not cancel registration letter of ZINKROL syrup (USP specs) having registration no# 092905 rather we are willing to get de-registration of our product ZINKROL syrup (IP specs) having registration no# 086949.

Keeping in view the response submitted by the firm and in line with section 42 of the Drugs Act, 1976, firm has been called for personal hearing before the Registration Board on 08th August, 2024 at 11:00 AM.

Proceeding 339th meeting:

Manager operation/Regulatory Affairs appeared before Registration Board. He again elaborated firm's stance and requested the Board to not cancel registration letter of ZINKROL syrup (USP specs) having registration no# 092905 rather they are willing to de-register their product ZINKROL syrup (IP specs) having registration no# 086949.

The Registration Board considered the firm's request and decided to cancel registration of product ZINKROL syrup (IP specs) having registration no# 086949.

Decision: Registration Board has decided to cancel the registration of ZINKROL syrup (IP specs) having registration no. 086949 by M/s Lisko Pakistan Pvt. Ltd. L- 10-D, Block no. 21, Shaheed Rashid Minhas Rd. F.B industrial area, Karachi 346 and decided to issue warning to firm for holding two registrations since long (dated 08.02.2019).

Case No. 02: Cancellation of registration of S-Rone tablet (Reg No 008379) by M/s Medicon Pharmaceutical industry, Peshawar

Registration Board in 316th meeting (held on 15th, 16th, 17th &18th March ,2022) deliberated on the matter regarding manufacturing facility/section approval by Licensing division for manufacturing of Dydrogesterone Tablet. As concluded after discussion with Licensing Division, DRAP, M/s Medicon, Peshawar (previously M/s S.D.H. Laboratories (Pak) Ltd) does not hold any approval of Tablet (Hormone) Section issued by Licensing Division, under Clause 5.2 of Schedule B under the Drug (L, R&A) Rules, 1976 under Drug Act, 1976.

Furthermore, firm was directed to comply official monograph i.e USP by DRAP, Peshawar (vide letter dated 02.05.2019) in compliance with the decision of 152nd meeting of Appellate Board (held on 24th and 25th April, 2019).

Proceeding regarding cancellation of product under discussion under section 7 (11) and Section 42 of the Drugs Act, 1976 could not be initiated as status quo was granted by Honorable, Civil Judge, Peshawar. Later on the court in its order dated 11.03.2024 has dismissed the suit.

Accordingly show cause was issued dated 04.07.2024 and directed to reply in writing within seven working days. However, firm has not submitted any reply against said show cause notice till date. In line with Section 42 of the Drugs Act, 1976, firm has been called for personal hearing before the Registration Board on 08th August, 2024 at 11:00 A.M.

Proceeding 339th meeting:

Production Incharge "Rasul Muhammad" appeared before Registration Board. He apprised Board about Lay out Plan applied to Licensing division for establishing manufacturing facility of Tablet (Hormone) section. He further stated that manufacturing of said drug has been stopped, once the said facility got approved by CLB firm will start manufacturing of Dydrogesterone tablet in line with USP as directed by Registration Board. elaborated firm's stance and requested the Board to not cancel registration letter of ZINKROL syrup

Registration Board deliberated the matter and decided as under:

Decision: Keeping in view the unavailability of manufacturing facility i.e Tablet (Hormone) section, Registration Board decided to cancel the registration of S-Rone tablet (Reg No 008379) by M/s Medicon Pharmaceutical industry, Peshawar.

Case No.03. Cancellation/ Revocation of Approval Granted to M/s Genix Pharma Pvt Ltd.

44,45B, Korangi Creek Road, Karachi, 75190, Pakistan for Registration of Ondonix 8mg Tablet

Registration Board in its 336th meeting, held on 04th-06th June, 2024, approved following product in favor of M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan

Table-I

S. No.	Product Name & Composition	Diary No. & Date	Decision of M-336
1.	**Ondonix 8mg Tablet** **Each Film Coated Tablet Contains:** **Ondansetron HCl Dihydrate Eq. to Ondansetron…8mg** **(USP specification)**	Dy.No 30592 dated 30-10-2022	Approved.

While processing for issuance of registration letter, it was identified that the firm has already been issued registration of same formulation in same strength and dosage form. Detail is as under:

Table-II			Letter No and date
S. No	**Reg. No.**	**Name of Drug(s) & Composition**	**F.3-5/2016-Reg-II(M-258)** **Dated 03.08.2016**
1.	081451	**Ondonix Tablet** **Each Tablet Contains:** **Ondansetron HCl Dihydrate Eq. to Ondansetron…8mg** (Manufacturer Specifications)	

Accordingly, the case has been placed before the Board for declaring the approval of 336th meeting as mentioned in Table-I above as redundant/ disposed of.

Decision: Registration Board considered the case and declared approvals of Ondonix 8mg tablet (336th meeting) as redundant/ disposed of.

Case No.04. Request for Change in Registration Status of Orlirise 120mg Capsule from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi (DML No. 000012) to M/s Aspin Pharma Pvt Ltd., Korangi Industrial Area Karachi (DML No. 000045).

The instant case was presented before the 307th meeting of the Registration Board, the Board deferred the case with the following decision:

"Deferred for submission of degradation studies (quantification of degradation products) at next time point till the remaining shelf life of the product."

However, instead of providing degradation quantification studies in the same product formulation for the time intervals in the remaining shelf life stability studies, the firm opted to change the source of drug substance (pellets) for the applied product (from M/s Surge Laboratories (Pvt) Ltd, 10th Km Faisalabad Road, Bikhi, District Sheikhupura (DML 000649) to M/s Murli Karishna Pharma Private Limited D-98,ranjangaon Taluka Shirur, Pune Maharashtra State, India) and provided the revised modules 2 and 3 of the application dossier with a pre-variation fee.

I	II	III	IV
	Reg. No.	**Product Name & Composition** **(As per the initial Registration letter)**	**Registration Trail**

	055576	Orlirise 120mg Capsule Each capsule contains: - Orlistat …….120mg	**Initial Reg. Date:** In the Name of M/s Merck Sharp & Dhome Pakistan 31-04-2009 Transfer of Registration from MSD to OBS Pakistan (Pvt.) Ltd 9th -07-2009 Renewal of Registration 17-06-2014 Change of title from OBS to SPL 10-06-2022 Last Renewal 26-03-2019
1.	**Name, address of Applicant / Marketing Authorization Holder**		M/s Aspin Pharma Pvt Pharma Pvt Ltd. **Address: Plots # 10 & 25, Sector 20 Korangi** **Industrial Area Karachi – 74900, Pakistan**
	Name, address of Manufacturing site.		M/s Aspin Pharma Pvt Pharma Pvt Ltd. **Address: Plots # 10 & 25, Sector 20 Korangi** **Industrial Area Karachi – 74900, Pakistan DML No-00045)** **(Transfer of Registration from M/S Searle Pakistan Limited formerly OBS (Pvt) Ltd.** **NOC attached dated:02-10-2023**
	Status of the applicant		☒Manufacturer ☐Importer ☐Is involved in none of the above (contract giver)
	Evidence of approval of manufacturing facility		The applicant has provided copies of the renewal of the DML letter. And facility GMP certificates of manufacturing site mentioning Capsule (General) among Formulation sections.
	Status of application		☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale

		☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated: 15-04-2019 & 15-02-2021 Dy.No : 24002 dated 02-10-2023
	Details of fee submitted	PKR 150,000/- DS 11511508 deposited on 06-05-2022
	The proposed proprietary name / brand name	**Orlirise Capsule 120mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Orlistat …….120mg
	Pharmaceutical form of applied drug	Hard gelatin capsule size 1 blue cap and white body containing white to off white color semi spherical pellets
	Pharmacotherapeutic Group of (API)	Anti-obesity
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Xenical Capsule 120mg FDA Approved
	For generic drugs (me-too status)	Orlifit Capsule 120mg by M/s Getz Pharma (Pvt)Ltd
	GMP status of finished product Manufacturer	The inspection report concluded M/s Aspin Pharma is running at a good level of GMP compliance based on the inspection conducted on 09.02.2022.
	Name and address of API (Pellets) Manufacturer.	Murli Karishna Pharma Private Limited. D-98,ranjangaon Taluka Shirur, Pune Maharashtra State, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per the WHO QOS-PD template and submitted summarized information related to nomenclature, general properties, structure, physical form, solubility, polymorphism, manufacturing site, manufacturing process and control, impurities, batch analysis, working standards, container closure system and stability studies of drug substance & drug products.
	Module-III Drug Substance:	The firm has submitted data on drug substance-related details of physical and chemical properties, manufacturers, structure elucidation studies, impurities characterization, and specifications based on USP and HIS (melting range). The firm described the analytical procedure and provided CoAs by DS and DP

		manufacturers. The Batch formula and brief manufacturing process, critical steps and excipient control were explained. An analytical process and its validation studies and CoAs were provided. Batch analysis complying with specifications, development and handling of working standards, and container closure system control studies were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The pellet manufacturer conducted stability studies on 3 batches (MKPPLR-ORE-18044, MKPPLR-ORE-18045 & MKPPLR-ORE-18046) in real-time, intermediate as per the following details: - • Real time: 25°C ± 2°C / 65% ± 5%RH for 24 months • Intermediate: 30°C ± 2°C / 65% ± 5%RH for 12 months • Zone IVB 30°C ± 2°C / 75% ± 5%RH for 36 months. The samples per packed in double polyethylene bags (transparent inner bag packed in black polyethylene bag) and then placed in an HDPE container. The DS shows remain stable and within specified limits.
	Module-III Drug Product:	The firm has submitted detailed information about the drug product, including a description of the product and composition, formulation development, manufacturing process, critical controls and validation protocol, pharmaceutical equivalence and CDP against Xenical 120mg capsules, specifications, analytical procedure and its validation studies, batch analysis and specification based on USP monograph, CoAs, working standard, container closure system and its CoAs, and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Xenical Capsule 120mg (Physical appearance, Identification, weight variation (content) disintegration Time Assay, dissolution, content uniformity organic impurities are assessed & on the basis of these test comparison both products are said to be pharmaceutically equivalent. The comparative dissolution of Orlirise Capsule 120mg was performed against the Xenical 120mg capsules manufactured by Delpharm Milano, Batcg M2434M3, Exp Date 03-2022, in the Test medium 1 (Hydrochloric Acid pH 1.2), Test medium 2 (Acetate buffer pH 4.5) and Test medium 3 (Phosphate buffer pH 6.8).

Sr	Medium	Time interval	Sample	Reference
	Acidic buffer (pH 1.2)	10 min	65.498%	39.070 %
		20 min	73.243%	60.066%
		30 min	73.737%	76.001%
		45 min	69.367%	86.517%
		60 min	61.822%	94.674%
		f1 = 26.063 f2= 33.616		
ii	Acetate buffer (pH 4.5)	10 min	79.17%	49.291 %
		20 min	93.09%	68.326%
		30 min	96.839%	74.547%
		45 min	97.720%	74.569%
		60 min	97.828%	75.861%
		f1=35.629 f2=30.449		
iii	Phosphate Buffer (pH 6.8)	10 min	79.334 %	32.868 %
		20 min	89.417%	43.607%
		30 min	92.475%	51.465%
		45 min	94.579%	58.966%
		60 min	94.165%	65.074%
		f1=78.574 f2=19.817		

The CDP results revealed that f1 and f2 values are non-compliant. However, the firm conducted CDP with the addition of BCS buffer at pH 6.0 which revealed the following results:

Sr	Medium	Time interval	Sample	Reference
	SLS+NaCl (pH 6.0)	10 min	83.35%	81.46 %
		15 min	86.99%	88.55%
		20 min	88.31%	89.54%

		30 min	95.75%	91.50%
		45 min	92.88%	92.88%
		60 min	92.94%	92.61%
		f1 = 1.724 f2= 81.958		

The both product were comparable at pH 6.0 with addition of buffer.

Analytical method validation/verification of product	Analytical Method verification studies have been submitted including System suitability, specificity, Accuracy, precision, Robustness & Solution stability

STABILITY STUDY DATA

Manufacturer of API	Murli Karishna Private limited. D 98,RANJANGAON MIDC,RANJANGAON,TALUKA-SHIRUR,PUNE 412209 MAHARASHTRA STATE,INDIA
API Lot No.	MKPPL-ORE-22101
Description of Pack Container closure system)	Orlirise 120mg Capsule is available in blister (ALU-ALU) Pack of 10's
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 06months
Frequency	Accelerated: 0, 3, (Months) **(The accelerated studies were discontinued after 03 months due to significant changes in physical appearance because the melting point of orlistat is 42°C -44°C.)** Real-Time: 0, 3, 6, 9,12,18, 24 (Months) (18 months studies data submitted)

Batch No.	196DS04	196DS05	196DS06
Batch Size	2500	2500	2500
Manufacturing Date	22.08.2022	22.08.2022	22.08.2022
Date of Initiation	06.09.2022	06.09.2022	06.09.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted a copy of the GMP Certificate of M/s Murli Krishna Pharma Private Limited issued by Food & Drugs Administration Bandre (E), Mumbai, M.S Maharashtra State, India Validity:06-07-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted a copy of invoice specifying the purchase of 2.5 kg Orlistat Pellets 50% w/w. Form-6 issued from DRAP Karachi dated:13-Jul-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted the data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted the Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6	Record of Digital data logger for temperature and humidity monitoring of stability chamber (Real time & Accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chamber (Real time & Accelerated)

Evaluator's Remarks:

Forced Degradation study was performed during Analytical Method Validation as under:

- Acidic degradation
- Alkaline degradation
- Oxidative degradation
- Thermal degradation

No major degradation observed after applying oxidative and thermal stress while major degradation occurred after applying acidic and alkaline stress to the solution of orlistat pellets in initial stage and 48hr respectively.

However, quantification of degradation product was t done during stability study up to the shelf life (so far 18 months).

Decision: Registration Board acceded to the request of firm for change of market authorization of product of Orlirise 120mg Capsule from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi (DML No. 000012) to M/s Aspin Pharma Pvt Ltd., Plots # 10 & 25, Sector 20 Korangi Industrial Area Karachi – 74900, Pakistan (DML No-00045).

Case No.01: Cancellation of Registration of Drugs in lieu of cancellation of DML.

Central Licensing Board in its 288th meeting held on 06-10-2022 cancelled Drug manufacturing licenses of M/s Envoy Pharmaceuticals (Pvt) Ltd. 27-Km Multan Road Maraka, Lahore. Detail is as under;

Decision of 288th Meeting of Central Licensing Board

"***The Board while considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000607 (formulation) of M/s Envoy Pharmaceuticals (Pvt) Ltd. 27-Km Multan Road Maraka, Lahore as the Drug Manufacturing License No. 000607 is no more valid as under Rule 5 (6) of The Drugs (L, R & A) Rules, 1976."***

[(No.F.1-54/2003-Lic (Vol-I) dated 23-12-2022]

Registration Board in its 307th meeting has authorized its Chairman for issuance of show cause notice for cancellation of registration after cancellation of DML. Accordingly, M/s. Envoy was issued show cause notice.

It was appraised that no response/reply to the showcause notice was received. The company filed an appeal against the decision of CLB which was decided in 166th sitting of Appellate Board held on 5th June, 2024 as under;

"In light of the foregoing, the Appellate Board holds that the impunged order…… the appeal is dismissed. The Drug Manufacturing Licence of Envoy Pharmaceuticals (Pvt) Limited having registered office and manufacturing unit at 27 KM, Multan Road, Maraka, Lahore shall remain cancelled."

Decision: Registration Board decided to cancel registration of all the drugs registered in the name of M/s Envoy Pharmaceuticals (Pvt) Ltd. 27-Km Multan Road Maraka, Lahore in the light of cancellation of Drug Manufacturing Licence by the CLB and Appellate Board.

Case No. 02: Correction in registration letter of M/s Unimark Pharmaceuticals Pvt Ltd. Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad.

Registration Board in its 331st meeting approved following registration application of M/s Unimark Pharmaceuticals Pvt Ltd. Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad. Detail is as under:

Name, address of Applicant / Marketing Authorization Holder	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
GMP status of the manufacturer	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission & Details of fee submitted	Dy.No 12630 dated 24-05-2022 Rs.75,000/- dated 29-03-2022
The proposed proprietary name / brand name	**Unidon 1gm IM Injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1gm
Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
Reference to Finished product specifications	USP specs
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	Ceftriaxone powder for solution for injection (MHRA Approved)
For generic drugs (me-too status)	Droncef injection by Seraph Pharmaceuticals
Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.

Evaluation by PEC:

The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Amson Vaccines and Pharma Pvt Ltd. Plot No. 154, Industrial Triangle Kahuta Road Islamabad
Manufacturer firm	M/s Seraph Pharmaceuticals Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	Cesod 1gm IV injection

Decision: Approved.

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

In light of above approval of the Board, registration letter was issued as per below mentioned details:

Sr. No.	Reg. No.	Name of Drug(s) & Composition
1.	121417	Elvis 1gm Injection IM Each vial contains: Ceftriaxone (as sodium) …… 1gm (USP Specifications)

Firm has submitted that their applied rout of administration was IV instead of IM and requested for correction in route of administration of their registered product. Firm has also submitted copy of registration application dated 24-05-2022, which reveals that firm's applied route was IV instead of IM.

Decision: **Registration Board approved correction in rout of administration as per following details:**

Sr. No.	Reg. No.	Name of Drug(s) & Composition with existing Rout of Administration	Name of Drug(s) & Composition with correct Rout of Administration
1.	**121417**	**Elvis 1gm Injection IV** **Each vial contains:** **Ceftriaxone (as sodium) … 1gm** **(USP Specifications)**	**Elvis 1gm Injection IM** **Each vial contains:** **Ceftriaxone (as sodium) … 1gm** **(USP Specifications)**

Case No. 03: Allocation of Quota for Control Substances Ephedrine HCl for the year 2017 to M/s. Sharex Laboratories, Sadiqabad.

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below: -

2. Proceedings of 275th Meeting of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the committee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product Tracodil Syrup‖ (Reg. No. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

3. **Decision of 275th meeting of Registration Board:**
Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

4. **Proceedings of 286th meeting of Registration Board:**
Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product Tracodil syrup (Reg.003158) without approval.

5. **Decision of 286th meeting of Registration Board:**
Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

6. **Accordingly, the case was referred to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:**

i. That M/s. Sharex Laboratory applied for the quota allocation of product Tracodil Syrup (Reg.No.003158).

ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of "Tracodil Syrup" (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of "Tracodil Syrup" (Reg.No.003158) and 60ml (dated 27th October, 1988).

iii. That the approved pack size of the product "Tracodil Syrup" (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).

iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product "Tracodil Syrup" (Reg.No.003158) without approval.

v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.

vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

7. Decision of 289th meeting of Registration Board:

In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue show cause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:

- Cancellation of registration.
- Suspension of registration.
- Prosecution in Drug Court

8. Accordingly, a showcause notice was served to M/s. Sharex Laboratories, Sadiqabad.

9. Registration Board in its **295th meeting** deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

10. In **296th meeting** M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm and stated that firm was unaware about the approval of pack sizes of Tracodil Syrup (Reg.No.003158) as on initial registration letter no pack size was written. He has further stated that firm will submit all the relevant documents / approvals granted by DRAP regarding said product.

11. Registration Board in 296th meeting deferred the case for further deliberation after submission of documents as stated by representative of the firm.

In compliance with 296th meeting of Registration Board firm has submitted following documents;

i. Initial registration letter of Ammonium Chloride Syrup Reg. No. 003158 dated 06-11-1977 in which Pack size & MRP are not mentioned.
ii. Change of brand name letter from Ammonium Chloride Syrup to Tracodil Cough Syrup dated 16-08-1979
iii. Price revision of locally manufactured / fixation of prices of additional packs letter dated 27-10-1988 in which Pack sizes along with MRPs are mentioned with following details;

Sr. No.	Reg. No.	Name of Drug	Packing	MRP
1.	003158	Tracodil Cough Syrup	120ml	8.00
			60ml	5.00
			450ml	18.50

12. **Decision of 308th Meeting of registration Board:**

Registration Board after through deliberation decided as follows:

- Referred the case to Costing & Pricing Division for proceeding as per rules for overcharging of MRP.
- Manufacturing of product as per approval granted by relevant forums.

13. Accordingly, above decision of Registration Board was communicated to **Costing & Pricing Division and reply** of said Division is as under;

"In light of opinion of the Legal Division, the matter is of selling of an un-approved pack size which may fall under violation of the conditions of Registration. Moreover, no evidence of overpricing has been provided. Therefore, Division of PE&R may proceed in accordance with the opinion of the Legal Division."

14. Opinion of Legal Affair's Division is as under;

i. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

ii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision of 317th meeting of RB

Registration Board deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

As per above decision of the Board, case was referred to **Legal Affairs Division and opinion of said division** is as under:

"The apex courts have guided that Principles of natural justice must be read into each and every statute unless and until it is prohibited by the statute itself---Even if there is no provision as to issuance of notice of personal hearing to the affected party, in a statute, it cannot override the principles of natural justice and an opportunity of a hearing has to be provided to the affected party. Registration Board is statutory Board constituted under Section 7 of the drugs act, 1976. And if some new facts came before the Registration Board regarding the firm, then an opportunity of personal herring may be provided to the firm before final decision of the Board if it thinks fit to fulfill the principle of natural justice. It is pertinent to note that in case of any grievance the firm has alternate remedy of appeal under Section 9 of the drugs act, 1976 before the Appellate Board of the Authority."

Proceedings of 323rd Meeting:

It was discussed in meeting that before proceeding for penalty for prohibitions, as per opinion of the Legal Affair's Division mention in para 14 above, showcause notice has to be issued to the firm for violation of condition of registration as firm is manufacturing un-approved pack size of their registered product.

Decision of 323rd Meeting of the Board

Registration Board decided to issue show-cause notice under Section 7 (11) (c) to M/s. Sharex Laboratories (Pvt) Ltd. KLP Road Sharex Colony, P.O Box No. 11, Sadiqabad District Rahim Yar Khan for violation of condition of registration.

As per above decision of the Board, Show-Cuase notice has been issued to the firm and reply of the firm is as under:

i. They have submitted that they have been manufacturing Tracodil Syrup (Ammonium Chloride Syrup) since 1965. When the Drug Act 1976 got implemented, they were issued a Registration Letter dated 06-11-1977 for Ammonium Chloride Syrup having registration number 003158. In this letter no pack size and no retail price was mentioned.
ii. On 16-08-1979, another letter was issued by Ministry of Health granting them the named of Tracodil Syrup for their registered product Ammonium Chloride Syrup Reg.No.003158.
iii. On 27-11-1988, a letter was issued for Tracodil Syrup where 60ml, 120ml and 450ml pack sizes were mentioned with MRP. It is important to mention that this product was de-controlled for pricing till 2000. At that time firm was manufacturing Tracodil Syrup in 400ml pack size and continued producing in the same pack size. As the price was decontrolled at that time, fixing MRP was not used to be an issue at that time.
iv. Firm continued producing and submitting Ephedrine HCl consumption record of Tracodil Syrup till early 2017 until the Assistant Director (CD) mentioned it in her letter dated 20-04-2017. It is to clarify that the consumption record the Ephedrine HCl was absolutely correct and no discrepancy was found as far as the consumption of Ephedrine was concerned.
v. They have further submitted that no mal intention what so ever was involved in the production of "Tracodil Syrup" 400ml as consumption record for Ephedrine HCl was submitted according to 400ml pack size. As this is 55-year-old registered product and at that time there were not much regulations and price was also de-controlled, this product somehow mistakenly kept manufactured in this pack size.
vi. They have requested to kindly forgive this mistake of their, as they are in this business for around 6 decades and never been involved in any unlawful activity.

Now, firm has been called for personal hearing.

Proceedings of 329th meeting:

M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and stated that they were manufacturing pack size of 400ml as till 2000, MRP of their product was decontrolled.

Decision of 329th Meeting of the Board:

Registration Board deferred the case for further deliberation

Decision of 331st meeting

The registration Board directed the PE&R division to consult the legal affairs division and Cost & pricing division and place the case in the next meeting.

Decision of 339th meeting: Registration Board after thorough deliberation with representative of Legal Affair's Division and in the light of response of Costing & Pricing Division decided as under:

i. To communicate status of product to Controlled Drugs Division that Tracodil Syrup (Reg. 003158) is a registered product of M/s. Sharex Laboratories (Pvt) Ltd. KLP Road Sharex Colony, P.O Box No. 11, Sadiqabad District Rahim Yar Khan with approved pack sizes of 60ml, 120ml and 450ml.

ii. To issue strict and stern warning to M/s. Sharex Laboratories (Pvt) Ltd., KLP Road Sharex Colony, P.O Box No. 11, Sadiqabad District Rahim Yar Khan and hereby ordered to manufacture Tracodil Syrup (Reg. 003158) as per approved granted by DRAP. Non-compliance of this order shall be dealt strictly under the law.

Case No. 1 Correction in Registration No. of Invital-D Injection M/s Kaizen Pharmaceutical Pvt Ltd, Karachi.

M/s Kaizen Pharmaceutical Pvt Ltd, Karachi has requested for change the product registration status of Invital D 5mg/5mL injection from M/s Ray Pharma (Pvt) Ltd, S-58 S.I.T.E, Karachi to their name. the matter was approved in 336th meeting of Registration Board. However, during recording of minutes of meeting registration number was mistakenly written as 10286 instead of 061284. The firm has requested for correction in registration number. Details is as below: -

Sr. No.	**Product name and composition**	**In correct registration no.**	**correct registration No.**
01.	Invital-D Injection Each ml contains: Cholecalciferol B.P…… 5mg eq. to 200,000 IU of Vitamin D	102826	061284

Decision: The Registration Board acceded to the request of firm for correction of registration number of Invital-D Injection from 102826 to 061284.

Case No. 01: **APPLICATION FOR ISSUANCE OF DIFFERENT REGISTRATION NUMBERS FOR FOLLOWING ALREADY REGISTERED DRUGS.**

M/s. OBS Pharma (Pvt.) Ltd., 108, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore has submitted an application for correction in registration numbers of already registered products. The firm was issued approval letter with same registration numbers for following products. The details are as under:-

Sr. No.	Reg. No.	Product Name & Formulation
1.	081644	Advantan Cream Each 1gm contains Methyl Prednisolone aceponate…….1mg
2.	081644	Advantan Ointment Each 1gm contains: Methyl Prednisolone aceponate…….1mg
3.	081644	Advantan Fatty Ointment Methyl Prednisolone aceponate…….1mg
4.	004105	Nerisone Cream Each 1gm contains: Diflucortolone valerate……..1mg
5.	004105	Nerisone Ointment Each 1gm contains: Diflucortolone valerate……1mg

Now the firm has informed that they want to retain the already allotted registration numbers for products at **Sr. No. 1 & 4 (Advantan Cream & Nerisone Cream)** and requested to issue new registration numbers for products at **Sr. No. 2, 3 & 5 (Advantan Ointment, Advantan Fatty Ointment & Nerisone Ointment)**. The firm has submitted the following documents:

1. Copy of registration & renewal letters.
2. Original fee challans of Rs. 10,000 x 3 = Rs. 30,000/- for each product.

Decision:

Registration Board acceded to the request of firm to grant separate registration numbers for Advantan Ointment, Advantan Fatty Ointment & Nerisone Ointment.

Case No. 02: **PERSONAL HEARING REGARDING BRAND NAME SIMILARITY/ RESEMBLANCE OF M/S. PHARMASOL PVT LTD., PLOT NO. 549, SUNDAR INDUSTRIAL ESTATE, LAHORE.**

M/s Pharmasol Pvt. Ltd., Lahore has been granted registration of Myfos Sachet vide Reg. No. 090415. It is pertinent to mention that the said brand name is resembling to already registered brand name of **Myfosin Sachet Reg. No. 080687 registered in name of M/s. GT Pharma Pvt. Ltd., Lahore**.

This aforementioned similarity with an already registered product is against the condition of registration and may be misleading. M/s Pharmasol Pvt. Ltd., Lahore had already been advised to change the brand name vide this DRAP letter No. F.No.3-1/2021 (PR-II) dated 18th January, 2023 and final reminder No. F.No.3-1/2021 (PR-II) dated 03rd August, 2023. The firm did not submit the response. Accordingly, a show cause notice was issued to the firm as per decision of 331st meeting of Registration Board and firm has been called for personal hearing before the Board.

Decision:

Registration Board deliberated that enough time has already been granted to the firm for change in brand name but the firm did not submit the reply to the DRAP letter and its reminder and the show cause notice/personal hearing or applied for change of brand name till date. Hence, Registration Board decided to suspend the registration of Myfos Sachet (Reg. No. 090415) till appearance of M/s Pharmasol Pvt. Ltd., Lahore before Registration Board or further orders by the Board.

Mr. Salateen Wasim Philip

Case No. 01: Change in Market Authorization Holder & Manufacturing Site

1.	**Change of Marketing Authorization Holder (Tablet URICONTROL 5mg – Reg. # 081070)**	
	From (existing MAH)	**To (Applicant)**
	M/s The Searle Pakistan Ltd. *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012)** **C-14 Mangopir Road SITE Karachi.**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045)** **Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Change in manufacturing site	
	From **M/s The Searle Pakistan Ltd.** **(DML # 000012)** **C-14 Mangopir Road SITE Karachi.**	**To** **M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045)** **Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29566 Dated: 22-12-2023
	Details of fee submitted	PKR 30,000/-: 15-11-2023 (Slip # 6721649163)
	The proposed proprietary name / brand name	**Tablet URICONTROL 5mg – Reg. # 081070** **Initial Registration:** 22-06-2016 **Renewal Status:** application received on 24-03-2021.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin Succinate …… 5 mg
	Pharmacotherapeutic Group of (API)	Anticholinergics
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Solifen Tablet by Getz Pharma
	Proposed Pack size	1 x 10s (ALU-AU Blister)
	Proposed unit price	PKR 410/-
Brief history of the case: The case of transfer of registration of drug product along with change in manufacturing site was initially presented in 293rd meeting of Drug Registration Board where in Board deferred		

the case for final recommendation/approval after submission of requisite information/documents including Stability Studies, Comparative Dissolution Profile, Process Validation Protocols & Analytical Method Validation/Verification performed at M/s Aspin Pharma (Pvt.) Ltd., Karachi.

Evaluation by DD-PE&R:

Now firm has change the source of API manufacturer as under:

Previous source	New source
Jubilant Generics Limited	**Curequest LifeSciences LLP**
# 18, 56, 57 & 58, K.I.A.D.B Industrial Area, Nanjangud-571 302 Mysore District Karanatka, India.	D-3/143, Dahej Industrial Estate, Dahej District, Bharuch, Gujarat India.

Firm has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3).

The previous manufacturer (Searle) has submitted NOC for transfer of registration along with manufacturing site.

The formulation of drug product is same as per innovator brand as well formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Vesicare 5 mg Tablet.

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Tablet URICONTROL 5mg (Reg. # 081070) as under:-

Tablet URICONTROL 5mg (Reg. # 081070)	**From**	**To**
Change in Marketing authorization holder	**M/s The Searle Pakistan Ltd.** *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012) C-14 Mangopir Road SITE Karachi.**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045) Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
Change in manufacturing site		

2.	**Change of Marketing Authorization Holder (Tablet URICONTROL 10mg – Reg. # 081071)**	
	From (existing MAH)	**To (Applicant)**
	M/s The Searle Pakistan Ltd. *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012) C-14 Mangopir Road SITE Karachi.**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045) Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Change in manufacturing site	
	From **M/s The Searle Pakistan Ltd. (DML # 000012) C-14 Mangopir Road SITE Karachi.**	**To** **M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045) Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29567 Dated: 22-12-2023
	Details of fee submitted	PKR 30,000/-: 15-11-2023 (Slip # 092677181114)
	The proposed proprietary name / brand name	**Tablet URICONTROL 10mg – Reg. # 081071** **Initial Registration:** 22-06-2016 **Renewal Status:** application received on 24-03-2021.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin Succinate …… 5 mg
	Pharmacotherapeutic Group of (API)	Anticholinergics
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Solifen Tablet by Getz Pharma
	Proposed Pack size	1 x 10s (ALU-AU Blister)
	Proposed unit price	PKR 410/-

Brief history of the case: The case of transfer of registration of drug product along with change in manufacturing site was initially presented in 293rd meeting of Drug Registration Board where in Board deferred the case for final recommendation/approval after submission of requisite information/documents including Stability Studies, Comparative Dissolution Profile, Process Validation Protocols & Analytical Method Validation/Verification performed at M/s Aspin Pharma (Pvt.) Ltd., Karachi.

Evaluation by DD-PE&R:

Now firm has change the source of API manufacturer as under:

Previous source	**New source**
Jubilant Generics Limited	**Curequest LifeSciences LLP**
# 18, 56, 57 & 58, K.I.A.D.B Industrial Area, Nanjangud-571 302 Mysore District Karanatka, India.	D-3/143, Dahej Industrial Estate, Dahej District, Bharuch, Gujarat India.

Firm has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3).

The previous manufacturer (Searle)has submitted NOC for transfer of registration along with manufacturing site.

The formulation of drug product is same as per innovator brand as well formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Vesicare 5 mg Tablet.

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Tablet URICONTROL 10mg (Reg. # 081071) as under:-

Tablet URICONTROL 10 mg (Reg. # 081071)	**From**	**To**
Change in Marketing authorization holder	**M/s The Searle Pakistan Ltd.** *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012) C-14 Mangopir Road SITE Karachi.**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045) Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
Change in manufacturing site		

3.	**Change of Marketing Authorization Holder (Tablet TRACETOL – Reg. # 081071)**	
	From (existing MAH)	**To (Applicant)**
	M/s The Searle Pakistan Ltd. *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012) C-14 Mangopir Road SITE Karachi.**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045) Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Change in manufacturing site	
	From	**To**
	M/s The Searle Pakistan Ltd.	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045)**

	(DML # 000012) **C-14 Mangopir Road SITE Karachi.**	**Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 3623 Dated: 15-04-2019
	Details of fee submitted	PKR 20,000/-: 15-04-2019
	The proposed proprietary name / brand name	**Tablet Tracetol – Reg. # 083188** **Initial Registration:** 15-03-2017 **Renewal Status:** application received on 10-03-2022.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCl …… 37.5 mg Paracetamol …… 325 mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Tonoflex –P by Sami Pharma
	Proposed Pack size	1 x 10s (ALU-AU Blister)
	Proposed unit price	As per SRO

Brief history of the case: The case of transfer of registration of drug product along with change in manufacturing site was initially presented in 293rd meeting of Drug Registration Board where in Board deferred the case for final recommendation/approval after submission of requisite information/documents including Stability Studies, Comparative Dissolution Profile, Process Validation Protocols & Analytical Method Validation/Verification performed at M/s Aspin Pharma (Pvt.) Ltd., Karachi.

Evaluation by DD-PE&R:
All shortcomings have been rectified by firm and found satisfactory.

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Tablet Tracetol (Reg. # 083188) as under:-

Tablet Tracetol Reg. # 083188	**From**	**To**
Change in Marketing authorization holder	**M/s The Searle Pakistan Ltd.** *(Formerly OBS Pakistan (Pvt.) Ltd.)* **(DML # 000012)**	**M/s Aspin Pharma (Pvt.) Ltd. (DML # 000045)**
Change in manufacturing site	**C-14 Mangopir Road SITE Karachi.**	**Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**

4.	**Change of Marketing Authorization Holder (Tablet CARDURA 2mg – Reg. # 011743)**	
	From (existing MAH)	**To (Applicant)**
	M/s Pfizer Pakistan Ltd. (DML # 000025) **B-2-S.I.T.E Karachi.**	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Change in manufacturing site	

	From **M/s Pfizer Pakistan Ltd. (DML # 000025)** **B-2-S.I.T.E Karachi.**	To **M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1374 Dated: 22-01-2024
	Details of fee submitted	PKR 30,000/-: 19-01-2024 (Slip # 73480018327)
	The proposed proprietary name / brand name	**Tablet CARDURA 2mg – Reg. # 011743** **Initial Registration:** 17-10-1990 **Transfer of registration:** 25-03-2010 **Transfer of registration:** 01-06-2011 **Renewal Status:** application received on 25-05-2021.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Doxasozin Mesylate equivalent to Doxasozin …… 2 mg
	Pharmacotherapeutic Group of (API)	Selective alpha blocker
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Uripas by Searle
	Proposed Pack size	20s & 30s (ALU-AU Blister)
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

At initial evaluation following information / documents were found deficient for which reply of the firm has been also reproduced.

Section	Observations	Reply of the firm
1.3.4	Submit technology transfer report, based on the data and information obtained during the project.	Submitted
1.6.5	Has sending unit (SU) i.e. Pfizer handed over DMF of API of their vendor to the receiving unit (RU) i.e. AGP?	Yes, the pharmaceutical equivalency studies have been conducted among the API source of Pfizer Singapore against API source from Sirini India and found consistent with each other because monograph of API has been public since long and available in USP Pharmacopeia.
3.2.P.1	Explain the nature of technology transfer adopted during technology transfer.	Documentation based know how technology transfer of process has been adopted.
3.2.P.8	Submit stability data of the last interval i.e. 06th month for the three stability batches along with stability summary sheets with comparison of analytical results between 0,3 & 6 month.	Submitted

Change in Source of API as under:

Previous source	New source
Pfizer Asia Manufacturing PTE Ltd Singapore.	**Sirini Pharmaceutical Pvt. Ltd.** Plot # 10, Road # 08, Film Nagar, Jubilee Hills, Hyderabad, India.

The specifications and critical material attributes of the starting materials (APIs and excipients) to be used at the Receiving unit (RU) is consistent with those materials used at the sending unit (SU).

The formulation of drug product is same as formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Cardura manufactured at previous plant.

Applicant (AGP Pharma) has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3). The previous manufacturer (Pfizer) has submitted NOC for transfer of registration along with manufacturing site.

The applicant has also submitted "Asset purchase agreement" acknowledged & authorized by Competition commission of Pakistan. OBS Pakistan (Private) Limited as a special purpose vehicle for AGP Pharma Group Companies under companies (Asset backed securitization) Rules 1999 acquired certain assets of "Viatris" including Tablet Cardura 2 mg. "Viatris" itself has no presence in Pakistan but its products are sold in Pakistan through M/s Pfizer Pakistan Limited. The transaction relates to acquisition of Cardura tablet including the license & intellectual property rights from "Viatris" & "Pfizer".

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Tablet CARDURA 2mg – Reg. # 011743 as under:-

Tablet CARDURA 2mg Reg. # 011743	**From**	**To**
Change in Marketing authorization holder	**M/s Pfizer Pakistan Ltd. (DML # 000025)**	**M/s AGP Ltd. (DML # 000348)**
Change in manufacturing site	**B-2-S.I.T.E Karachi.**	**Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

5.	**Change of Marketing Authorization Holder (Tablet CARDURA 4mg – Reg. # 012444)**	
	From (existing MAH)	**To (Applicant)**
	M/s Pfizer Pakistan Ltd. (DML # 000025) **B-2-S.I.T.E Karachi.**	**M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Change in manufacturing site	
	From **M/s Pfizer Pakistan Ltd. (DML # 000025)** **B-2-S.I.T.E Karachi.**	**To** **M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1375 Dated: 22-01-2024
	Details of fee submitted	PKR 30,000/-: 19-01-2024 (Slip # 29402140)
	The proposed proprietary name / brand name	**Tablet CARDURA 4mg – Reg. # 012444** **Initial Registration:** 24-01-1991 **Transfer of registration:** 25-03-2010 **Transfer of registration:** 01-06-2011 **Renewal Status:** application received on 25-05-2021.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Doxasozin Mesylate equivalent to Doxasozin …… 4 mg
	Pharmacotherapeutic Group of (API)	Selective alpha blocker
	Reference to Finished product specifications	USP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Uripas by Searle
	Proposed Pack size	20s & 30s (ALU-AU Blister)
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

At initial evaluation following information / documents were found deficient for which reply of the firm has been also reproduced.

Section	Observations	Reply of the firm
1.3.4	Submit technology transfer report, based on the data and information obtained during the project.	Submitted
1.6.5	Has sending unit (SU) i.e. Pfizer handed over DMF of API of their vendor to the receiving unit (RU) i.e. AGP?	Yes, the pharmaceutical equivalency studies have been conducted among the API source of Pfizer Singapore against API source from Sirini India and found consistent with each other because monograph of API has been public since long and available in USP Pharmacopeia.
3.2.P.1	Explain the nature of technology transfer adopted during technology transfer.	Documentation based know how technology transfer of process has been adopted.
3.2.P.8	Submit stability data of the last interval i.e. 06th month for the three stability batches along with stability summary sheets with comparison of analytical results between 0,3 & 6 month.	Submitted

Change in Source of API as under:

Previous source	New source
Pfizer Asia Manufacturing PTE Ltd Singapore.	**Sirini Pharmaceutical Pvt. Ltd.** Plot # 10, Road # 08, Film Nagar, Jubilee Hills, Hyderabad, India.

The specifications and critical material attributes of the starting materials (APIs and excipients) to be used at the Receiving unit (RU) is consistent with those materials used at the sending unit (SU).

The formulation of drug product is same as formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Cardura manufactured at previous plant.

Applicant (AGP Pharma) has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3). The previous manufacturer (Pfizer) has submitted NOC for transfer of registration along with manufacturing site.

The applicant has also submitted "Asset purchase agreement" acknowledged & authorized by Competition commission of Pakistan. OBS Pakistan (Private) Limited as a special purpose vehicle for AGP Pharma Group Companies under companies (Asset backed securitization) Rules 1999 acquired certain assets of "Viatris" including Tablet Cardura 2 mg. "Viatris" itself has no presence in Pakistan but its products are sold in Pakistan

through M/s Pfizer Pakistan Limited. The transaction relates to acquisition of Cardura tablet including the license & intellectual property rights from "Viatris" & "Pfizer".

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Tablet CARDURA 4mg – Reg. # 012444 as under:-

Tablet CARDURA 4mg – Reg. # 012444	**From**	**To**
Change in Marketing authorization holder	**M/s Pfizer Pakistan Ltd. (DML # 000025)**	**M/s AGP Ltd. (DML # 000348)**
Change in manufacturing site	**B-2-S.I.T.E Karachi.**	**Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

6. Change of Marketing Authorization Holder (Capsule Lyrica 75 mg – Reg. # 044817)

From (existing MAH)	**To (Applicant)**
M/s Pfizer Pakistan Ltd. **12-Dockyard Road, West wharf, Karachi.**	**M/s AGP Ltd. (DML # 000044)** **D-109 S.I.T.E, Karachi.**
Change in manufacturing site from import to local manufacturing	
From **Pfizer manufacturing Deutschalnd GmbH** **Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.**	**To (Contract manufacturing)** **M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1376 Dated: 22-01-2024
Details of fee submitted	PKR 75,000/-: 19-01-2024 (Slip # 030443302793)
The proposed proprietary name / brand name	**Capsule Lyrica 75 mg – Reg. # 044817** **Initial Registration:** 23-01-2007 **Transfer of registration:** 29-10-2009 **Transfer of registration:** 29-06-2011 **Renewal Status:** application received on 21-06-2021.
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 75 mg
Pharmacotherapeutic Group of (API)	Anticonvulsant
Reference to Finished product specifications	BP Specification
The status in reference regulatory authorities	MHRA UK approved formulation
For generic drugs (me-too status)	Nurica by Macter
Proposed Pack size	14s
Proposed unit price	As per SRO

Evaluation by DD-PE&R:

At initial evaluation following information / documents were found deficient for which reply of the firm has been also reproduced.

Section	Observations	Reply of the firm
1.3.4	Submit technology transfer report, based on the data and information obtained during the project.	Submitted
1.6.5	Has sending unit (SU) i.e. Pfizer handed over DMF of API of their vendor to the receiving unit (RU) i.e. AGP?	Yes, the pharmaceutical equivalency studies have been conducted among the API source of Pfizer Singapore against API source from Sirini India and found consistent with each other because monograph of API has been public since long and available in USP Pharmacopeia.
3.2.P.1	Explain the nature of technology transfer adopted during technology transfer.	Documentation based know how technology transfer of process has been adopted.
3.2.P.8	Submit stability data of the last interval i.e. 06th month for the three stability batches along with stability summary sheets with comparison of analytical results between 0,3 & 6 month.	Submitted

Change in Source of API as under:

Previous source	New source
Pfizer Asia Manufacturing PTE Ltd Singapore.	**Zhejiang Hunhai Pharmaceutical Co. Ltd.** Chuannan, Duiquo, Linhai, Zhejiang, China.

The specifications and critical material attributes of the starting materials (APIs and excipients) to be used at the Receiving unit (RU) is consistent with those materials used at the sending unit (SU).

The formulation of drug product is same as formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Cardura manufactured at previous plant.

Applicant (AGP Pharma) has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3). The applicant has submitted legalized NOC issued by Viatris for transfer of registration along with manufacturing site to applicant.

The applicant has also submitted "Asset purchase agreement" acknowledged & authorized by Competition commission of Pakistan. OBS Pakistan (Private) Limited as a special purpose vehicle for AGP Pharma Group Companies under companies (Asset backed securitization) Rules 1999 acquired certain assets of "Viatris" including Tablet Cardura 2 mg. "Viatris" itself has no presence in Pakistan but its products are sold in Pakistan through M/s Pfizer Pakistan Limited. The transaction relates to acquisition of Cardura tablet including the license & intellectual property rights from "Viatris" & "Pfizer".

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Capsule Lyrica 75 mg – Reg. # 044817 as under:-

Capsule Lyrica 75 mg – Reg. # 044817	**From**	**To**
Change in Marketing authorization holder	**M/s Pfizer Pakistan Ltd. 12-Dockyard Road, West wharf, Karachi.**	**M/s AGP Ltd. (DML # 000044) D-109 S.I.T.E, Karachi.**
Change in manufacturing site	**Pfizer manufacturing Deutschalnd GmbH Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.**	**(Contract manufacturing) M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

7.	Change of Marketing Authorization Holder (Capsule Lyrica 150 mg – Reg. # 044818)	
	From (existing MAH)	**To (Applicant)**
	M/s Pfizer Pakistan Ltd. **12-Dockyard Road, West wharf, Karachi.**	**M/s AGP Ltd. (DML # 000044)** **D-109 S.I.T.E, Karachi.**
	Change in manufacturing site from import to local manufacturing	
	From **Pfizer manufacturing Deutschalnd GmbH** **Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.**	**To (Contract manufacturing)** **M/s AGP Ltd. (DML # 000348)** **Plot No. B-23 Sindh Industrial Trading Estate Karachi.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1377 Dated: 22-01-2024
	Details of fee submitted	PKR 75,000/-: 26-12-2023 (Slip # 094803283)
	The proposed proprietary name / brand name	**Capsule Lyrica 150 mg – Reg. # 044818** **Initial Registration:** 23-01-2007 **Transfer of registration:** 29-10-2009 **Transfer of registration:** 29-06-2011 **Renewal Status:** application received on 21-06-2021.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 150 mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Nurica by Macter
	Proposed Pack size	14s
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

At initial evaluation following information / documents were found deficient for which reply of the firm has been also reproduced.

Section	Observations	Reply of the firm
1.3.4	Submit technology transfer report, based on the data and information obtained during the project.	Submitted
1.6.5	Has sending unit (SU) i.e. Pfizer handed over DMF of API of their vendor to the receiving unit (RU) i.e. AGP?	Yes, the pharmaceutical equivalency studies have been conducted among the API source of Pfizer Singapore against API source from Sirini India and found consistent with each other because monograph of API has been public since long and available in USP Pharmacopeia.

3.2.P.1	Explain the nature of technology transfer adopted during technology transfer.	Documentation based know how technology transfer of process has been adopted.
3.2.P.8	Submit stability data of the last interval i.e. 06th month for the three stability batches along with stability summary sheets with comparison of analytical results between 0,3 & 6 month.	Submitted

Change in Source of API as under:

Previous source	**New source**
Pfizer Asia Manufacturing PTE Ltd Singapore.	**Zhejiang Hunhai Pharmaceutical Co. Ltd.** Chuannan, Duiquo, Linhai, Zhejiang, China.

The specifications and critical material attributes of the starting materials (APIs and excipients) to be used at the Receiving unit (RU) is consistent with those materials used at the sending unit (SU).

The formulation of drug product is same as formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Cardura manufactured at previous plant.

Applicant (AGP Pharma) has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3). The applicant has submitted legalized NOC issued by Viatris for transfer of registration along with manufacturing site to applicant.

The applicant has also submitted "Asset purchase agreement" acknowledged & authorized by Competition commission of Pakistan. OBS Pakistan (Private) Limited as a special purpose vehicle for AGP Pharma Group Companies under companies (Asset backed securitization) Rules 1999 acquired certain assets of "Viatris" including Tablet Cardura 2 mg. "Viatris" itself has no presence in Pakistan but its products are sold in Pakistan through M/s Pfizer Pakistan Limited. The transaction relates to acquisition of Cardura tablet including the license & intellectual property rights from "Viatris" & "Pfizer".

Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Capsule Lyrica 150 mg – Reg. # 044818 as under:-

Capsule Lyrica 150 mg – Reg. # 044818	**From**	**To**
Change in Marketing authorization holder	**M/s Pfizer Pakistan Ltd. 12-Dockyard Road, West wharf, Karachi.**	**M/s AGP Ltd. (DML # 000044) D-109 S.I.T.E, Karachi.**
Change in manufacturing site	**Pfizer manufacturing Deutschalnd GmbH Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.**	**(Contract manufacturing) M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

8.	**Change of Marketing Authorization Holder (Capsule Lyrica 300 mg – Reg. # 044819)**	
	From (existing MAH)	**To (Applicant)**
	M/s Pfizer Pakistan Ltd. 12-Dockyard Road, West wharf, Karachi.	**M/s AGP Ltd. (DML # 000044) D-109 S.I.T.E, Karachi.**
	Change in manufacturing site from import to local manufacturing	
	From	**To (Contract manufacturing)**
	Pfizer manufacturing Deutschalnd GmbH Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.	**M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 1378 Dated: 22-01-2024
	Details of fee submitted	PKR 75,000/-: 26-12-2023 (Slip # 632254129483)
	The proposed proprietary name / brand name	**Capsule Lyrica 300 mg – Reg. # 044819** **Initial Registration:** 23-01-2007 **Transfer of registration:** 29-10-2009 **Transfer of registration:** 29-06-2011 **Renewal Status:** application received on 21-06-2021.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …… 300 mg
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	BP Specification
	The status in reference regulatory authorities	MHRA UK approved formulation
	For generic drugs (me-too status)	Nurica by Macter
	Proposed Pack size	14s
	Proposed unit price	As per SRO

Evaluation by DD-PE&R:

At initial evaluation following information / documents were found deficient for which reply of the firm has been also reproduced.

Section	Observations	Reply of the firm
1.3.4	Submit technology transfer report, based on the data and information obtained during the project.	Submitted
1.6.5	Has sending unit (SU) i.e. Pfizer handed over DMF of API of their vendor to the receiving unit (RU) i.e. AGP?	Yes, the pharmaceutical equivalency studies have been conducted among the API source of Pfizer Singapore against API source from Sirini India and found consistent with each other because monograph of API has been public since long and available in USP Pharmacopeia.
3.2.P.1	Explain the nature of technology transfer adopted during technology transfer.	Documentation based know how technology transfer of process has been adopted.
3.2.P.8	Submit stability data of the last interval i.e. 06th month for the three stability batches along with stability summary sheets with comparison of analytical results between 0,3 & 6 month.	Submitted

Change in Source of API as under:

Previous source	New source
Pfizer Asia Manufacturing PTE Ltd Singapore.	**Zhejiang Hunhai Pharmaceutical Co. Ltd.** Chuannan, Duiquo, Linhai, Zhejiang, China.

The specifications and critical material attributes of the starting materials (APIs and excipients) to be used at the Receiving unit (RU) is consistent with those materials used at the sending unit (SU).

The formulation of drug product is same as formulation of drug product in previous manufacturing site. Firm has submitted Pharmaceutical equivalence and comparative dissolution profile against Cardura manufactured at previous plant. Applicant (AGP Pharma) has submitted application as per DRAP guidelines for Post Registration Variation (MaV-3). The applicant has submitted legalized NOC issued by Viatris for transfer of registration along with manufacturing site to applicant. The applicant has also submitted "Asset purchase agreement" acknowledged & authorized by Competition commission of Pakistan. OBS Pakistan (Private) Limited as a special purpose vehicle for AGP Pharma Group Companies under companies (Asset backed securitization) Rules 1999 acquired certain assets of "Viatris" including Tablet Cardura 2 mg. "Viatris" itself has no presence in Pakistan but its products are sold in Pakistan through M/s Pfizer Pakistan Limited. The transaction relates to acquisition of Cardura tablet including the license & intellectual property rights from "Viatris" & "Pfizer".
Decision: The Board acceded to the request of the applicant for Change in Marketing Authorization Holder and manufacturing site of drug product Capsule Lyrica 300 mg – Reg. # 044819 as under:-

Capsule Lyrica 300 mg – Reg. # 044819	**From**	**To**
Change in Marketing authorization holder	**M/s Pfizer Pakistan Ltd. 12-Dockyard Road, West wharf, Karachi.**	**M/s AGP Ltd. (DML # 000044) D-109 S.I.T.E, Karachi.**
Change in manufacturing site	**Pfizer manufacturing Deutschalnd GmbH Betroensstatte Freiburg, Mooswaldallee 1, 79090, Freiburg, Germany.**	**(Contract manufacturing) M/s AGP Ltd. (DML # 000348) Plot No. B-23 Sindh Industrial Trading Estate Karachi.**

Case No. 02: <u>Change in manufacturing site from Self-manufacturing to Contract manufacturing</u>

9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Change in manufacturing site	
	From self-manufacturing M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.	**To contract-manufacturing M/s Global Pharmaceuticals Pakistan (DML # 000724) *(formerly Reliance Pharma)* Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37 Dated: 01-01-2024
	Details of fee submitted	PKR 75,000/-: 28-12-2023 (Slip # 8128243810)
	The proposed proprietary name / brand name	**Mazine Cream 1% (*Reg. # 035757)* Date of Registration:** 01-03-2005
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Silver Sulfadazine……10 mg
	Pharmacotherapeutic Group of (API)	Sulfonamide antibiotics

	Reference to Finished product specifications	USP Specification
	Proposed Pack size	20-gram Aluminum tube in a unit carton with leaflet.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Locally registered.
Evaluation by DD-PE&R: All necessary documents / information has been evaluated as per DRAP guidelines document forMaV-3 and found satisfactory.		
Decision: • **The Board acceded to the request of the applicant for change in manufacturing site for the drug product Mazine Cream 1% (*Reg. # 035757)* from M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad to M/s Global Pharmaceuticals Pakistan (DML # 000724) *(formerly Reliance Pharma)* Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.** • **The letter shall be issued after submission of fee required for change in name of the manufacturer.**		
10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.**
	Change in manufacturing site	
	From self-manufacturing M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.	**To contract-manufacturing M/s Global Pharmaceuticals Pakistan (DML # 000724) *(formerly Reliance Pharma)* Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 698 Dated: 11-01-2024
	Details of fee submitted	PKR 75,000/-: 08-01-2024 (Slip # 128113534096)
	The proposed proprietary name / brand name	**Phusilan Cream 2% (*Reg. # 026991)* Date of Registration:** 24-07-2001
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Fusidic Acid……20 mg
	Pharmacotherapeutic Group of (API)	Fusidanes antibiotics
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	5 & 15-gram Aluminum tube in a unit carton with leaflet.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Locally registered.
Evaluation by DD-PE&R: All necessary documents / information has been evaluated as per DRAP guidelines document forMaV-3 and found satisfactory.		
Decision:		

- **The Board acceded to the request of the applicant for change in manufacturing site for the drug product Phusilan Cream 2% (*Reg. # 026991)* from M/s Global Pharmaceuticals (DML # 000417) Plot No 204-205 Kahuta Triangle Industrial Area Islamabad to M/s Global Pharmaceuticals Pakistan (DML # 000724) *(formerly Reliance Pharma)* Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat.**
- **The letter shall be issued after submission of fee required for change in name of the manufacturer.**

11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore.**
	Change in manufacturing site	
	From self-manufacturing M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore.	**To contract manufacturing M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24944 Dated: 12-10-2023
	Details of fee submitted	PKR 75,000/-: 26-09-2023 (Slip # 8193785828)
	The proposed proprietary name / brand name	**Orpase 400 mg Capsule *(Reg. # 032495)* Date of Registration:** 10-04-2004
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as tri-hydrate) ……400 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation.
	For generic drugs (me-too status)	Locally registered.
Evaluation by DD-PE&R: All necessary documents / information has been evaluated as per DRAP guidelines document forMaV-3 and found satisfactory.		
Decision: The Board acceded to the request of the applicant for change in manufacturing site for the drug product Orpase 400 mg Capsule *(Reg. # 032495)* from M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore to M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.		
12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore.**
	Change in manufacturing site	
	From self-manufacturing M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore.	**To contract manufacturing M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24945 Dated: 12-10-2023
	Details of fee submitted	PKR 75,000/-: 26-09-2023 (Slip # 7770877934)
	The proposed proprietary name / brand name	**Orpase Suspension 100mg/5ml *(Reg. # 032496)*** **Date of Registration:** 10-04-2004
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: *(after reconstitution)* Cefixime (as tri-hydrate) ……100 mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	30 ml & 60 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation.
	For generic drugs (me-too status)	Locally registered.
Evaluation by DD-PE&R: All necessary documents / information has been evaluated as per DRAP guidelines document forMaV-3 and found satisfactory.		
Decision: The Board acceded to the request of the applicant for change in manufacturing site for the drug product Orpase Suspension 100mg/5ml *(Reg. # 032496)* from M/s Seatle (Pvt.) Ltd. (DML # 000481) 45 KM Multan Road Lahore to M/s Citi Pharma (Pvt) Ltd. (DML # 000512) 3-Km Head Balloki Road Phool Nagar Kasur.		

Export Facilitation Desk

Case No.01: Registration of Drug (s) of M/s Surge Laboratories (Pvt.) Ltd, 10th Km, Faisal Abad Road, Bikhi District, Sheikhupura, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided Approval of relevant section verified from cGMP Inspection report dated 25-0-2022 .
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 25-08-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**

1.	Moxisurg Infusion 400mg/100ml Each 100ml contains: Moxifloxacin hydrochloride equivalent to moxifloxacin USP.....400mg	Purchase order from Kenya	Dy. No. 5365/23 (27.05.2024) Rs.75,000/- (25.03.2024)

Decision:

Registration Board deferred the case for submission of evidence of availability of formulation in country of import i.e. Kenya.

Case No.02: Registration of Drug (s) of M/s Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi, for export purposes only.

Sr. No.	Name of Manufacturer & Fee Details	Brand Name & Composition	Generic/RRA Status	Application ID
2.	**Opal Laboratories (Pvt.) Ltd.,** LC-41, L.I.T.E., Landhi, Karachi License Number: **000046** Fee Paid: 30000.0 Challan No: 037473991974 Fee Paid for correction: 7500/- Challan No. 3052563717	**Clariset Suspension 250mg** Each 5ml reconstituted suspension contains: Clarithromycin (as taste masked granules)……..250mg	**Respiklar of M/s Titlis Pharma**	**BAG-R3R-RZR5**
3.	**Opal Laboratories (Pvt.) Ltd.,** LC-41, L.I.T.E., Landhi, Karachi License Number: **000046** Fee Paid: 30000.0 Challan No: 84997304 Fee Paid for correction: 7500/- Challan No. 8862328830	**Clariset Suspension 125mg** Each 5ml reconstituted suspension contains: Clarithromycin (as taste masked granules)……..125mg	**Respiklar of M/s Titlis Pharma**	**ZDM-44J-JN7D**

The brand name "Clariset' is already registered in name of M/s Mediate Pharmaceuticals. The firm has submitted that their brand name is already registered in FDA Philippines and provided the copy of registration certificate issued by Philippines.

Decision:

Registration Board acceded to request of firm for registration of above products for Export Purpose to Philippines only.

Case No.03: Registration of Drug (s) of M/s Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi, for export purposes only.

Sr. No.	Name of Manufacturer & Fee Details	Brand Name & Composition	Generic/RRA Status	Application ID
4.	**Swiss Pharmaceuticals Pvt. Ltd.,** A/159, S.I.T.E.-II, Super Highway, Karachi License Number: **0000438** Fee Paid: 30000.0 Challan No: 538884666 Differential Fee Paid: 45000/-	**D-ABS 200,000IU Softgel Capsule** Each soft gel capsule contains: Cholecalciferol…200000IU	**Not Available**	**EAY-2W5-ZQNU**

	Challan No. 30122006312			

Decision:

Registration Board deliberated that the above formulation is the purview of Health & OTC Division of DRAP. Hence, decided to dispose of the application and to advise the firm to apply to relevant forum.

Deferred/ Miscellaneous Cases

CASE OF 109-PRVC

Case No.04: Registration of Drug (s) of M/s PharmEvo (Pvt.) Ltd, A-29, North western Industrial Zone Port Qasim, Karachi, for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided Approval of relevant section verified from letter No. F 2-1-/98-Lic dated 21-02-2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 22-02-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
5.	Tromix 500mg Tablet Each film coated tablet contains: Azithromycin dihydrate equivalent to Azithromycin……..500mg	Azomax by M/s Novartis	Dy. No. 1438/23 (01.12.2023) Rs.30,000/- (31.10.2023)

Decision of 109th PRVC:

"The Chairman Registration Board on recommendation of Committee considered the case and acceded to request of the firm for registration of above mentioned products for Export Purpose Only subject to submission of more brand names (which do not resemble with already registered drugs)."

Update Status

The brand name "Tromix' resembles to already registered brand name "Tromid" of M/s CIBA Pharmaceuticals. The firm has submitted that their brand name is already registered in Azerbaijan and provided the copy of registration certificate issued by Azerbaijan.

Decision: Registration Board acceded to request of firm for registration of above product for Export Purpose to Azerbaijan only.

Case. No.01:- **Request of M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore for registration from import to local manufacturing of already registered veterinary drugs.**

M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore has requested registration from import to local manufacturing of already registered imported veterinary drugs. The details are as under:-

Sr.No.	Regn.No.	Name of Manufacturer	Name of Drug(s/Composition	Approved pack site(s)	Date of initial regn./ Renewal	Remarks
1.	022175	M/s. Farvet Laboratories , BV, office if at Handelsweg 25,5531 AE Bladel, The Netherlands.	Vitamin AD_3E Injection Each ml contains:- Retinyl Palmitate (Vitamin A).....…80,000IU Tocopherol Acetate (Vitamin E)……...….20mg Cholecalciferol (Vitamin D_3)……..…..40,000IU	50ml	04-12-1998 17-11-2023	Dy.No.7119-R&I Dated 12-07-2024
			Vitamin AD_3E Injection Each ml contains:- Retinyl Palmitate (Vitamin A)...…….80,000IU Tocopherol Acetate (Vitamin E)……...20mg Cholecalciferol (Vitamin D_3)……..40,000IU	100ml		
2.	026452		Oxyfar 10% Injectable Solution Each ml contains:- Oxytetracycline (as hydrochloride)…..100mg	50ml	06-02-2001 11-03-2021	

			Oxyfar 10% Injectable Solution Each ml contains:- Oxytetracycline (as hydrochloride)…..100mg	100ml		
3.	015448		Gentafar 10% Injectable Solution Each ml contains:- Gentamicin Sulphate equivalent to 100mg Gentamicin base.	50ml	19-10-1994 07-10-2019	
			Gentafar 10% Injectable Solution Each ml contains:- Gentamicin Sulphate equivalent to 100mg Gentamicin base.	100ml		
4.	020761		Fartylo 200 Injection Each ml contains:- Tylosin……..200mg	50ml	04-12-1997 07-10-2019	
			Fartylo 200 Injection Each ml contains:- Tylosin……..200mg	100ml		

M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No.5-Pharmacity, 30-Km Multan Road, Lahore has deposited the required fee of **Rs.30,000 x 8 = Rs. 240,000/-** and submitted following supporting documents:-

(i) Copies of registration letters/renewal.

(ii) Original NOC from manufacturer abroad M/s. Farvet Laboratories , BV, office if at Handelsweg 25,5531 AE Bladel, The Netherlands

(iii) Copy of latest GMP inspection report.

(i) Registration dossiers for each product.

Decision: -
The Registration Board referred the case to the evaluation cell for a review of the technical data and directed to present the case in coming meeting for considrtaion of the board.

Case No.02:- Request of M/s. Star Laboratories (Pvt) Ltd., 23-Km, Multan Road, Lahore for Standardization of Formulation in Accordance with the Innovator's Product/Reference Regulatory Authorities and Pharmacopeia.

M/s. Star Laboratories (Pvt) Ltd., 23-Km, Multan Road, Lahore has requested for standardization of formulation with the innovator's product/reference regulatory authorities and pharmacopeia of their following registered drug as per detail mentioned against each:-

Regn. No.	Product Granted Composition	Demanded Composition	Remarks
058938	Urosulpha Bolus. Each bolus contains:- Sulphanilamide……1.92gm Sulphathiazole……...320 mg Urea……..…3.5 gm	Urosulpha Bolus. Each bolus contains:- Sulphanilamide……1.92gm Sulphathiazole……...320mg Urea…….13.44gm	Apply through E-office **Initial Reg:** 30-07-2009 **Renewal** 12-07-2019 Last renewal not provided.

M/s. Star Laboratories (Pvt) Ltd., 23-Km, Multan Road, Lahore has deposited the required fee of **Rs.30,000/-** and submitted following supporting documents:-

(i) Copy of Registration & renewal letters.

(ii) Evidence of reference country.

(iii) Copy of Drug Manufacturing License.

(iv) Undertaking.

Decision:- Registration Board acceded to request of the firm for correction of revised//standardization of formulation in accordance with the innovator's product/reference regulatory authorities as per following details:

S. No.	Regn. No.	Existing composition	New Approved Correct/Revised Composition
1.	058938	Urosulpha Bolus. Each bolus contains:- Sulphanilamide……1.92gm Sulphathiazole……..320mg Urea……...3.5gm	Urosulpha Bolus. Each bolus contains:- Sulphanilamide……1.92gm Sulphathiazole……...320mg Urea…….13.44gm

Item No. II Recommendations of sub-committee on Veterinary Drugs

1. Reference Regulatory Authorities for Veterinary Drugs

Registration Board in its 274th meeting discussed the matter of reference regulatory authorities for veterinary drugs and advised PPMA to submit proposal in forthcoming meeting.

- PPMA has submitted that for Veterinary Drugs countries such as India, China, Brazil, Argentina, Korea and Thailand where Veterinary Population is large and veterinary diseases are similar to Pakistan due to hot and humid Weather and Farmers Practices should be included as reference. This shall be done with approval and guidance from Expert Veterinary Member already present in the Board. Veterinary Drugs and Supplements go directly hand in hand as Food Security Plan for any country as they are used in Food Producing Animals but are not restricted to only them but also for Pet Animals having variety of species. Veterinary Drugs plays a vital and important role to combat diseases and also encompasses many other varieties of drugs for species not present in all countries such as Camels and Water Buffaloes. Newer and Wide Range of Research based Molecules and combinations with varying concentrations are needed to totally cover the range of various diseases.
- PPMA has further submitted that after recommendations from highly respected technical recognized experts associated with Veterinary Agriculture Universities Faisalabad, UVAS, Lahore, Technical experts DVM (Doctor of Veterinary Medicine) from Veterinary Pharmaceutical Manufacturers and respected Expert Member of Registration Board 2016-2018 DR. Qurban Ali, have formulated the following recommendations:

    1) Veterinary Drugs in many countries do not necessarily fall under Drug Regulatory Regime and may be regulated and registered under Ministry of Health, Ministry of Agriculture and Dairy. Ministry of Feed and Animal Resources.
    2) Include list of 33 countries where databases are available in book form, veterinary doctor guide books, and some on the web including Argentina, Austria, Australia, Belgium, Canada, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Ireland, Israel, Italy, Japan, South Korea, Malta, Malaysia, Netherlands, Norway, New Zealand, Sweden, Singapore, Thailand, Taiwan, United States, Saudia Arabia, Turkey, Brazil, Indonesia, Poland and Portugal

Decision 275th: Registration Board decided to further deliberate the matter. Meanwhile, present practice of considering already registered generic versions as reference shall be continued after being reviewed by veterinary expert of the Board.

Registration Board in its 275th meeting adopt 21 reference regulatory authorities including EMA & WHO for registration of Human Drugs.
Table shows veterinary drugs regulatory bodies of human adopted reference countries;

Approved RRA for Human Drugs	Proposed RRA for Veterinary Drugs

Registration Board adopted following regulatory authorities / agencies as reference for molecules/ formulations (in same dosage form and strength) alongwith clinical trials for human purpose in its 275th meeting.

a. Food & Drug Administration (FDA) of USA
b. Health Canada of Canada
c. Therapeutic Good Administration (TGA) of Australia
d. Pharmaceuticals and Medical Devices Agency (PMDA) of Japan
e. Medicines and Healthcare Regulatory Agency (MHRA) of UK
f. National Agency for the Safety of Medicine and Health Products (ANSM) of France.
g. Federal Institute for Drugs and Medical Devices of Germany
h. Medicines Evaluation Board of Netherland
i. Swissmedic of Switzerland
j. Austrian Agency for Health and Food Safety of Austria
k. Danish Medicines Agency of Denmark
l. Medical Products Agency of Sweeden
m. Norwegian Medicines Agency of Norway
n. Federal Agency for Medicines and Health Products of Belgium
o. Finnish Medicine Agency of Finland
p. Italian Medicine Agency (AIFA) of Italy
q. Health Products Regulatory Authority (HPRA) of Ireland
r. Icelandic Medicine Agency of Iceland
s. Spanish Agency for Medicines and Health Products of Spain
t. European Medicines Agency (EMA) of Europe.
u. World Health Organization (WHO)

Veterinary regulatory authorities / agencies of these countries.

a. Food & Drug Administration (FDA) of USA
b. Veterinary Drugs Directorate (VDD) is part of Health Canada's Health
c. Australian Pesticides and Veterinary Medicine Authority (APVMA)
d. The Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan
e. Veterinary Medicines Directorate of UK
f. The French Agency for Veterinary Medicinal Products (ANMV) of France.
g. The Federal Office of Consumer Protection and Food Safety (BVL) of Germany.
h. Medicines Evaluation Board of Netherland
i. Swissmedic of Switzerland
j. Austrian Federal Office for Safety in Health Care (BASG) of Austria
k. The Danish Veterinary and Food Administration
l. Medical Products Agency of Sweeden
m. Norwegian Medicines Agency of Norway
n. Federal Agency for Medicines and Health Products of Belgium
o. Finnish Medicine Agency of Finland
p. Italian Medicine Agency (AIFA) of Italy
q. Health Products Regulatory Authority (HPRA) of Ireland
r. Icelandic Medicine Agency of Iceland
s. Spanish Agency for Medicines and Health Products of Spain
t. European Medicines Agency (EMA) of Europe
u. World Organization for Animal Health (WOAH)

Recommendation of Sub-committee:

After deliberation, the sub-committee on Veterinary Drugs observed that since the Registration Board approved reference regulatory authorities for human drug registration in its 275th meeting, the sub-committee decided to consider the same countries bodies for veterinary drug registration. However, the sub-committee recommends adding four more countries as authorities/agencies to serve as references for molecules/formulations (in the same dosage form and strength) along with clinical trials for veterinary purposes. Details are as follows:

a. Food & Drug Administration (FDA) of USA
b. Veterinary Drugs Directorate (VDD) is part of Health Canada's Health
c. Australian Pesticides and Veterinary Medicine Authority (APVMA)
d. The Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan
e. Veterinary Medicines Directorate of UK
f. The French Agency for Veterinary Medicinal Products (ANMV) of France.

g. The Federal Office of Consumer Protection and Food Safety (BVL) of Germany.
h. Medicines Evaluation Board of Netherland
i. Swissmedic of Switzerland
j. Austrian Federal Office for Safety in Health Care (BASG) of Austria
k. The Danish Veterinary and Food Administration
l. Medical Products Agency of Sweeden
m. Norwegian Medicines Agency of Norway
n. Federal Agency for Medicines and Health Products of Belgium
o. Finnish Medicine Agency of Finland
p. Italian Medicine Agency (AIFA) of Italy
q. Health Products Regulatory Authority (HPRA) of Ireland
r. Icelandic Medicine Agency of Iceland
s. Spanish Agency for Medicines and Health Products of Spain
t. European Medicines Agency (EMA) of Europe
u. World Organization for Animal Health (WOAH)
v. National Service of Agri-Food Health and Quality, (SENASA), Argentina
w. Animal and Plant Quarantine Agency (APQA), Ministry of Agriculture, Food and Rural Affairs (MAFRA) South Korea.
x. Ministry for Primary Industries (MPI), Agricultural Compounds and Veterinary Medicines (ACVM) Group, New Zealand.
y. Animal & Veterinary Service (AVS), National Parks Board (NParks), Singapore.

2. Locally Manufactured Veterinary Drugs

Deferred Cases of Different Meetings of Registration Board

(M-293)

1.	Name and address of manufacturer / Applicant	M/s. Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	En-Cena Liquid
	Composition	Each ml contains:- Enrofloxacin……75mg Sulphamethoxy Pyridazine…….75mg Sulphamethazine……..…50mg Trimethoprim…….……..25mg
	Diary No. Date of R& I & fee	Dy.No 36982 dated 08-11-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre, 10Litre: Decontrolled
	Me-too status (with strength and dosage form)	CENATIN ORAL LIQUID of "M/S. HAWK BIO PHARMA (PVT) LTD.
	GMP status	same as recorded for above application
	Remarks of Evaluator	
	Decision: Deferred for review of formulation by committee of experts on veterinary drugs as applied formulation is combination of antibiotics.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

Case No. 02: Deferred case of (M-308)		
2.	Name and address of manufacturer/ Applicant	M/s. Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi (Oral Liquid Syrup veterinary).
	Brand Name + Dosage Form + Strength	P-flox Liquid
	Composition	Each Liter contains:- Pefloxacin as Methane Sulfonate ……100gm
	Diary No. Date of R & I & fee	Dy. No 4963 dated 04-02-2019; Rs.20,000/- dated 04-02-2019 vide deposit slip No. 0622348 (Duplicate).
	Pharmacological Group	Antibacterial.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	100ml, 500ml, 1000ml & decontrolled.
	Me-too status	Peperoxin Solution, imported by M/s Hassan Brothers, Reg. No. 082807.
	GMP status	Conclusion (04-10-2019): The firm is found complied of GMP as of today for two sections. The firm is advised to continue improvement as GMP is a continuous process of improvement. Strength of building and quality of individual batches manufactured is responsibility of manufacturer. No responsibility on regulator in such behalf.
	Remarks of the Evaluator [XIII]	
	Decision: Deferred for review as pefloxacin is also used in human	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

Case No. 03: Deferred case of (M-320)

3.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceuticals (Pvt) Ltd., 23-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Florfen Col Liquid
	Composition	Each 100ml contains:- Florfenicol…….10g Colistin Sulphate…….50 MIU
	Diary No. Date of R& I & fee	11221, 07-08-2017, 20,000/-, 07-08-2017
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 400ml, 500ml, 1000ml; Decontrolled
	Me-too status	Florobex C Liquid of M/s Elegance Pharma (Reg#078286)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Remarks of the Evaluator.	The R&I receipt has been verified from the Incharge R&I against the diary no. mentioned above.
	Decision: Referred to Expert Working Group for review of applied formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

Case No. 03: Deferred case of (M-321)		
4.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceutical (Pvt) Ltd, 23 Km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Renotone Plus Oral Powder
	Composition	Each 1000gm contains:- Hexamine……...…..480gm Sodium Acid Phosphate.……..160gm Ascorbic acid……..…....30gm Trihydroxyethyl Rutin…….….3gm
	Diary No. Date of R& I & fee	18-01-2011 vide diary No. 381 Rs.8,000 & 30-07-2013 vide diary No. 937 Rs.12000
	Pharmacological Group	Anti-Infective
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	Decontrolled/ 100gm, 250gm, 500gm, 1000gm & 2.5 Kg.
	Me-too status	Exitone Oral Powder of M/s A & K Pharma (Reg#033289)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following (M-265) Complete product specifications Last GMP inspection report conducted within one year Clarification regarding availability of potentiometer as claimed by applicant for analysis of API.
	Evaluation by PEC	The firm has claimed manufacturer's specifications. The firm is granted GMP certificate based on inspection conducted on 13-08-2020.
	Decision: Referred to Expert Working Group on Veterinary Drugs for review of applied formulation for the intended role as "Anti-infective".	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
5.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	Tocosel Oral Solution
	Composition	Each 1000ml contains:- Vitamin E…….500mg Selenium…….120g
	Diary No. Date of R & I & fee	Dy. No 123161 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Antibacterial
	Type of Form	Form - 5
	Finished product Specification	innovator
	Pack size & Demanded Price	100ml,150ml,250ml,500ml,1Litre,2.5 Litre,25Litre
	Approval status of product in Reference Regulatory Authorities	Not Applicable

	Me-too status	Immunosel Oral Solution, 034539, ATTABAK PHARMACEUTICALS, ISLAMABAD,	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building, production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management. • Evidence of me-too status of product registered in Pakistan. • Pack Size, container and closure is not provided.	Firm has submitted fee challan No.02051 67051 dated 16-06-2022 of 30000/= along with revised form -5 with revised strength of label claim API as under: Each ml contains: Vitamin E…...120 000mg Selenium as Sodium selenite…….2200mg

			Firm has also submitted revised Form- 5, Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**			
6.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	Bacticom Injection	
	Composition	Dimetridazole ……..….100mg Tylosin Tartrate……..50mg Colistin Sulphate……10mg	
	Diary No. Date of R & I & fee	Dy. No 12156 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Board spectrum antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator	
	Pack size & Demanded Price	100ml, Type II glass vial.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Bacticom Injection, 043140, SELMORE PHARMACEUTICALS, LAHORE, LAHORE,	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section	

		were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Form-5 cover letter dully signed by management. • Pack Size, container and closure is not provided. • Per ml composition is not provided.	Firm has submitted fee challan No.9552576752 dated 16-06-2022 of 30000/= along with revised form-5 with revised per ml label claim as under: Each ml contains:- Dimetridazole..100mg Tylosin Tartrat...50mg Colistin Sulpha

			te…10 mg Firm has also submitted revised Form-5, Manufacturing method, master formulation, Pack size, and finished product specification.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**			
7.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	Oxyfen LA Injection	
	Composition	Oxytetracycline…….……100mg Ketoprofen……..…30mg	
	Diary No. Date of R & I & fee	Dy. No 12153 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	innovator	
	Pack size & Demanded Price	100ml, type II glass vial.	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Oxyfen LA injection, 071091, SELMORE PHARMACEUTICALS, LAHORE.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material	

		management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Firm did not mention per ml composition. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan.	• Firm has submitted fee challan No.47138 59323 dated 16-06-2022 of 30000/= along with revised form -5 with revised per label claim as under: Each ml contains: Oxytetracycline as Dihydrate ……20 0mg Ketoprofen……...30 mg • Firm has also submitted revised Form- 5, Manufacturing method,

			master formulation, Pack size, and finished product specification. • However, Composition of me -too is as under; Oxytetracycline…200mg Ketoprofen…30mg
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**			
8.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	Tetra Delta Suspension Injection (Sterile)	
	Composition	Each ml contains:- Neomycin……..…105mg Procaine Penicillin G……1000000 IU Novobiocin (As Sodium Novobiocin) ….…100mg Dihydrostreptomycin (As Dihydrostreptomycin Sulphate) ……..100mg	
	Diary No. Date of R & I & fee	Dy. No 12304 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotic	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification	
	Pack size & Demanded Price	24*10ml	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	TETRA-DELTA STERILE SUSPENSION, 015480, UPJOHN LTD UK (manufacturer), UPJOHN ISLAMABAD (Importer)	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as“ In view of above inspection proceedings and facilities verified such as	

		company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system, personnel and documentation etc. the firm M/s. Mylab (Pvt) Ltd. Khanqah Sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5. (Challan fee not submitted, change of formulation in label claim)	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of contai

			ner as plastic bottle. Each ml Contains: 1-Neomycin as Sulphate…105mg 2-Procaine Penicillin G……1000000IU 3-Novobiocin (As Sodium Novobiocin) …100 mg 4-Dihydrostreptomycin (As Dihydrostreptomycin Sulphate)..100mg 5.Prednisolone Acetate……10mg
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**			

9.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	Utafix Injection	
	Composition	Each 20ml contains:- Oxytetracycline……500mg Iodochlogroxy Quinolone……500mg **Furazolidone……500mg** Vitamin E……..200mg	
	Diary No. Date of R & I & fee	Dy. No.12167 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.	
	Pharmacological Group	Broad Spectrum Antibiotic with vitamin	
	Type of Form	Form - 5	
	Finished product Specification	Innovator Specification.	
	Pack size & Demanded Price	20ml	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	Uterous Injector Floor, Reg No. 017913 ,mfg by : Floris Veterinary , Netherland , Import by : selmore Agencies Lahore.	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as" In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5	• Firm has sub mitte d reply with fee chall an No. 2896

		• Evidence of me-too status of product already registered in Pakistan.	53847 dated 01-08-2022 of 7500/= along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as plastic

			bottle.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to reject the above formulation for veterinary use.**			
10.	Name and address of manufacturer/ Applicant	M/s. Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur.	
	Brand Name + Dosage Form + Strength	Multiject IMM Injection	
	Composition	Each 5gm contains:- Procaine Penicillin…….1000000IU Streptomycin Sulphate……..…100mg Neomycin Sulphate……..100mg Prednisolone……10 mg	
	Diary No. Date of R & I & fee	Dy. No 12305 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.	
	Pharmacological Group	Antibiotics and steroid combination	
	Type of Form	Form - 5	
	Finished product Specification	Innovator specification	
	Pack size & Demanded Price	24*5gm	
	Approval status of product in Reference Regulatory Authorities	Not Applicable	
	Me-too status	MULTIJECT IMM INJECTION, 018871, NAWAN TRADING CORP. KARACHI	
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as“ In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing,machinery/equipment,material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection” Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)	

	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • Evidence of me-too status of registered product in Pakistan.	Firm has submitted reply along with revised and signed form 5 with undertaking, master formulation, outline of manufacturing method, Finished good specification as innovator specs and details of container as Glass vial. (Challan Fee Not Submitted for preregistration variations)
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**			

11.	Name and address of manufacture / Applicant	M/s. Alina Cmbine Pharmaceuticals (Pvt.) Ltd. A/27, S.I.T.E, Super Highway, Karachi.
	Brand Name + Dosage Form and Strength	Doxin-EF Soluble Powder (Veterinary)
	Composition	Each 100gm contains:- Doxycycline HCl……..…..10gm Tylosin Tartrate……..……5gm **Furaltradone HCl……..…..15gm** Erthromycin Thiocyanate……...6gm
	Dairy No. date of R &I fee	Dy. No 11681 dated 06-03-2019 Rs.20,000/- dated 05-03-2019 Challan No.0835040 dated: 02.03.2019
	Pharmacological Group	Antibacterial and anti-infective
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	100gm, 500gm, 1Kg & 2.5 Kg, De-controlled
	Approval status of product in Reference Regulatory Authorities	…….
	Me-too-status	Bio-Multibiotic powder of M/s. Biolabs Pvt ltd. Islamabad. Registration No.043182
	GMP Status	Routine GMP inspection conducted on 08-01-2018 with conclusion: Based on the above observations their overall GMP compliance level is rated as satisfactory.
	Remark of the Evaluator (PEC-XVII)	• Cover letter and Form 5 not signed by the firm/applicant. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial.
	Decision: Deferred for review of formulation by Expert Working group.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to reject the above formulation for veterinary use.**		
12.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med Coc Oral Powder
	Composition	Each 1000gm contains:- Sulfamerazine……..…100gm Sulfadiazene……..…….60gm Sulfathiazole……..….40gm Trimethoprim…….40gm

	Diary No. Date of R& I & fee	Dy No:10038, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & Anticoccidial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	TS-30 Powder by M/s Elegance Pharmaceuticals (Reg#074002)
	Remarks of the Evaluator	

Decision: Referred to EWG on veterinary drugs

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

13.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Quinodine C Oral Powder
	Composition	Each 1000gm contains:-
		Enrofloxacin……..…120gm
		Colistin Sulphate…..500 MIU
		Amantadine HCL…….50gm
	Diary No. Date of R& I & fee	Dy No:10041, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Colabex Powder by M/s Elegance Pharmaceutical (Reg#073924) (Not same as applied formulation)
	GMP status	05-11-2021
		Panel inspection for grant of DML
		Panel recommended grant of DML.
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.

		• Amantadine combination. • Composition in covering letter and form-5 is not same.

Decision: Registration Board referred the case to Expert Working Group for review of formulation.

Recommendation of Sub-committee:

The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in combination in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health.

14.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	**Fura Med Oral Powder**
	Composition	Each 1000gm contains:- **Furazolidone……244gm**
	Diary No. Date of R& I & fee	Dy No:10049, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Furazone-M Feed Supplement Powder by M/s Manhattan Pharma (Reg#014574)
	Remarks of the Evaluator	

Decision: Registration Board referred the case to Expert Working Group for review of formulation.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided to reject the above formulation for veterinary use.

15.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Phenyl Dox Oral Powder
	Composition	Each 1000gm contains:- Doxycycline HCl……..200gm Tylosin Tartrate……100gm Colistin Sulphate……..500 MIU **Phenyl Butazone**……12gm
	Diary No. Date of R& I & fee	Dy No:10046, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Broncodox Water Soluble Powder by M/s Westmont Pharmaceutical Industries (Reg#048203) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.

Decision: Registration Board referred the case to Expert Working Group for review of formulation.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

16.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med Mix N Oral Powder
	Composition	Each 1000gm contains:- Neomycin Sulphate……..……10gm Streptomycin Sulphate…..……36gm Procaine Penicillin……12gm Zinc Bacitracin……..52gm
	Diary No. Date of R& I & fee	Dy No:10039, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1Kg, 5Kg, 25Kg/ Decontrolled
	Me-too status (with strength and dosage form)	Flemibiotic Powder by M/s. Grand Pharma (Pvt) Ltd (Reg#103942)
	Remarks of the Evaluator	
	Decision: Refer to EWG on veterinary drugs	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
17.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Minarine Injection (10ml)
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine ……..….. 131mg
	Diary No. Date of R& I & fee	Dy No.21805: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	Formulation under discussion
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
18.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber.

	Brand Name +Dosage Form + Strength	Minarine Injection (50ml)
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine …….. 131mg
	Diary No. Date of R& I & fee	Dy No.21806: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
19.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Minarine Injection (100ml)
	Composition	Each ml contains:- Diminazine Aceturate …… 105mg Antipyrine …….. 131mg
	Diary No. Date of R& I & fee	Dy No.21807: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Anti Protozoal
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Dianox Injection (Nawan Laboratories) Reg # 072674
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
20.	**Name and address of manufacturer / Applicant**	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Zincol Mix-1000 Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..……12g Streptomycin Sulphate BP …….……36g Colistin Sulphate BP …… 60MIU Zinc Bacitracin BP ……..…….. ….52g
	Diary No. Date of R& I & fee	Dy No. 21780: 02.08.2022

		PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Zeptocol w/s Powder (Selmore Pharma) Reg # 080962
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Referred to EWG on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
21.	Name and address of manufacturer / Applicant	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Zincol Mix-2000 Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..……16g Streptomycin Sulphate BP ……..…….40g Colistin Sulphate BP ……..… 80MIU Zinc Bacitracin 10% BP ……....100g
	Diary No. Date of R& I & fee	Dy No. 21781: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification
	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Colibac-SP 160 w/s Powder (Nawan Laboratories) Reg # 082488
	Remarks of the Evaluator	Composition in covering letter and form-5 is not same.
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
22.	Name and address of manufacturer / Applicant	M/s. D-HAANS Pharmaceuticals of Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Neo Cane-Z Powder
	Composition	Each Kg contains:- Procaine Penicillin BP ……..……..12g Streptomycin Sulphate BP ……..…….36g Neomycin Sulphate BP ……...10g Zinc Bacitracin BP ……..…….. ..52g
	Diary No. Date of R& I & fee	Dy No. 21778: 02.08.2022 PKR. 30,000/-; 01.08.2022
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specification

	Pack size & Demanded Price	500g, Kg, 2.5Kg, 5Kg, 25Kg/Decontrolled
	Me-too status (with strength and dosage form)	Biocillin-SN w/s Powder (Bio-Labs Pharma) Reg # 097941
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to Expert Working Group for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
23.	**Name and address of manufacturer / Applicant**	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	DP Injection
	Composition	Each ml contains:- Prednisolone (as Acetate)……...7.5mg Dexamethasone(as sodium Phosphate)…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 22291: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection (M/s. Mylab Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
24.	**Name and address of manufacturer / Applicant**	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	DP Injection
	Composition	Each ml contains:- Prednisolone (As Acetate)…….7.5mg Dexamethasone(As sodium Phosphate)……2.5mg
	Diary No. Date of R& I & fee	Dy No. 22292 : 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection (M/S Mylab Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
25.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	DP Injection
	Composition	Each ml contains:- Prednisolone (As Acetate)……...7.5mg Dexamethasone(As sodium Phosphate)…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 22293: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Duracort Injection (M/S My Labs Pharma) Reg # 073913
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
26.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	PCM 14 Injection
	Composition	Each ml contains:- Prednisolone ……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22294: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/s. Selmore Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
27.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan

	Brand Name +Dosage Form + Strength	PCM 14 Injection
	Composition	Each ml contains:- Prednisolone……..……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22295: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/s. Selmore Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
28.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	PCM 14 Injection
	Composition	Each ml contains:- Prednisolone ……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy No.22296: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Solomin Injection (M/s. Selmore Pharma) Reg # 049642
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
29.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	PCM 35 Injection
	Composition	Each ml contains: - Prednisolone Acetate……..…25mg Chlorpheniramine Maleate…….10mg
	Diary No. Date of R& I & fee	Dy No.22297: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled

	Me-too status (with strength and dosage form)	Predmine Injection (M/s. Cherished Pharma) Reg # 057084
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
30.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan.
	Brand Name +Dosage Form + Strength	PCM 35 INJECTION
	Composition	Each ml contains:- Prednisolone Acetate……..…25mg Chlorpheniramine Maleate…….10mg
	Diary No. Date of R& I & fee	Dy No. 22298: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	20ml/Decontrolled
	Me-too status (with strength and dosage form)	Predmine Injection (M/s. Cherished Pharma) Reg # 057084
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
31.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Dexbro Injection
	Composition	Each ml contains:- Colistine Sulphate…..……1250mg Tylosin Tartrate…….……10mg Bromhexine HCL……..…100mg Dexamethasone……..……50mg
	Diary No. Date of R& I & fee	Dy No.22299: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/s. Allina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
32.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan

	Brand Name +Dosage Form + Strength	Dexbro Injection
	Composition	Each ml contains:- Colistine Sulphate……1250mg Tylosin Tartrate……10mg Bromhexine Hcl……100mg Dexamethasone……50mg
	Diary No. Date of R& I & fee	Dy No.22300: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/s. Alina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
33.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Dexbro Injection
	Composition	Each ml contains:- Colistine Sulphate…….1250mg Tylosin Tartrate……..…10mg Bromhexine HCL……100mg Dexamethasone…….50mg
	Diary No. Date of R& I & fee	Dy No. 22301: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Broncho-Dilator
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Colitylo Plus Injection (M/s. Allina Combine) Reg # 052336
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
34.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	TADEX Injection
	Composition	Each ml contains:- Oxytetracycline HCL……..…150mg Dexamethasone Sodium Phosphate……0.5mg Tripelennamine HCL……...…….10mg

	Diary No. Date of R& I & fee	Dy No.22302: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Decaline Injection(M/s. Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
35.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Tadex Injection
	Composition	Each ml contains:- Oxytetracycline HCL……..…150mg Dexamethasone Sodium Phosphate……0.5mg Tripelennamine HCL……...….10mg
	Diary No. Date of R& I & fee	Dy No. 22303: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Decaline Injection (M/S Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
36.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Tadex Injection
	Composition	Each ml contains:- Oxytetracycline HCL……...…150mg Dexamethasone Sodium Phosphate……..…0.5mg Tripelennamine HCL……10mg
	Diary No. Date of R& I & fee	Dy No.22304: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications

	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Decaline Injection (M/s. Hilton Pharma) Reg # 028543
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
37.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Gento Injection
	Composition	Each 100ml contains: - Tylosin Tartrate…….……15gm Gentamycin Sulphate……..….6gm Dexamethasone……0.0265gm Chlorpheniramine…….…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22305: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	GentaCombisone Injection(M/S LeadsPharma) Reg # 046696
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
38.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Gento Injection
	Composition	Each 100ml contains:- Tylosin Tartrate…….……15gm Gentamycin Sulphate……..….6gm Dexamethasone ……...…0.0265gm Chlorpheniramine…….…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22306: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Genta Combisone Injection (M/s. Leads Pharma) Reg # 046696
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

39.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Gento Injection
	Composition	Each 100ml contains:- Tylosin Tartrate……...….15gm Gentamycin Sulphate…….…….6gm Dexamethasone ……..0.0265gm Chlorpheniramine…….0.750gm
	Diary No. Date of R& I & fee	Dy No.22307: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	Genta Combisone Injection (M/s. Leads Pharma) Reg # 046696
	Remarks of the Evaluator	Apply for salt form correction
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
40.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan.
	Brand Name +Dosage Form + Strength	Thiasol Injection
	Composition	Each ml contains:- Thiamphenicol……..200mg Tylosin ……..……..57.5mg Prednisolone…..……..….5mg
	Diary No. Date of R& I & fee	Dy No.22308: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylopen Injection (M/s. Selmore Agencies) Reg # 058815
	Remarks of the Evaluator	Apply for salt form as per reference
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
41.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Dextyl Injection (20ml)
	Composition	Each ml contains:- Tylosin……..…….200mg Dexamethasone ……1mg
	Diary No. Date of R& I & fee	Dy No.22310: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic

	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	20ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylovet Plus Injection (M/S Leads Pharma) Reg # 057055
	Remarks of the Evaluator	Apply for salt form as per reference
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
42.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Dextyl Injection (10ml)
	Composition	Each ml contains:- Tylosin ……..200mg Dexamethasone ……1mg
	Diary No. Date of R& I & fee	Dy No.22309: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	10ml/Decontrolled
	Me-too status (with strength and dosage form)	Tylovet Plus Injection (M/s. Leads Pharma) Reg # 057055
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
43.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Kena Dex Injection (100ml)
	Composition	Each ml contains:- Kanamycin Sulphate……..50mg Colistine Sulphate……....100,000IU Neomycin Sulphate…….50mg Dexamethasone Sodium Phosphate…0.5mg
	Diary No. Date of R& I & fee	Dy No.22312: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	100ml/Decontrolled
	Me-too status (with strength and dosage form)	KonoDex Injection (M/s. Allina Combine) Reg # 052347
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

44.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group of Plot No 3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan
	Brand Name +Dosage Form + Strength	Kena Dex Injection (50ml)
	Composition	Each ml contains:- Kanamycin Sulphate……...……..50mg Colistine Sulphate……..100,000IU Neomycin Sulphate…….……...50mg Dexamethasone Sodium Phosphate…….0.5mg
	Diary No. Date of R& I & fee	Dy No.22311: 05.08.2022 PKR. 30,000/-; 03.08.2022
	Pharmacological Group	Steroid, Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As Per Innovators Specifications
	Pack size & Demanded Price	50ml/Decontrolled
	Me-too status (with strength and dosage form)	Kano Dex Injection (M/s. Allina Combine) Reg # 052347
	Remarks of the Evaluator	
	Decision: Referred to Expert Working Group on veterinary drugs for review of formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
Case No. 04: Deferred case of (M-322)		
45.	Name and address of manufacturer / Applicant	M/s. Elko Organization (Pvt) Ltd , Plot No. 27 & 28, sector 12-B North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Link injection
	Diary No. Date of R& I & fee	Dy.No.24288, 12-6-7, Rs. 15,000/- (12,july 2018), 5000 (12 July 2018)
	Composition	Each ml contains:- Buserelin acetate…0.0042mg eq to 0.004mg Buserelin
	Pharmacological Group	Gonadotropin releasing hormone analogues
	Type of Form	Form-5
	Finished Product Specification	In house
	Pack size & Demanded Price	5ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Busol – 0.004 mg/ml solution for injection aniMedica GmbH, UK
	Me-too status	Conceptal Injection of Star Laboratories (Pvt) Ltd, Lahore (Reg # 058939).
	GMP status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today
	Remarks of the Evaluator.	VET
	Decision of 285th meeting:	Deleted since it is not priority
	Remarks of Evaluator:'	Firm has submitted the reference of already registered product "LINK INJECTION (50ml) (Reg No 084981)" and stated that 5ml pack size is more economical for the farmers, it has much priority for firm to market the said drug for poor farmers.

		Generc version: Conceptal Injection of Star Laboratories (Pvt) Ltd, Lahore (Reg # 058939).
	Decision: Deferred for opinion of Veterinary expert committee.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
46.	Name and address of manufacturer / Applicant	M/s. Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amanta Fort Powder
	Composition	Each gm contains:- Amantadine HCl…….980mg
	Diary No. Date of R& I & fee	Dy.No 13473 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100g, 200g, 500g, 1Kg: As per SRO
	Me-too status	Hansredin 98% Powder of M/s D-HAANS Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 102207)
	GMP status	▪ Last GMP inspection is conducted on 31-10-2019 and the report concludes that firm was considered to be operating at a reasonable level of GMP compliance.
	Remarks of the Evaluator [X]	▪ Dry Powder Section (veterinary) granted vide letter No. F.1-48/2003-Lic dated 25-11-2016
	Decision: Deferred for review by Expert Working Group	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
Case No. 05: Deferred case of (M-323)		
47.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals (Pvt) Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med TS Oral Liquid
	Composition	Each 1000ml contains:- Enrofloxacin……..75gm Sulphamethoxypyridazine….75gm Sulphamerazine …….50gm Trimethoprim…….…....25gm
	Diary No. Date of R& I & fee	Dy No:10033, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic

Type of Form	Form-5
Finished product Specifications	Manufacturer's Specifications
Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
Me-too status (with strength and dosage form)	Cina T.S Oral Suspension by M/s Vety-Care Pharmaceutical (Pvt) Ltd (Reg#031456)
Remarks of the Evaluator	Me-too is not same

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Firm submitted generic status Cina T.S Oral Suspension by M/s. Vety-Care Pharmaceutical (Pvt) Ltd (Reg#031456)

Decision: Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.

48.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Paradox Oral Powder
	Composition	Each 1000gm contains:- Doxycycline HCl……..……..200gm Tylosin Tartrate……..……100gm Colistin Sulphate……..…...500 MIU Aminophylline HCl……...…100gm Paracetamol……..…..100gm
	Diary No. Date of R& I & fee	Dy No:10047, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic, mucolytic & antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	**Not submitted**
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: **Decision:- Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		

49.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.

Brand Name +Dosage Form + Strength	Med Exel Oral Powder
Composition	Each 1000gm contains:- Neomycin Sulphate…….10gm Streptomycin Sulphate……36gm Procaine Penicillin…..……..12gm Zinc Bacitracin……..…52gm Colistin Sulphate……500,000 IU
Diary No. Date of R& I & fee	Dy No:10043, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
Pharmacological Group	Antibiotic
Type of Form	Form-5
Finished product Specifications	Manufacturer's Specifications
Pack size & Demanded Price	20gm, 100gm, 500gm, 1Kg, 5Kg, 25Kg/ Decontrolled
Me-too status (with strength and dosage form)	Flemibiotic Powder by M/s Grand Pharma (Pvt) Ltd (Reg#103942) (Not same as applied formulation)
Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.

Decision: Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.

50.	Name and address of manufacturer / Applicant	M/s. Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Amantagen 10 Water Soluble Powder
	Composition	Each Kg contains:- **Amantadine HCl**…….10% w/w
	Diary No. Date of R& I & fee	Dy.No 13784 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5Kg: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	Antamits Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078316)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Amantadine containing formulation for veterinary use could not be confirmed in any RRA.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
51.	Name and address of manufacturer / Applicant	M/s. Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Neodexa Injection 50mg/100,000 IU/50mg/0.5mg
	Composition	Each ml contains:- Kanamycin Sulphate……..50mg Colistin Sulphate……100,000 IU Neomycin Sulphate…….50mg Dexamethasone……..…0.5mg
	Diary No. Date of R& I & fee	Dy.No 13753 dated 07-03-2019 **Rs.20,000 dated 07-03-2019 (Fee challan is missing)**
	Pharmacological Group	Antibacterial/ Steroid
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10ml, 30ml, 50ml, 100ml: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	KONO DEX Injection of M/s Alina Combine Pharmaceutical (Pvt) Ltd. Karachi (Reg. No. 052347)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.

	Remarks of the Evaluator [X]	• Original Fee challan is missing, provide original yellow copy for fee verification as per procedure adopted by the Registration Board in its 285th meeting. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide conversion of Colistin Sulphate IU to mg. • Fee Rs.7,500/- for revision of finished product specifications. • Initially, multiple pack sizes (10ml, 30ml, 50ml, 100ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml pack size**. **Shortcoming:** Evidence of approval of Liquid injection (Steroid) Section
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
5 **2.**	Name and address of manufacturer / Applicant	M/s. Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Virakil Oral Powder 10gm
	Composition	Each 100Gm contains:- **Amantadine HCl…….10Gm**
	Diary No. Date of R& I & fee	Dy.No 16182 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	Amandin Water Soluble Powder of M/s FIZI Pharmaceuticals and Chemical Laboratories, Lahore.(Reg. No. 103819)
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications.

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
5 3.	Name and address of manufacturer / Applicant	M/s. Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reo Asper C Powder
	Composition	Each 100gm contains:- Acetylsalicyclic Acid…6.70gm Vitamin C…….20gm
	Diary No. Date of R& I & fee	Dy.No 16837 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antistress in action
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	Gesix-C Water Soluble Powder of M/s PRIX Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043286)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided. **Shortcomings:** **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
5 4.	Name and address of manufacturer / Applicant	M/s. Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reoamant 10% Powder
	Composition	Each 100gm contains:- Amantadine HCl……10gm
	Diary No. Date of R& I & fee	Dy.No 16828 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-viral
	Type of Form	Form 5

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

		• Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 25458448996.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
5 6.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobiket Injection
	Composition	Each ml contains:- Ketoprofen……100mg
	Diary No. Date of R& I & fee	Dy.No 16592 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	BP Vet Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Dinalgen Injection of M/s Mylab (Pvt) Ltd. Bahawalpur. (Reg. No. 074012)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Liquid Vial Injection (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed BP Vet specifications **without submitting fee for inclusion of finished product specifications.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
5 7.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Cylic Vit Powder
	Composition	Each 1000gm contains:- Acetyl Salicylic Acid.…67gm Vitamin C…….200gm
	Diary No. Date of R& I & fee	Dy.No 4870 dated 30-04-2019 Rs.20,000/- dated 30-04-2019
	Pharmacological Group	Restorative
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm, and 1Kg, 2.5Kg and 5Kg; Decontrolled
	Me-too status	Sali-C Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043537)

	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 088127575. **Shortcomings:** • **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C is required.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
58.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amantacin Water Soluble Powder
	Composition	Each 100gm contains:- Enrofloxacin……..10gm Colistin……..…3.5gm Amantadine……..…4gm
	Diary No. Date of R& I & fee	Dy.No 6491 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Antibacterial/anti-viral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Enflox Plus Powder, Reg. No. 052344.
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Firm has submitted approval of **Oral Dry Powder Suspension (veterinary) Section.** • Firm has revised spec to "**As per Innovator's Specifications**" • Firm has revised formulation as per reference with submission of full fee vide challan No. 0379985438 as **Each 100gm Contains:** **Enrofloxacin……10gm** **Colistin sulphate…3.5gm** **Amantadine HCl…..4gm** **Rationale of amantadine with antibiotics formulation**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: **The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in combination in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health.**		
59.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mandin Water Soluble Powder
	Composition	Each 1000gm contains:- Amantadine HCl……..980gm
	Diary No. Date of R& I & fee	Dy.No 6490 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Dopaminergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Hansredin 98% Powder of M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber, Azad Kashmir. (Reg. No. 102207)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [x]	• Approval of **Oral powder sachet (General/Antibiotic) (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 1992629762.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
60.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Febrol Injection 50ml
	Composition	Each ml contains:- Aceclofenac……25mg
	Diary No. Date of R& I & fee	Dy.No 7567 dated 29-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	NSAID/Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 50ml vial; As per SRO
	Me-too status	Vetafenac-Super Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.

	Remarks of the Evaluator [X]	• Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 4746891203.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
6 1.	Name and address of manufacturer / Applicant	M/s. Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	El-Keto Injection 100mg/ml
	Composition	Each ml contains:- Ketoprofen…….100mg
	Diary No. Date of R& I & fee	Dy.No 5559 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	NSAID, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
6 2.	Name and address of manufacturer / Applicant	M/s. Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ketoproline Injection

	Composition	Each ml contains:- Oxytetracycline……..200mg Ketoprofen……30mg
	Diary No. Date of R& I & fee	Dy.No 5556 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antibiotic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Not submitted
	Remarks of the Evaluator [x]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product and adjust its weight as per salt factor in master formula accordingly. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Full fee of registration for revision of label claim/ master formula, and finished product specifications. • Lidocain HCl is included in list of excipients mentioned in master formula and outline of method of manufacture while the same has not been reflected in label claim, clarify. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation.**		
6 3.	Name and address of manufacturer / Applicant	M/s. International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Jalc Plus Powder
	Composition	Each gram contains:- Aspirin……..…200mg Vitamin C……..…600mg Sodium Chloride……35mg Sodium Citrate…….7mg

	Diary No. Date of R& I & fee	Dy.No 11132 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Electrolytes/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg; As per DPC
	Me-too status	Electro Ras Plus W/S Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062188)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [x]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 1980709737. **Shortcomings:** • Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
6 4.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Paramax-C Oral Powder
	Composition	Each 100gm contains:- Paracetamol……..…..2gm Vitamin C……..…..20gm Calcium Carbonate..…..4.5gm Magnesium Sulphate….3.5gm Potassium Chloride……4gm
	Diary No. Date of R& I & fee	Dy.No 12007 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Analgesic, stress controller
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	SPIN-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	Not submitted
	Remarks of the Evaluator [x]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along

		with the fee of Rs. 7,500/- via deposit slip no 3027034788. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
6 5.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Coolant Oral Powder
	Composition	Each 100gm contains:- Paracetamol…….20gm Vitamin C……..5gm Potassium Carbonate…12.5gm Sodium Bicarbonate….12.5gm Vitamin E…….12.5gm
	Diary No. Date of R& I & fee	Dy.No 12025 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Analgesic, Stress controller
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Para CE Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063812)
	GMP status	Not submitted
	Remarks of the Evaluator [x]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 60066419. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
6 6.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta-10 Powder
	Composition	Each 100gm contains:- **Amantadine HCl**……..10gm
	Diary No. Date of R& I & fee	Dy.No 12017 dated 16-07-2019 Rs.20,000/- dated 16-07-2019

	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Amandin Water Soluble Powder of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore. (Reg. No. 103819)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 69840062651. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
6 **7.**	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta-98 Powder
	Composition	Each 100gm contains:- **Amantadine HCl**…….98gm
	Diary No. Date of R& I & fee	Dy.No 12018 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Hansredin 98% Powder of M/s D-Haans Pharmaceuticals and Chemical Laboratories, Bhimber, Azad Kashmir. (Reg. No. 102207)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 44192889100. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
68.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATH-OXY Oral Water Soluble Powder
	Composition	Each 100g contains:- Paracetamol…….20g Potassium Carbonate…12.5g Sodium Carbonate…….12.5g Vitamin E…….12.5g Vitamin C……..…5g
	Diary No. Date of R& I & fee	Dy. No 33149 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anti-inflammatory, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50gm, 100gm, 200gm, 400gm, 500gm, 1000gm: Decontrolled
	Me-too status	Cemol Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 103909)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator X	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
Case No. 06: Deferred case of (M-324)		
69.	Name and address of manufacturer / Applicant	M/s. Suave Pharmaceuticals Pvt. Ltd. Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta Sove 10 Oral Powder
	Composition	Each 100gm contains:- Amantadine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 39357 dated 29-12-2022 Rs.30,000/- dated 29-12-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer’s Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Roxidine-10 Water Soluble Powder of M/s. Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh (Reg. No. 112364)
	GMP status	New DML
	Remarks of the Evaluator X	Oral Powder (General/Antibiotic)-Veterinary section granted vide letter No. F.1-9/2018 dated 10-11-2022
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
70.	Name and address of manufacturer / Applicant	M/s. Suave Pharmaceuticals Pvt. Ltd. Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta Sove 98 Oral Powder
	Composition	Each 100gm contains:- Amantadine HCl……..98gm
	Diary No. Date of R& I & fee	Dy.No 39358 dated 29-12-2022 Rs.30,000/- dated 29-12-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s. Leads Pharma Pvt Ltd, Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator X	Oral Powder (General/Antibiotic)-Veterinary section granted vide letter No. F.1-9/2018 dated 10-11-2022
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
71.	Name and address of manufacturer / Applicant	M/s. Suave Pharmaceuticals Pvt. Ltd. Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Paravit C Oral Powder
	Composition	Each 1000gm contains:- Paracetamol…….……200gm Vitamin C…….…….50gm Potassium Carbonate…..125gm Sodium Bicarbonate……125gm Vitamin E……125gm
	Diary No. Date of R& I & fee	Dy.No 39341 dated 29-12-2022 Rs.30,000/- dated 29-12-2022
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 450gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Parascorbic Powder of M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 087140)
	GMP status	New DML
	Remarks of the Evaluator X	Oral Powder (General/Antibiotic)-Veterinary section granted vide letter No. F.1-9/2018 dated 10-11-2022 Shortcomings: Incorrect pharmacological group i.e. "Anti-inflammatory" was mentioned. Firm has now revised the pharmacological group to "Immune Booster". Firm shall submit fee of Rs.7500/- for correction in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
72.	Name and address of manufacturer / Applicant	M/s. Suave Pharmaceuticals Pvt. Ltd. Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Phenromion Solution for Injection
	Composition	Each ml contains:- Pheniramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 39353 dated 29-12-2022 Rs.30,000/- dated 29-12-2022
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml amber vial; Decontrolled
	Me-too status	Ann-Vil Injection (50ml) of M/s. Venus Pharma, Lahore. (Reg. No. 035158)
	GMP status	New DML
	Remarks of the Evaluator X	Liquid Injection (General/Antibiotic)-Veterinary section granted vide letter No. F.1-9/2018 dated 10-11-2022
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
73.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Pacid P Oral Suspension
	Composition	Each ml contains:- Sulphadimidine……..35mg Sulphadiazine…….36mg Streptomycin Sulphate……..7.6mg Neomycin Sulphate……...1.8mg Sodium Chloride……....11.33mg Calcium Gluconate……2.2mg Magnesium Sulphate……0.6mg Potassium Chloride……3.6mg Kaolin……..103.33mg Pectin…….7.1mg Glycine…….20.9mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 14646 dated 08-08-2019 Rs.20,000/- dated 07-08-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 5Liter: Decontrolled
	Me-too status	No-Scour Oral Suspension of M/s. Nawan Laboratories (Pvt) Ltd, Karachi. (Reg. No. 072673)
	GMP status	GMP of relevant section
	Remarks of the Evaluator X	• Firm has revised finished product specification from in-house to "**As per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 566871277080

		• **Liquid section** confirmed vide letter No. F.1-26/93-Lic (Vol. I)(M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
74.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-Mitadin 10% Water Soluble Powder
	Composition	Each 100gm Powder contains:- **Amantadine HCl**……10gm
	Diary No. Date of R& I & fee	Dy.No 14421 dated 07-08-2019 Rs.20,000/- dated 06-08-2019
	Pharmacological Group	Antiviral, antiparkinsonian and antihyperalgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 1Kg: Decontrolled
	Me-too status	Antamits Water Soluble Powder of M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078316)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Dry Powder section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
75.	Name and address of manufacturer / Applicant	M/s. Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Asper-C Water Soluble Powder
	Composition	Each 1000gm contains: Vitamin C……..…200gm Acetylsalicylic Acid…..…67gm Potassium Chloride…….3gm Sodium Citrate……7gm
	Diary No. Date of R& I & fee	Dy.No 15022 dated 20-08-2019 Rs.20,000/- dated 19-08-2019
	Pharmacological Group	Vitamin, analgesic and electrolyte
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Vita Shell Water Soluble Powder of M/s. Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 075772)

	GMP status	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
76.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan.
	Brand Name +Dosage Form + Strength	Fevofas Injection
	Composition	Each ml contains:- Aceclofenac……25mg
	Diary No. Date of R& I & fee	Dy.No 16419 dated 02-09-2019 Rs.20,000 dated 30-08-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Clofenac Injection (50ml) of M/s. Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088082)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) Section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
77.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Diclostar Injection
	Composition	Each ml contains:- Aceclofenac Sodium eq. to Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 18062 dated 19-09-2019 Rs.20,000 dated 19-09-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Clofenac Injection (50ml) of M/s. Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088082)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022

	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 20ml, 50ml, 100ml, 450ml, 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml pack size**. • Firm has mentioned salt form while the reference formulation is **Each ml contains:** **Aceclofenac.....25mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
78.	Name and address of manufacturer / Applicant	M/s. Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Pneumodox Oral Powder
	Composition	Each 1000gm contains:- Doxycycline HCl…….200gm Tylosin Tartrate……..100gm Colistin Sulphate…….500 MIU Bromhexine HCl……5gm Streptomycin Sulphate….20gm
	Diary No. Date of R& I & fee	Dy.No 17326 dated 12-09-2019 Rs.20,000 dated 12-09-2019
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: Decontrolled
	Me-too status	Respi Dox Water Soluble Powder of M/s. D-Maarson Pharmaceuticals, Islamabad. (Reg. No. 072684)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Oral Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • Provided conversion of Colistin Sulphate from IU to miligrams. (19000IU of Colistin Sulphate = 1mg)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
79.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Evonac Injection
	Composition	Each ml contains:- Aceclofenac……25mg

	Diary No. Date of R& I & fee	Dy.No 21637 dated 23-10-2019 Rs.20,000 dated 21-10-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	**10ml, 50ml**,: Decontrolled
	Me-too status	Vetafenac-Super Injection **(50ml)** of M/s. S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) Section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020. • Initially, multiple pack sizes (10ml, and 50ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml pack size**.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
80.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Hi-Fenac Injection
	Composition	Each ml contains:- Aceclofenac as Sodium……..25mg
	Diary No. Date of R& I & fee	Dy.No 21534 dated 22-10-2019 Rs.20,000/- dated 22-10-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Vetafenac-Super Injection **(50ml)** of M/s. S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** • Firm has mentioned salt form while the reference formulation is **Each ml contains:** **Aceclofenac.....25mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		

81.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Menta-100 Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl……980mg**
	Diary No. Date of R& I & fee	Dy.No 21497 dated 21-10-2019 Rs.20,000/- dated 18-10-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 500gm, 1Kg, 5Kg, 10Kg, 20Kg: Decontrolled
	Me-too status	Mentafarm Powder of M/s. Farm Aid Group, Haripur. (Reg. No. 113612)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
82.	Name and address of manufacturer / Applicant	M/s. Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Roxilyte Oral Water Soluble Powder
	Composition	Each gm contains:- Roxithromycine…….10mg Tylosin Tartrate…….10mg Guaifenesin…….17.5mg
	Diary No. Date of R& I & fee	Dy.No 28437 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	Roxi-TG Oral Powder of M/s. Mallard Pharmaceutical (Pvt) Ltd Multan. (Reg. No. 058931)
	GMP status	Inspection conducted on 15-12-2021 concludes good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Jar Powder Veterinary (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
83.	Name and address of manufacturer / Applicant	M/s. Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ketocam-100 Injection

	Composition	Each ml contains:- **Ketoprofen**…….100mg
	Diary No. Date of R& I & fee	Dy.No 28433 dated 27-12-2019 Rs.20,000/- dated 27-12-2019
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s. Biorise Pharmaceuticals Multan. (Reg. No. 113398)
	GMP status	Inspection conducted on 15-12-2021 concludes good level of GMP compliance.
	Remarks of the Evaluator [X]	**Sterile Liquid Injectable (General) section** confirmed vide letter No. F. 2-2/92-Lic (Vol-II) dated 30-06-2020. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), with the **applied fill volume/ pack size,** alongwith registration number, brand name and name of firm. • The firm has claimed **BP Vet specifications** while the official monograph of applied formulation does not exist in BP.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
84.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Afonac Injection
	Composition	Each ml contains:- **Aceclofenac As Sodium**……..25mg
	Diary No. Date of R& I & fee	Dy.No 32402 dated 31-01-2020 Rs.20,000/- dated 31-01-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20ml vial,: Decontrolled
	Me-too status	Aceclovetz Injection (20ml) of M/s. Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 088160)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings:** • Firm has mentioned sodium salt of Aceclofenac while the reference formulation is **Each ml contains:** **Aceclofenac.....25mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
85.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobimint 98% Powder
	Composition	Each Kg contains:- **Amantadine HCl**…….980gm
	Diary No. Date of R& I & fee	Dy.No 29812 dated 08-01-2020 Rs.20,000/- dated 08-01-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s. Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 094402)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.**
	Remarks of the Evaluator [X]	Approval of **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
86.	Name and address of manufacturer/ Applicant	M/s. MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Amanta XL 10 Powder
	Composition	Each 100gm contains:- Amantadine HCl……..10gm
	Diary No. Date of R& I & fee	Dy.No 225 dated 04-02-2020 Rs.20,000/- dated 30-12-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5Kg; Decontrolled
	Me-too status	Amantabak 10% Powder of M/s. Attabak Pharmaceuticals, Islamabad. (Reg. No. 075697)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **Oral Powder section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
87.	Name and address of manufacturer / Applicant	M/s. MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Amantaric XL Oral Powder
	Composition	Each Kg contains:- Amantadine HCl……..980gm
	Diary No. Date of R& I & fee	Dy.No 224 dated 04-02-2020 Rs.20,000/- dated 30-12-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s. Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 094402)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **Oral Powder section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
88.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Fenoxy Injection
	Composition	Each ml contains:- Oxytetracycline HCl…...200mg **Ketoprofen**……30mg
	Diary No. Date of R& I & fee	Dy.No 5140 dated 20-03-2020 Rs.20,000/- dated 20-03-2020
	Pharmacological Group	Antibiotic/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Vetoxy-K Injection (50ml) of M/s. Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 109240) Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022

	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
89.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Vetpro 10% Injection 20ml
	Composition	Each ml contains:- **Ketoprofen**…….100mg
	Diary No. Date of R& I & fee	Dy.No 3194 dated 02-03-2020 Rs.20,000/- dated 27-02-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid injection (General) section** confirmed vide panel inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 report for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
90.	Name and address of manufacturer / Applicant	M/s. Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Amanta Grand-98 Oral Powder
	Composition	Each Kg contains:- Amantadine HCl…..…0.98Kg
	Diary No. Date of R& I & fee	Dy.No 4632 dated 16-03-2020 Rs.20,000/- dated 16-03-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm,1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Emanta-98 Oral Powder of M/s. Evergreen Pharmaceuticals, Lahore. (Reg. No. 081735)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the

		report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder section (General) Veterinary** confirmed vide letter No. 1-36/2006-Lic (Vol-I) dated 26-09-2019
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
91.	Name and address of manufacturer / Applicant	M/s. Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Amanta Grand-10 Oral Powder
	Composition	Each Kg contains:- Amantadine HCl…….10gm
	Diary No. Date of R& I & fee	Dy.No 4631 dated 16-03-2020 Rs.20,000/- dated 16-03-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm,1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Antamits Water Soluble Powder of M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078316)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder section (General) Veterinary** confirmed vide letter No. 1-36/2006-Lic (Vol-I) dated 26-09-2019
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
92.	Name and address of manufacturer / Applicant	M/s. Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Para Mix Oral Powder
	Composition	Each 100gm contains:- **Paracetamol**……..20gm Vitamin C……5gm Potassium Carbonate…..12.5gm Sodium Bicarbonate…...12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 4628 dated 16-03-2020 Rs.20,000/- dated 16-03-2020
	Pharmacological Group	NSAID/Vitamin/Electrolyte
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm,1Kg, 2.5Kg, 5Kg: Decontrolled

	Me-too status	Para CE Oral Powder of M/s. Biogen Pharma, Rawat. (Reg. No. 063812)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder section (General) Veterinary** confirmed vide letter No. 1-36/2006-Lic (Vol-I) dated 26-09-2019
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
93.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobioxy-K Injection
	Composition	Each ml contains:- Oxytetracycline HCl…20mg **Ketoprofen**……3mg
	Diary No. Date of R& I & fee	Dy.No 10157 dated 06-05-2020 Rs.20,000/- dated 06-05-2020
	Pharmacological Group	Antibacterial and anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml vial: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Panel inspection of M/s. Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.**
	Remarks of the Evaluator [X]	Approval of **Veterinary Liquid Vial injection (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

94.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Oxyvetz Super Injection 100ml
	Composition	Each ml contains:- Oxytetracycline HCl…..200mg **Ketoprofen……..**…30mg
	Diary No. Date of R& I & fee	Dy.No 13140 dated 09-06-2020 Rs.20,000/- dated 09-06-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxyfen LA Injection (100ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
95.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Evanta Water Soluble Powder
	Composition	Each gm contains:- Amantadine HCl…….100mg
	Diary No. Date of R& I & fee	Dy.No 14232 dated 19-06-2020 Rs.20,000/- dated 18-06-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg,: Decontrolled
	Me-too status	Antamits Water Soluble Powder of M/s. Wimits Pharmaceuticals, Lahore. (Reg. No. 078316)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
96.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Mylanta Water Soluble Powder

	Composition	Each 100gm contains:- Amantadine HCl……98gm
	Diary No. Date of R& I & fee	Dy.No 14233 dated 19-06-2020 Rs.20,000/- dated 18-06-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg,: Decontrolled
	Me-too status	Amadine-98 Oral Powder of M/s. Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093841)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
97.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Profenol Injection 50ml
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 14854 dated 25-06-2020 Rs.20,000/- dated 24-06-2020
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	KETO-P Injection (50ml) of M/s Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063625)
	GMP status	GMP of relevant section
	Remarks of the Evaluator [X]	• **Injectable section** confirmed vide letter No. F.1-26/93-Lic (Vol. I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
98.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Profenol Injection 100ml
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 14857 dated 25-06-2020 Rs.20,000/- dated 24-06-2020
	Pharmacological Group	Analgesic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	KETO-P Injection (100ml) of M/s. Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063625)
	GMP status	GMP of relevant section
	Remarks of the Evaluator [X]	• **Injectable section** confirmed vide letter No. F.1-26/93-Lic (Vol. I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
99.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Lefenac Injection
	Composition	Each ml contains:- Aceclofenac……..25mg
	Diary No. Date of R& I & fee	Dy.No 18240 dated 29-06-2021 Rs.30,000/- dated 28-06-2021
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml,50ml, 100ml: Decontrolled
	Me-too status	**Registered with 10ml, 20ml and 50ml fill volume/pack sizes**
	GMP status	GMP of relevant section
	Remarks of the Evaluator [X]	**Liquid Injection Vet (General)** section confirmed vide panel inspection report for renewal of DML based on inspection conducted on 25-02-2020. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), **with same fill volume/ pack size as applied,** alongwith registration number, brand name and name of firm
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to review again the above formulation for veterinary use.**		
Case No. 07: Deferred case of (M-326)		

100.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Prokill Powder
	Composition	Alkyl (60% C_{14}, 30% C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium Chloride…….. 40% Inert Ingredient: urea……..60%
	Diary No. Date of R& I & fee	Rs.30,000/- (21009/26.07.2022)
	Pharmacological Group	External Powder Preparation (Disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	250g , 500g , 1Kg , 5Kg / Decontrolled
	Me-too status	TIMSEN Powder Registration No: 043101 by M/s. Ghazi Brothers, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too not same as applied product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The firm has revised the formulation according to reference product as: Alkyl (60% C14, 30% C16, 5%C12, 5%C18) dimethyl Benzyl ammonium chloride… 40% and deposited the Fee of Rs. 30000/- vide bank deposited Slip No. **5747962544** dated **16.09.2022** **Decision:- Deferred for clarification regarding intended use / indication of applied formulation.** **Firm submitted Indications** of PROKILL i.e. It is a complete biocide, highly effective for environment and equipment disinfection even in the presence of organic material. Effective for poultry, swine, goat and aquaculture.	
Decision:- Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.		
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
101.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Septisel 10% Solution
	Composition	Each Litre contains:- Di-decyl-di-methyl-ammonium bromide….10%
	Diary No. Date of R& I & fee	Rs.30,000/- (21004/26.07.2022)
	Pharmacological Group	External Liquid Preparation (disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 Litre, 2.5 Litre, 5 Litre / Decontrolled
	Me-too status	BROMO-SEPT Solution. Registration No: 017054, by M/s SELMORE AGENCIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Generic is not same as applied.
	Decision: Deferred for clarification regarding intended use / indication of applied formulation.	

	Firm submitted Indications of SEPTISEL10% solution i.e. It is used as disinfectant against gram (+/-) bacteria, spore-forming bacteria, fungi, yeast, pathogenic viruses and mycoplasma	
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities. **Recommendation of Sub-committee:** **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
102.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Moryso Water Soluble Powder
	Composition	Each gram contains:- **Lysozyme……**…22% Vitamin E 50…..…0.5%
	Diary No. Date of R& I & fee	Dy.No 17585 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	**Antibiotic combination**
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,500gm,1000gm: Decontrolled
	Me-too status	Apla-Zee Oral Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 097887)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**…vder Section (General)** confirmed vide panel inspection report … renewal of DML. …p mentioned in the form-5 is not correct. The firm shall submit … correction/pre-approval change in product specifications and …p as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	Decision: Referred to expert working group for rationality and solubility of applied formulation.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
103.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	PSB More-N Water Soluble Powder
	Composition	Each Kg contains:- **Procaine Penicillin……**…12gm **Streptomycin Sulphate**…..36gm **Neomycin Sulphate**……10gm **Zinc Bacitracin……...**…52gm
	Diary No. Date of R& I & fee	Dy.No 17587 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	Biocillin SN Powder of M/s Bio-Labs (Pvt) Ltd.,

		Islamabad. (Reg. No. 097941)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
104.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	PSB Plus Water Soluble Powder
	Composition	Each Kg contains:- **Procaine Penicillin……12gm** **Streptomycin…….36gm** **Colistin Sulphate…...…60 MIU** **Zinc Bacitracin……52gm**
	Diary No. Date of R& I & fee	Dy.No 17584 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	C-ZPS 100/60 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113454)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility. Colistin Sulphate from MIU to grams. or Procaine Penicillin…12gm, **Streptomycin…36gm,** Colistin IU and Zinc Bacitracin…52gm per Kg, while the referred **Each Kg contains:** **Procaine Penicillin……12gm** **Streptomycin sulphate…….36gm** **Colistin Sulphate…..60,00000 IU** **Zinc Bacitracin……..52gm**
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
105.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.

	Brand Name +Dosage Form + Strength	Enro More Plus Oral Liquid
	Composition	Each ml contains:- **Enrofloxacin……**…75mg **Sulphamethoxy pyridazine**…75mg **Sulphamethazine**…….……50mg **Trimethoprim**……..25mg
	Diary No. Date of R& I & fee	Dy.No 17592 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Marko-Cena Forte Oral Liquid of M/s Vetec Laboratories, Rawat, Rawalpindi (Reg. No. 101493)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
106.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Diaban Oral Liquid
	Composition	Each ml contains:- **Sulphadimidine**…….35mg **Sulphadiazine**……36mg **Streptomycin Sulphate…**…7.6mg **Neomycin Sulphate**…….1.8mg Sodium Chloride……..11.33mg Calcium Gluconate…….2.2mg Magnesium Sulphate.…..0.6mg Potassium Chloride…….3.6mg Kaolin……..…103.33mg Pectin…….……..7.1mg Glycine…….……..…20.9mg
	Diary No. Date of R& I & fee	Dy.No 16154 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial with minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 500ml,1000ml: Decontrolled
	Me-too status	No-Scour Oral Suspension of M/s Nawan Laboratories (Pvt) Ltd., Karachi (Reg. No. 072673)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator X	**Oral Liquid (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.

	Decision: Referred to expert working group for the suitability of formulation. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
107.	Name and address of manufacturer / Applicant	M/s. Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobipara-C Oral Powder
	Composition	Each 100gm contains:- **Paracetamol**……2gm Vitamin C……...20gm Calcium Carbonate……...4.5gm Potassium Chloride……..…4gm Magnesium Sulphate……3.5gm
	Diary No. Date of R& I & fee	Dy.No 15545 dated 01-07-2020 Rs.20,000/- dated 30-06-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Paralite-C Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079518)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 •
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
108.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Antizine Injectable Powder
	Composition	Each vial contains:- Diminazine Aceturate..…1.05gm Antipyrine……1.31gm
	Diary No. Date of R& I & fee	Dy.No 17172 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2.36gm vials: Decontrolled
	Me-too status	Tryptowan Injection of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. No. 025761)

	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for review by expert working group for veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
109.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Rasnor-200 Oral Liquid
	Composition	Each 100ml contains:- Norfloxacin HCl……20gm
	Diary No. Date of R& I & fee	Dy.No 17576 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml,1Litre, 5Litre, 25Litre; N/A
	Me-too status	Nor-Oxime Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 080137)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for review by expert working group for veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
110.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan .
	Brand Name +Dosage Form + Strength	Norflox-250 Oral Liquid
	Composition	Each 100ml contains:- Norfloxacin HCl……25gm
	Diary No. Date of R& I & fee	Dy.No 17575 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml,1L, 5L, 25L; N/A
	Me-too status	Normak Liquid of M/s A & K Pharmaceutical Faisalabad (Reg. No. 058943)

	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**al) Vet section** confirmed vide panel inspection report based -03-2021 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for review by expert working group for veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
111.	Name and address of manufacturer / Applicant	M/s. Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Am-Cina Liquid
	Composition	Each ml contains:- **Enrofloxacin**……75mg **Sulphamethoxypyridazine.**…75mg **Sulphamethazine**……50mg **Trimethoprim**…….25mg
	Diary No. Date of R& I & fee	Dy.No 17725 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Marko-Cena Forte Oral Liquid of M/s Vetec Laboratories, Rawat, Rawalpindi (Reg. No. 101493)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide t based on inspection conducted on 05-09-2019 for grant of
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
112.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tricopure Powder
	Composition	Each 1000gm contains:- Trichlorfon…….0.980Kg
	Diary No. Date of R& I & fee	Dy.No 22878 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled

	Me-too status	Amsefon-980 Oral Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No.112286)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
113.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	CIN-SST Oral Solution
	Composition	Each ml contains:- **Enrofloxacin**……75mg **Sulphamethoxypyridazine**…..75mg **Sulphamethazine**…….……50mg **Trimethoprim**……..25mg
	Diary No. Date of R& I & fee	Dy.No 22089 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 250ml, 500ml, 1000ml, 2.5Litre, 5Litre, 10Litre, 25Litre: Decontrolled
	Me-too status	Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031456)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • The firm has applied for "**SOLUTION"** dosage form while the referred generic product exists as **"SUSPENSION",** clarify and accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
114.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Ak-Nag Liquid
	Composition	Each 100ml contains:- Norfloxacin……20gm

		Guaiphenesin……..20gm Aminophylline……..…8gm
	Diary No. Date of R& I & fee	Dy.No 22094 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibiotic/ Bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 500ml, 1000ml, 2.5Litre, 5Litre, 10Litre, 25Litre: Decontrolled
	Me-too status	Noramin-G Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044976)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
115.	Name and address of manufacturer / Applicant	M/s. Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Norphylin-G Liquid
	Composition	Each 100ml contains:- Aminophylline…..……8gm Guaifenesin…….……20gm Norfloxacin…….20gm
	Diary No. Date of R& I & fee	Dy.No 20573 dated 19-08-2020 Rs.20,000/- dated 18-08-2020
	Pharmacological Group	Antibiotic, Bronchodilator, Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 15Litre, 20Litre, 25Litre ; Decontrolled
	Me-too status	Noramin-G Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044976)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Refer to EWG on veterinary drugs	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
116.	Name and address of manufacturer / Applicant	M/s. Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Cina-Flox Oral Liquid
	Composition	Each ml contains:- Enrofloxacin…….75mg

		Sulphamethoxypyridazine……50mg Sulphamethazine……..50mg Trimethoprim……25mg
	Diary No. Date of R& I & fee	Dy.No 28439 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad (Reg. No. 074786)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**I and Oral Liquid Section-II (Veterinary)** confirmed vide t based on inspection conducted on 05-09-2019 for grant of
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
117.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dimarina Injection
	Composition	Each ml contains:- Diminazine Aceturate…105mg **Antipyrine**……..131mg
	Diary No. Date of R& I & fee	Dy.No 31452 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Durazene Easy Injection (10ml, 20ml, 50ml, 100ml) of Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074017)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 20ml, 50ml, 100ml, 450ml and 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml** pack size.
	Decision: Deferred for review by expert working group for veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
118.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.

	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection 100ml
	Composition	Each ml contains:- Oxytetracycline as HCl…200mg **Ketoprofen**…….30mg
	Diary No. Date of R& I & fee	Dy.No 30034 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
119.	Name and address of manufacturer / Applicant	M/s. Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection
	Composition	Each ml contains:- Oxytetracycline as HCl…..…200mg **Ketoprofen**……...30mg
	Diary No. Date of R& I & fee	Dy.No 30037 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
120.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Oxy-Pro Injection
	Composition	Each ml contains:- Oxytetracycline HCl…….200mg **Ketoprofen**…….30mg

	Diary No. Date of R& I & fee	Dy.No 27128 dated 14-10-2020 Rs.20,000/- dated 14-10-2020
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
121.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Clofenac Injection
	Composition	Each ml contains:- Aceclofenac Sodium eq. to Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 26574 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Afonac Injection (10ml) of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 095656)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. **Shortcomings:** • Firm has mentioned salt form while the reference formulation is **Each ml contains:** **Aceclofenac.....25mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to EWG on veterinary drugs to review environment safety requirements	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
122.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.

	Brand Name +Dosage Form + Strength	Amanda-10 Powder
	Composition	Each Kg contains:- **Amantadine HCl**……100gm
	Diary No. Date of R& I & fee	Dy.No 28789 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Antamits Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 078316)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
123.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Vita-C Plus Powder
	Composition	Each Kg contains:- **Paracetamol……**…20gm Vitamin C……..….200gm Calcium Carbonate……..45gm Magnesium Sulphate…...35gm Potassium Chloride……..40gm
	Diary No. Date of R& I & fee	Dy.No 28788 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antipyretic/ Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

124.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Asper-C Powder
	Composition	Each Kg cntains:- **Vitamin C**……200gm **Aspirin……**…67gm Potassium Chloride…..…3gm Sodium Citrate……..…7gm
	Diary No. Date of R& I & fee	Dy.No 28797 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Cyper-C Water Soluble Powder of M/s Farm Aid Group, Haripur. (Reg. No. 088019)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
125.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Amantacol-Liquid
	Composition	Each Litre contains:- Enrofloxacin…….100gm **Amantadine**……40gm
	Diary No. Date of R& I & fee	Dy.No 29793 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibacterial, Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in combination in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health**		
126.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Ecodin Liquid
	Composition	Each Litre contains:- Enrofloxacin……..……..100gm Colistin Sulphate…..….500MIU Bromhexine……..40gm **Amantadine**……5gm
	Diary No. Date of R& I & fee	Dy.No 28805 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic, Antiviral, Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Colistin Sulphate from MIU to gram. • Clarification regarding applied formulation is required since Enrofloxacin…100gm, Colistin Sulphate…500MIU, **Bromhexine…40gm and Amantadine…5gm/** Litre is mentioned on form 5 while Enrofloxacin…100gm, Colistin Sulphate…500MIU, **Bromhexine…5gm and Amantadine…40gm/** Litre is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in combination in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health**		
127.	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.

	Brand Name +Dosage Form + Strength	Restil-C Powder
	Composition	Each 100gm contains:- **Paracetamol……..**…2gm Ascorbic Acid……..…20gm Calcium Carbonate……..…4.5gm Magnesium Sulphate…….3.5gm Potassium Chloride……4gm
	Diary No. Date of R& I & fee	Dy.No 34525 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Analgesic, Antipyretic, Vitamin and mineral supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1Kg: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Oral Powder (General) section** confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
128.	Name and address of manufacturer / Applicant	M/s. Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Diminariq Injection 50ml
	Composition	Each ml contains:- Diminazine Aceturate……..105mg Antipyrine……131mg
	Diary No. Date of R& I & fee	Dy.No 34604 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antipyretic, Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Durazene Easy Injection (50ml) of Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074017)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Deferred for review by expert working group for veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		

129.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Oxy-K LA Injection
	Composition	Each ml contains:- Oxytetracycline……200mg **Ketoprofen**…….30mg
	Diary No. Date of R& I & fee	Dy.No 32484 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Antibacterial/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
130.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Metrifonvet Oral Powder
	Composition	Each gm contains:- Trichlorphone (Metrifonate)……960mg
	Diary No. Date of R& I & fee	Dy.No 32482 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 100gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Ectofon Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 041295)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
131.	Name and address of manufacturer / Applicant	M/s. Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Repto Powder

	Composition	Each gm contains:- **Chlortetracycline HCl**……..……200mg **Neomycin Sulphate**……60mg **Colistin Sulphate**……10mg **Streptomycin Sulphate……..**…20mg
	Diary No. Date of R& I & fee	Dy.No 33436 dated 16-12-2020 Rs.20,000/- dated 09-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Streptochlor Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080738)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
132.	Name and address of manufacturer / Applicant	M/s. Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Amantaflu-98 Oral Powder
	Composition	Each Kg contains:- **Amantadine HCl**……..0.980Kg
	Diary No. Date of R& I & fee	Dy.No 34446 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, and 2500gm; Decontrolled
	Me-too status	Menta Shell Oral Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 101968)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Powder (antibiotic)** and **Veterinary oral Powder (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
133.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acavon 98% Water Soluble Powder
	Composition	Each 100gm contains:- Metrifonate (Trichlorophon)…98gm

	Diary No. Date of R& I & fee	Dy.No 6826 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Cholinesterase inhibitor/ insecticide
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Trinoor-98 Oral Powder of M/s Kohinoor Industries, Sahiwal. (Reg. No. 081306)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
134.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acavon 96% Water Soluble Powder
	Composition	Each 100gm contains:- Metrifonate (Trichlorophon)……96gm
	Diary No. Date of R& I & fee	Dy.No 6827 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Cholinesterase inhibitor/ insecticide
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg,2.5Kg, 5Kg: Decontrolled
	Me-too status	Nawagan Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 053922)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
135.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Parapex-C Water Soluble Powder
	Composition	Each 100gm contains:- **Paracetamol**…..…….20gm Vitamin C……..…...5gm Potassium Carbonate…...12.5gm Sodium Bicarbonate..…..12.5gm Vitamin E……12.5gm
	Diary No. Date of R& I & fee	Dy.No 6821 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Analgesic /Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Para Ce Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063812)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
136.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acme-Aspro-C Water Soluble Powder
	Composition	Each 100gm contains:- **Vitamin C**……...20gm **Aspirin**……6.7gm
	Diary No. Date of R& I & fee	Dy.No 6803 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Salicylate/Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	B.G Aspro-C Water Soluble Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No.080146)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
Case No. 07: Deferred case of (M-327)		
137.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sulflox Plus Oral Liquid
	Composition	Each ml contains:- **Enrofloxacin**……75mg **Sulphamethoxypyridazine…..**…50mg **Sulphamethazine**…….…….50mg **Trimethoprim**……..25mg
	Diary No. Date of R& I & fee	Dy.No 6876 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	New DML
	Remarks of the Evaluator [X]	

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
138.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sulflox DS Oral Liquid
	Composition	Each ml contains:- **Enrofloxacin**……75mg **Sulphamethoxypyridazine**…….75mg **Sulphamethazine**…….50mg **Trimethoprim**……..25mg
	Diary No. Date of R& I & fee	Dy.No 6875 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No.031456)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
139.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Apra-C Oral Powder
	Composition	Each gram contains:- Vitamin C…….….200mg **Paracetamol**……..…..20mg Potassium Chloride…..……40mg Calcium Carbonate……...450mg Magnesium Sulphate…..…35mg
	Diary No. Date of R& I & fee	Dy.No 6798 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Vitamin/ NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Paravit-C Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074081)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.		
140.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Acmentadin 10% Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl……..**…100mg
	Diary No. Date of R& I & fee	Dy.No 6824 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Amancin-10 Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi (Reg. No. 112234)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
141.	Name and address of manufacturer / Applicant	M/s. Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Acmentadin 98% Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl…..**…0.980gm
	Diary No. Date of R& I & fee	Dy.No 6825 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
142.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cina-Zone 50 Oral Solution
	Composition	Each 1000ml contains:- Enrofloxacin (BP Vet))…….75g Sulphamethoxypyradazine (BP Vet)…...50g Sulphamethazine (USP)……50g Trimethoprim (BP)……25g
	Diary No. Date of R& I & fee	Dy. No. 8113 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Sulphacina Oral solution Mfg. by M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 75mg/ml but the claimed dosage form is Oral Suspension. Clarification required in this regard.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
143.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cina-Zone 75 Oral Suspension
	Composition	Each ml contains:- Enrofloxacin (BP Vet)……75mg Sulphamethoxypyradazine (BP Vet)…..…75mg Sulphamethazine (USP)…….50mg Trimethoprim (BP)…….25mg
	Diary No. Date of R& I & fee	Dy. No. 8112 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Cina T.S Oral Suspension Mfg. by M/s. Vety-Care Pharmaceuticals, Islamabad. (Reg. No. 031456)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	i. Firm has already applied a similar formulation with only difference being the strength of Sulphamethoxypyradazine as 50mg/ml but the claimed dosage form is Oral Solution. Clarification required in this regard.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
144.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Nora-Zone Oral Drench
	Composition	Each 100ml contains:- Norfloxacin (BP)……..20g Aminophylline (BP)……...…8g Guaifenesin (USP)……20g
	Diary No. Date of R& I & fee	Dy. No. 8124 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Nor Plus-20% Oral Liquid Mfg. by M/s. Bio Labs, Islamabad. (Reg. No. 033241)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
145.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Eca-Zone Oral Solution
	Composition	Each 1000ml contains:- Enrofloxacin (BP Vet)……20g Colistin Sulphate (BP)……35g Amantadine (BP)……40g
	Diary No. Date of R& I & fee	Dy. No. 8125 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled
	Me-too status	Amantaflox-C Mfg. by M/s. Baariq Pharma, Lahore. (Reg. No. 073946)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **The sub-committee on Veterinary Drugs deliberated on the matter and observed that, in the absence of any recognized scientific data regarding the use of amantadine in combination in any Reference Regulatory Authority (RRA), all such combinations are recommended may be forwarded to M/o NFS&R for their comments before deregistration in the best interest of public health**		
146.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Scour-Zone Oral Solution
	Composition	Each ml contains:- Sulphadiazine (BP)…….33.500mg Neomycin Sulphate (BP)……..…1.800mg Pectin (USP)……..…7.100mg Vitamin B1 (BP)……0.150mg Sulphadimdine (BP Vet)…….28.400mg Hyoscine Methyl Bromide (Ph. Eur)……0.040mg Kaolin (BP)……103.300mg Vitamin B2 (BP)……0.200mg
	Diary No. Date of R& I & fee	Dy. No. 8131 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1 L, 2.5 L, 5 L : Decontrolled

	Me-too status	Scour-X Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 029661)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
147.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	PCB-20 Oral Powder
	Composition	Each 100g contains:- Paracetamol (BP)……...…20g Vitamin E (USP)……..…12.5g Vitamin C (BP)…….……...5g Sodium Bicarbonate (BP)….…….12.5g Potassium Carbonate (BP)…….12.5g
	Diary No. Date of R& I & fee	Dy. No. 8096 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Anti-inflammatory, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Cemol Oral Powder Mfg. by M/s. Selmore Pharmaceuticals, Lahore. (Reg. No. 103909)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
148.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Parazone 6.7 Oral Powder
	Composition	Each 1000g contains:- Acetylsalicylic Acid (BP)……67g Vitamin C (BP)……...…200g Sodium Citrate (BP)…….……..7g Potassium Chloride (BP)……3g
	Diary No. Date of R& I & fee	Dy. No. 8097 dated 22-03-2023, Rs. 30,000/- Dated 16-03-2023
	Pharmacological Group	Analgesic/Vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Asperlyte-C Powder Mfg. by M/s. Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074789)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	

	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
149.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Cocozone Oral Powder
	Composition	Each 100g contains:- Sulphaquinoxaline (USP)…….16g Diaveridine…….……4g Vitamin A (BP)……0.40 MIU Vitamin K3 (USP)……..1g
	Diary No. Date of R& I & fee	Dy. No. 8100 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Cocoplus Oral Powder Mfg. by M/s. Intervac Pharmaceuticals, Lahore. (Reg. No. 046604)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
150.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amazone-10 Oral Powder
	Composition	Each 1000g contains:- Amantadine HCl (BP)…….100g
	Diary No. Date of R& I & fee	Dy. No. 8089 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Rescue-100 Oral Powder Mfg. by M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 079812)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
151.	Name and address of manufacturer / Applicant	M/s. QAS International, Plot No. 153/155, Mustafaabad, Tehsil Kamonke, Gujranwala.
	Brand Name +Dosage Form + Strength	Amazone-98 Oral Powder

	Composition	Each 100g contains:- Amantadine HCl (BP)……98g
	Diary No. Date of R& I & fee	Dy. No. 8090 dated 22-03-2023, Rs. 30,000/- Dated 15-03-2023
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator Specifications
	Pack size & Demanded Price	10g, 20g, 50g, 100g, 250g, 500g, 1kg, 10kg, 12.5kg, 25kg : Decontrolled
	Me-too status	Amadine-98 Oral Powder Mfg. by M/s. Aptly Pharmaceuticals, Faisalabad (Reg. No. 093841)
	GMP status	DML Issued on 16-02-2023, Last inspection: 22-12-2022
	Remarks of the Evaluator	
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
152.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Kryptin Oral Liquid
	Composition	Each ml contains:- Enrofloxacin (EP)……..75mg Sulphamethoxypyrizadine (EP)…….75mg Sulphamethazine (USP)…….50mg Trimethoprim (EP)…….25mg
	Diary No. Date of R& I & fee	Dy. No. 1192 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	Cina TS Oral Suspension Mfg. by M/s. Vety care Pharmaceuticals, Islamabad (Reg. No. 031456)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
153.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Age-Kryp Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin (EP)……..…….10mg Aminophylline (BP)……..……..…4g Guaifenesin (USP)……10g
	Diary No. Date of R& I & fee	Dy. No. 1196 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic/Expectorant/Bronchodilator
	Type of Form	Form 5

	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1L, 2.5L, 5L : Decontrolled
	Me-too status	EG Enro plus liquid Mfg. by M/s. Elegance Pharmaceuticals, Rawalpindi (Reg. No. 074099)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
154.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	KP-Resto D Oral Powder
	Composition	Each 1000g contains:- Tylosin Tartarate (EP)……..…100g Doxycycline HCl (BP)…….200g Colistin Sulphate (BP)… …..500 MIU Bromhexine (EP)…….5g Phenylbutazone (USP)……..…12g
	Diary No. Date of R& I & fee	Dy. No. 1181 dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	50g, 100g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg : Decontrolled
	Me-too status	Resco Powder Mfg. by M/s. Leads Pharmaceuticals, Islamabad (Reg. No. 044965)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product. ii. Firm has not provided the conversion of Colistin Suphate from MIU to grams.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
155.	Name and address of manufacturer / Applicant	M/s. Krypton Pharma (Pvt.) Ltd., Plot No. 52, M-3, Industrial City Sahainwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Strepto-Kyp Oral Powder
	Composition	Each 1000g contains:- Tylosin Tartarate (EP)……..…10% Doxycycline Hyclate (BP)……..…20% Colistin Sulphate (BP)……..450 MIU Bromhexine HCl (EP)…….0.5% Streptomycin Sulphate (EP)……3.6%
	Diary No. Date of R& I & fee	Dy. No. 1203- dated 08-01-2021, Rs. 20,000/- Dated 07-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	In-house Specifications

	Pack size & Demanded Price	50g, 100g, 200g, 250g, 450g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg : Decontrolled
	Me-too status	Biodox-T Powder Mfg. by M/s. Nobel Pharma Mirpur, AJ&K (Reg. No. 075609)
	GMP status	Inspection for issuance of DML conducted on 12-20-2020.
	Remarks of the Evaluator	i. Firm has claimed in-house specifications for finished product. ii. Firm has not provided the conversion of Colistin Suphate from MIU to grams or %.
	Decision: Deferred for review of formulation by expert working group on veterinary drugs.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
Case No. 08: Deferred case of (M-329)		
156.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Mepyrvetz Injection
	Composition	Each ml contains:- Mepyramine Maleate……50mg
	Diary No. Date of R& I & fee	Dy.No 856 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-allergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Meprax Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 112258)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator X	1. **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its food safety concerns in regional and global regulatory authorities.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
157.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Oxy KP Injection
	Composition	Each ml contains:- Oxytetracycline HCl……200mg **Ketoprofen……..**…...30mg
	Diary No. Date of R& I & fee	Dy.No 2828 dated 25-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10ml, 20ml, 30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection **(10ml, 20ml, 30ml, 50ml, 100ml)** of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022
	Remarks of the Evaluator X	Approval of **Liquid Injection Section (General-Veterinary)** confirmed vide panel inspection report dated 29-11-18 and 01- 01-2019, for issuance of GMP certificate. **Shortcomings:** 1. The firm has applied for Oxytetracycline HCl…200mg and Ketoprofen…30mg, while the referred generic product contains **Each ml contains:-** **Oxytetracycline (as HCl)** **….200mg** **Ketoprofe…….30mg** Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board; or revise formulation in line with reference product. 2. Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. 3. Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
158.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Oxkit Injection
	Composition	Each ml contains:- Oxytetracycline as HCl…200mg **Ketoprofen……**…30mg
	Diary No. Date of R& I & fee	Dy.No 194 dated 01-01-2021 Rs.20,000/- dated 19-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection **(10ml, 20ml, 30ml, 50ml, 100ml)** of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)

	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator X	**1.** **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08- 07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** **2.** Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. **3.** Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
159.	Name and address of manufacturer / Applicant	M/s. Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi.
	Brand Name +Dosage Form + Strength	Gumbogence Powder
	Composition	Each gm contains:- Ammonium Chloride……300mg DL-Methionine…….100mg Sorbitol……...50mg Vitamin A……..150,0 IU **Vitamin C**……100mg **Aspirin……**…100mg
	Diary No. Date of R& I & fee	Dy.No 5384 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Amino acid, Multivitamin, Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Gumbosol Powder of M/s Westmont Pharmaceutical Industry, Gujar Khan, Distt. Rawalpindi (Reg. No. 063752)
	GMP status	
	Remarks of the Evaluator X	**Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use

160.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Monium-C Powder
	Composition	Each gm contains:- Ammonium Chloride…….300gm **Aspirin**……100mg **Vitamin C**……...100mg DL-Methionine……100mg Vitamin A……..1500 IU Sorbitol……..50mg
	Diary No. Date of R& I & fee	Dy.No 4203 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Electrolyte supplement, Expectorant, NSAID, **Diuretic**
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	Scada Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 079819)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator X	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** Firm shall submit fee of Rs.7,500/- for correction in pharmacological group, as per notification No.F.7-11/2012- B&A/DRAP dated 07-05-2021.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use

161.	Name and address of manufacturer / Applicant	M/s. Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Menditage Oral Liquid
	Composition	Each ml contains:- **Enrofloxacin**…….75mg **Sulphamethoxypyridazine**……...75mg **Sulphamethazine**……..50mg **Trimethoprim**……25mg
	Diary No. Date of R& I & fee	Dy.No 9458 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Pro Chick Oral Liquid of M/s Majestic Pharma, Faisalabad. (Reg. No. 089834)
	GMP status	

	Remarks of the Evaluator X	**Shortcomings:** 39. Latest GMP inspection report conducted within the period of last three years. 40. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
162.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 7660 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ketoject Injection (10ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator X	**Shortcomings:** 3. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
163.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains: **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 7656 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)

	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator X	**Shortcomings:** 5. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
164.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- **Ketoprofen…….**…100mg
	Diary No. Date of R& I & fee	Dy.No 7618 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator X	**Shortcomings:** 7. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
165.	Name and address of manufacturer / Applicant	M/s. Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 7649 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) Specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of

		DML
	Remarks of the Evaluator X	**Shortcomings:** 9. Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit
		panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
166.	Name and address of manufacturer / Applicant	M/s. Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi.
	Brand Name +Dosage Form + Strength	Acerin-C Powder
	Composition	Each gm contains:- **Aspirin……...**…200mg **Vitamin C……..**…600mg
	Diary No. Date of R& I & fee	Dy.No 9475 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	NSAID/ Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Bio-Aspervet-C Oral Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No.079104)
	GMP status	
	Remarks of the Evaluator X	**Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
167.	Name and address of manufacturer / Applicant	M/s. Majestic Pharma, Plot No. 21, Phase No.1-A, M-3Industrial City, Sahianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Maji Mant Oral Powder
	Composition	Each gram contains:- **Amantadine HCl**……100mg
	Diary No. Date of R& I & fee	Dy.No 9880 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm; Decontrolled

	Me-too status	Amantage Oral Powder of M/s Vantage Pharmaceutical, Shahkot Road, District Faisalabad. (Reg. No. 088851)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator X	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: : Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
168.	Name and address of manufacturer / Applicant	M/s. Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Farmadox-M Powder
	Composition	Each gm contains: **Tylosin Tartrate**……..10% **Doxycycline Hyclate……**…20% **Colistin Sulphate**……450000 IU Bromhexine HCl……..0.5% **Streptomycin Sulphate……...**…3.6%
	Diary No. Date of R& I & fee	Dy.No 9886 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 2500gm; Decontrolled
	Me-too status	Bacto-5 Powder of M/s Noble Pharma, Mirpur Azad Kashmir (Reg. No. 075609)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator X	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
169.	Name and address of manufacturer / Applicant	M/s. Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Donamide Water Soluble Powder
	Composition	Each gm contains:- Furosemide……..…20mg **Belladonna Extract**……..2mg
	Diary No. Date of R& I & fee	Dy.No 9463 dated 26-03-2021 Rs.20,000/-

		dated 26-03-2021
	Pharmacological Group	Diuretic/ anticholinergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Bella Flush Water Soluble Powder of Ms Attabak Pharmaceuticals, Islamabad (Reg. No. 075724)
	GMP status	
	Remarks of the Evaluator X	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** 16. Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
170.	Name and address of manufacturer / Applicant	M/s. Venus Pharma, 23 km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexamethasone 1mg/2ml 50CC Injection
	Composition	Each ml contains:- Dexamethasone Sodium Phosphate Eq. to Dexamethasone Phosphate……..…0.5mg
	Diary No. Date of R& I & fee	Dy.No 11383 dated 14-04-2021 Rs.20,000/- dated 14-04-2021
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Dexamethasone Injection (50ml) of M/s Lawrance Pharma (Pvt) Ltd, Lahore (Reg. No. 063874)
	GMP status	
	Remarks of the Evaluator X	**Shortcomings:**
		Latest GMP inspection report (conducted within the period of last three years) Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
171.	Name and address of manufacturer / Applicant	M/s. Venus Pharma, 23 km, Multan Road, Lahore.

	Brand Name +Dosage Form + Strength	Dexsone 50cc Injection
	Composition	Each ml contains:- Dexamethasone as Sodium Phosphate……..…2.5mg Prednisolone As Acetate…….7.5mg
	Diary No. Date of R& I & fee	Dy.No 11384 dated 14-04-2021 Rs.20,000/- dated 14-04-2021
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Symocortinol-S Injection (50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 072672)
	GMP status	
	Remarks of the Evaluator X	**Shortcomings:** Latest GMP inspection report (conducted within the period of last three years) Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
172.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sultrop Liquid
	Composition	Each ml contains:- **Enrofloxacin**…….75mg **Sulphamethoxypyridazine**……..50mg **Sulphamethazine**…….…….50mg **Trimethoprim**…….……..25mg
	Diary No. Date of R& I & fee	Dy.No 12273 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 700ml,1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator X	**27. Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-

		2016.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
173.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Predniphen Injection
	Composition	Each ml contains:- Prednisolone Acetate……10mg Chlorpheniramine Maleate…….4mg
	Diary No. Date of R& I & fee	Dy.No 18244 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 942549143218)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator X	**Shortcomings:** 41. Latest GMP inspection report conducted within the period of last three years. 42. Approval of **Liquid Injection Section (Steroid- Veterinary)** by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. 43. Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
		19. Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic verification.**		

174.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Nortin-20 Solution
	Composition	Each ml contains:- **Norfloxacin**……200mg
	Diary No. Date of R& I & fee	Dy.No 15369 dated 02-06-2021 Rs.30,000/- dated 02-06-2021 (slip No. 162071626)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Manster B 90 Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 071097)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
175.	Name and address of manufacturer / Applicant	M/s. D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Detoxy-Liv Oral Liquid
	Composition	Each ml contains:- **Silymarin**……..21mg **Vitamin E……..**…15mg
	Diary No. Date of R& I & fee	Dy.No 17233 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 925710619267)
	Pharmacological Group	Hepato-protective agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Hepatocare Oral Suspension of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 062167)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML

	Remarks of the Evaluator X	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** 15. Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
176.	Name and address of manufacturer / Applicant	M/s. D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber.
	Brand Name +Dosage Form + Strength	Trisulph-En Oral Liquid
	Composition	Each ml contains:- **Enrofloxacin**……..…..75mg **Trimethoprim**…….25mg **Sulphamethoxypyridizine.**…75mg **Sulphamethazine**……50mg
	Diary No. Date of R& I & fee	Dy.No 17237 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 401182722367)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Cinafas Oral Suspension of M/s Intervac (Pvt) Ltd., Lahore (Reg. No. 048264)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator X	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** 17. Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
177.	Name and address of manufacturer / Applicant	M/s. D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Hansymol-C Water Soluble Powder
	Composition	Each gram contains:- Vitamin C…….……50mg **Paracetamol**…….……..200mg Potassium Carbonate…..…..…125mg Sodium Bicarbonate……..…125mg Vitamin E…….125mg

	Diary No. Date of R& I & fee	Dy.No 17240 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 41811692460)
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Parascorbic Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 087140)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator X	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** 19. Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**	
	Case No. 09: Deferred case of (M-330)	
178.	Name and address of manufacturer / Applicant	M/s. Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Cin Powder
	Composition	Each gram contains:- **Neomycin Sulphate……**…60mg **Colistin Sulphate**……10mg **Chlortetracycline HCl**…..200mg **Spectinomycin Sulphate.**…20mg
	Diary No. Date of R& I & fee	Dy.No 20049 dated 16-07-2021 Rs.30,000/- dated 15-07-2021 (slip No. 1066563781)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Streptochlor Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080738)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.

	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on 29-10-2018. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
179.	Name and address of manufacturer / Applicant	M/s. Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wal Cetamol Powder
	Composition	Each gram contains:- Vitamin C……..……..50mg **Paracetamol**…….……200mg Potassium Carbonate…….125mg Sodium Bicarbonate……..125mg Vitamin E…125mg
	Diary No. Date of R& I & fee	Dy.No 19758 dated 14-07-2021 Rs.30,000/- dated 13-07-2021 (slip No. 091565212)
	Pharmacological Group	Analgesic, Antipyretic, Antioxidant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm ; Decontrolled
	Me-too status	Paracet Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad (Reg. No. 079826)
	GMP status	The firm was inspected on **29-10-2018** with the following conclusion: Firm is compliant to Current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [X]	• **Oral dry powder (General) (Veterinary) Section** confirmed from GMP compliance inspection report conducted on **29-10-2018**. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
180.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ketogen Injection
	Composition	Each ml contains:- **Ketoprofen……..…**100mg

	Diary No. Date of R& I & fee	Dy.No 18474 dated 01-07-2021 Rs.30,000/- dated 28-06-2021 (slip No. 2916250106)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No.113398)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of Injectable (General) Veterinary section by CLB
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
181.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 20432 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 70534384404)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
182.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains: **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 20431 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 82678962247)
	Pharmacological Group	NSAID

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
183.	Name and address of manufacturer / Applicant	M/s. Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Proxifen Injection
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 20433 dated 27-07-2021 Rs.30,000/- dated 26-07-2021 (slip No. 77703107862)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm shall submit revised form-5 with its new title along with fee Rs. 30,000/- for change of title of the firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
184.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 22609 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 77983104)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (10ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106694)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
185.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 22604 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 10792384591)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (50ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106695)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
186.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isketo Injection
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 22605 dated 17-08-2021 Rs.30,000/- dated 06-07-2021 (slip No. 718116033117)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoexel 100 Injection (100ml) Of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106696)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.

	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
187.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection
	Composition	Each ml contains:- Vitamin A……..100,000 IU Vitamin D3……..…80,000 IU Vitamin E……40mg
	Diary No. Date of R& I & fee	Dy.No 22617 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 6768206298)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation.**		
188.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection
	Composition	Each ml contains:- Vitamin A……..100,000 IU Vitamin D3……..80,000 IU Vitamin E……40mg
	Diary No. Date of R& I & fee	Dy.No 22618 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 646015370135)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and apck size**

	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation**		
189.	Name and address of manufacturer / Applicant	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Is-Ade Plus Injection
	Composition	Each ml contains:- Vitamin A…….100,000 IU Vitamin D3…….80,000 IU Vitamin E……..40mg
	Diary No. Date of R& I & fee	Dy.No 22619 dated 17-08-2021 Rs.30,000/- dated 08-07-2021 (slip No. 59220361316)
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation**		
190.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Meparas Injection
	Composition	Each ml contains:- **Mepyramine Maleate……**….50mg
	Diary No. Date of R& I & fee	Dy.No 21972 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 8549203524)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications

	Pack size & Demanded Price	50ml; N/A
	Me-too status	Meprax Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 112258)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. • **Target species:** i. Cattle and horses ii. Sheep **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
191.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Dermaras-25 Injection
	Composition	Each ml contains:- Pheniramine Maleate……25mg
	Diary No. Date of R& I & fee	Dy.No 21973 dated 11-08-2021 Rs.30,000/- dated 10-08-2021 (slip No. 3780931269)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	Ann-Vil Injection (50ml) of M/s Venus Pharma, Lahaore (Reg. No.035158)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) (Veterinary)** section confirmed vide letter No. F. 1-46/2010-Lic (Vol-I) dated 27-05-2021. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
192.	Name and address of manufacturer / Applicant	M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura
	Brand Name +Dosage Form + Strength	Feverceena Oral Solution
	Composition	Each ml contains:- Meloxicam……..…7.50mg

		Paracetamol…….…10mg
	Diary No. Date of R& I & fee	Dy.No 24546 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 869217749)
	Pharmacological Group	Antirheumatic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	120ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation**		
193.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Super Cool Water Soluble Powder
	Composition	Each gram contains:- **Vitamin C**…….200mg **Acetyl Salicylic Acid……..**…67mg Calcium Carbonate……..….50mg Sodium Chloride…….…….40mg Magnesium Sulphate…..…..…40mg Sodium Citrate……0.7mg
	Diary No. Date of R& I & fee	Dy.No 27300 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 8424971818)
	Pharmacological Group	Antipyretic, Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Coolant Powder of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 081721)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
194.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Para-Electro C Water Soluble Powder
	Composition	Each gram contains:- **Paracetamol**……..…..……200mg Vitamin C……..50mg Potassium Carbonate…….…125mg Sodium Bicarbonate……125mg Vitamin E…12.5mg
	Diary No. Date of R& I & fee	Dy.No 27298 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 87676242855)
	Pharmacological Group	Antipyretic, Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Peravit ST-20 Powder of M/s Vetec Laboratories, Rawalpindi. (Reg. No. 097973)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
195.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Electro-C Water Soluble Powder
	Composition	Each gram contains:- **Paracetamol**…….20mg Ascorbic Acid…..……200mg Calcium Carbonate……45mg Magnesium Sulphate….35mg Potassium Chloride……40mg
	Diary No. Date of R& I & fee	Dy.No 27297 dated 04-10-2021 Rs.30,000/- dated 24-09-2021 (slip No. 40561715804)
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
196.	Name and address of manufacturer / Applicant	M/s. Epoch Pharmaceuticals, Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ketolin Injection Vet I/M, S/C
	Composition	Each ml injection contains:- Oxytetracycline as HCl…….200mg **Ketoprofen**……..…30mg

	Diary No. Date of R& I & fee	Dy.No.3474 dated 22-01-2019; Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti- infective/ NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml, 100ml & Decontrolled
	Me-too status	Keto- Oxy La Injection M/s International Pharma Labs, Defence Road, Lahore 094412
	GMP status	Last GMP inspection was conducted on 28-09-2020 And the report concludes: "In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board.
	Remarks of the Evaluator	• GMP status is not compliant.
	Decision of 297th meeting: Deferred for updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status	
	Updated status: The firm has submitted cGMP certificate dated 20-12-2022 based on inspection conducted on 21-11-2022	
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
197.	Name and address of manufacturer / Applicant	M/s. Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	P.Entadine 10 Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl**…….100mg
	Diary No. Date of R& I & fee	Dy.No 14660 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 1252961726)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Amancin-10 Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi (Reg. No. 112234)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Registration Board deferred the case for further deliberation and directed PE&R Division to present working paper on international regulatory status of "Amantadine Drug for Veterinary use", in upcoming Board meeting.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
198.	Name and address of manufacturer / Applicant	M/s. Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	P.Entadine 98 Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl**……980mg
	Diary No. Date of R& I & fee	Dy.No 14654 dated 12-06-2023 Rs.30,000/- dated 07-06-2023 (slip No. 581489383)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator [x]	
	Decision: Registration Board deferred the case for further deliberation and directed PE&R Division to present working paper on international regulatory status of "Amantadine Drug for Veterinary use", in upcoming Board meeting.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
199.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Thipesing Injection
	Composition	Each ml contains:- Thiamphenicol…….200mg Tylosin……57.5mg Prednisolone Acetate……..5mg
	Diary No. Date of R& I & fee	Dy.No 34072 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No. 81671906212
	Pharmacological Group	Antibiotic; steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	TRIOX-P INJECTION Reg. No. 069638 M/s S.J & G FAZUL ELLAHIE (PVT) LIMITED, KARACHI (20ML, 50ML, 100ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	•
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
200.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Laphenra-35 Injection

	Composition	Each ml contains:- Prednisolone Acetate…….25mg Chlorpheniramine Maleate….10mg
	Diary No. Date of R& I & fee	Dy.No 34071 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.0973612285
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Reg. No.057084 Predmine Injection M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore (5ML,10ML,20ML)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	• As the applied formulation also includes Prednisolone, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
201.	Name and address of manufacturer / Applicant	M/s. Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Liquid Injectable (Steroid) Veterinary Section
	Brand Name +Dosage Form + Strength	Laphenra-14 Injection
	Composition	Each ml contains:- Prednisolone Acetate…….….10mg Chlorpheniramine Maleate……4mg
	Diary No. Date of R& I & fee	Dy.No 34070 dated 30-12-2021; Rs.30,000/- vide Deposit Slip No.697809101378
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished Product Specification	Innovators' Specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Reg No.049642 Solomin Injection Selmore Pharmaceuticals (Pvt) Ltd., Lahore (10ml, 20ml, 50ml, 100ml)
	GMP status	GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection.
	Remarks of the Evaluator[xxiii].	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
202.	Name and address of manufacturer / Applicant	M/s. Poulvet Pharmaceuticals (Pvt) Ltd, 0.5 Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan (DML No.000970) Oral Liquid/Drench (General) Veterinary Section
	Brand Name +Dosage Form + Strength	POUL CIN T ORAL LIQUID
	Composition	Each ml contains:- Enrofloxacin……..….75mg Sulphamethoxypyridazine…….75mg Sulphamethazine…….50mg Trimethoprim…….…..25mg
	Diary No. Date of R& I & fee	Dy.No 14692 dated 12-06-2023; Rs.30,000/- vide Deposit Slip No.01430015294
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	100ml,250ml,450ml,500ml,1000ml,5000ml; Decontrolled
	Me-too status	Ensufic Liquid Reg No. 088140 M/S. Biorific Pharma, Islamabad
	GMP status	Not applicable
	Remarks of the Evaluator[xxiii].	• As the applied formulation is a combination of four antibiotics, the application may be referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.
	Decision: Deferred for review of EWG on veterinary drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
203.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Doxy Plus Powder
	Composition	Each 1000gm contains:- **Tylosin Tartrate……..……..**…100gm **Doxycycline HCl**…….……..200gm Bromhexine HCl……5gm **Colistin Sulphate……..…..**…450 MIU **Streptomycin Sulphate**……...36gm
	Diary No. Date of R& I & fee	Dy.No 24870 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antibacterial, Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Could not be confirmed in the applied strength and combination
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.

	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Colistin Sulphate from MIU to grams.
	Decision of 326th meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Colistin Sulphate from MIU to grams	
	Updated status: The firm has now provided the following. ➢ **Metoo status:** Pulmodox-S Powder of M/s Attabak Pharmaceutical Islamabad. (Reg. No. 071069) ➢ Conversion of Colistin Sulphate (1mg of Colistin Sulphate = 19000IU) Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Referred to Sub-Committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
204.	Name and address of manufacturer / Applicant	M/s. Poulvet Pharmaceuticals Pvt Ltd. 0.5-Km, West Canal, 25-Km, Pull Rango, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Paramol CE Oral Powder
	mposition	Each gram contains:- **Paracetamol**……..200mg Vitamin C……50mg Potassium Carbonate…….125mg Sodium Bicarbonate……..125mg Vitamin E……...125mg
	Diary No. Date of R& I & fee	Dy.No 14649 dated 12-06-2023 Rs.30,000/- dated 05-06-2023 (slip No. 737034728)
	Pharmacological Group	Analgesic, Antipyretic with Vitamin C, E & Electrolytes
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Para CE Oral Powder of M/s Biogen Pharma, Rawat. (Reg. No.063812)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to Sub-committee on Veterinary Drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

Case No. 10: Deferred case of (M-331)

205.	Name and address of manufacturer / Applicant	M/s. Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketosan-10 Injection
	Composition	Each ml contains:- **Ketoprofen……**…100mg
	Diary No. Date of R& I & fee	Dy.No 4642 dated 18-02-2022 Rs.30,000/- dated 15-02-2022 (slip No. 225878235554)
	Pharmacological Group	Analgesic, Antipyretic and NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketorise Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113397)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: **Latest GMP inspection report conducted within a period of last three years.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**		
206.	Name and address of manufacturer / Applicant	M/s. Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketosan-10 Injection
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 4643 dated 18-02-2022 Rs.30,000/- dated 15-02-2022 (slip No. 1711292825)
	Pharmacological Group	Analgesic, Antipyretic and NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketorise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113398)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: **Latest GMP inspection report conducted within a period of last three years.**	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use		
207.	Name and address of manufacturer / Applicant	M/s. Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vetpro 100 Injection
	Composition	Each ml contains:- **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 5088 dated 23-02-2022 Rs.30,000/- dated 14-02-2022 (slip No. 5098129909)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Catoprofen Injection (20ml) of M/s Hilton Pharma (Pvt) Ltd., Korangi, Karachi. (Reg. No.101472)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
208.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Penzicol-N Premix Powder
	Composition	Each gram contains:- **Procaine Penicillin**……..12mg **Streptomycin Sulphate**……..36mg **Zinc Bacitracin 10%.....**…52mg **Neomycin Sulphate**……10mg
	Diary No. Date of R& I & fee	Dy.No 1845 dated 20-01-2022 Rs.30,000/- dated 11-01-2022 (slip No.7225641827)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 10000gm: Decontrolled
	Me-too status	PSB-Excel Powder of M/s Nawan Labs Karachi (Reg. No.082489)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Powder (Penicillin) Veterinary section** confirmed vide letter No. F. 1-25/2015-Lic dated 29-08-2018. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for the following: • **Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following:** • **Latest GMP inspection report conducted within a period of last three years.**	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use		
209.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prednityl Injection
	Composition	Each ml contains:- Thiamphenicol……..….200mg Tylosin Tartrate.....57.5mg **Methyl Prednisolone as Prednisolone….**..5mg
	Diary No. Date of R& I & fee	Dy.No 3413 dated 04-02-2022 Rs.30,000/- dated 03-02-2022 (slip No.21728446146)
	Pharmacological Group	Antibacterial with corticosteroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied combination**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid injectable (steroid)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Approval of Liquid injectable (steroid) section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation**		
210.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ketox Injection
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 8911 dated 07-04-2022 Rs.30,000/- dated 06-04-2022 (slip No.7263589648)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection

		conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), **in the applied pack size,** alongwith registration number, brand name and name of firm. • Approval of **relevant manufacturing facility (LVP)**.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Choice of one pack size** • **Approval of relevant manufacturing facility (LVP).** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status), in the 450ml and 500ml pack sizes, alongwith registration number, brand name and name of firm.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
211.	Name and address of manufacturer / Applicant	M/s. Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Vitamune Oral Powder
	Composition	Each gram contains:- Lysozyme HCl……220mg Vitamin E……...5mg
	Diary No. Date of R& I & fee	Dy.No 18315 dated 23-06-2022 Rs.30,000/- dated 23-06-2022 (slip No.27374805364)
	Pharmacological Group	Anti-infective, vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5000gm, 20000gm: Decontrolled
	Me-too status	Milizym E Oral Powder of M/s Mili Vet Pharmaceuticals (Pvt) Ltd District Lahore. (Reg. No. 112206)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
212.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan

	Brand Name +Dosage Form + Strength	Predicam Sterile Suspension for Injection 50ml
	Composition	Each ml contains:- Isoflupredone Acetate…….2mg
	Diary No. Date of R& I & fee	Dy.No 13711 dated 07-06-2022 Rs.30,000/- dated 07-06-2022 (slip No. 98364771214)
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Isopred Suspension (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceutical Karachi. (Reg. No. 063701)
	GMP status	
	Remarks of the Evaluator [X]	The official monograph of the applied product **does not exist in available editions of USP** **Shortcomings:** • Approval of **Liquid injection (steroid) section** from CLB. • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Approval of Liquid injection (steroid) section from CLB** • **Latest GMP inspection report conducted within a period of last three years**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
213.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Sulpha-T 96 Liquid
	Composition	Each ml contains:- **Enrofloxacin**……..75mg **Sulphamethoxypyridazine**…..……50mg **Sulphamethazine**……50mg **Trimethoprim**……..…25mg
	Diary No. Date of R& I & fee	Dy.No 6118 dated 07-03-2022 Rs.30,000/- dated 24-01-2022 (slip No. 4198832567)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml, 100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and latest GMP inspection report conducted within the period of last three years.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
214.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	AR Vital C Powder
	Composition	Each gram contains:- **Vitamin C**…….200mg **Acetyl Salisylic Acid**……..67mg
	Diary No. Date of R& I & fee	Dy.No 5682 dated 01-03-2022 Rs.30,000/- dated 07-01-2022 (slip No. 6417212719)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1000gm, 2500gm, 5000gm; Decontrolled
	Me-too status	Hyper-C Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 081732)
	GMP status	
	Remarks of the Evaluator [X]	**Powder (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
215.	Name and address of manufacturer / Applicant	M/s. Mallard Pharmaceuticals Pvt Ltd, 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	AR Amanta-98 Powder
	Composition	Each gram contains:- **Amantadine HCl**……..980mg
	Diary No. Date of R& I & fee	Dy.No 13716 dated 07-06-2022 Rs.30,000/- dated 07-06-2022 (slip No. 2234219103)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm; Decontrolled
	Me-too status	Ranio Dine 98% Water Soluble Powder of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 113492)
	GMP status	
	Remarks of the Evaluator [X]	**Powder (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

216.	Name and address of manufacturer / Applicant	M/s. Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Grand Detox Water Soluble Powder
	Composition	Each gram contains:- Furosemide……20mg **Belladonna Extract**……...2mg
	Diary No. Date of R& I & fee	Dy.No 8047 dated 25-03-2022 Rs.30,000/- dated 18-03-2022 (slip No. 1635239757)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	5gm, 10gm, 50gm, 100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Diu-Rapid Water Soluble Powder of M/s Biogen Pharma, Rawat (Reg. No. 057034)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral Powder section (General) Veterinary** confirmed vide letter No. 1-36/2006-Lic (Vol-I) dated 26-09-2019.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
217.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Anti Protoza Injection
	Composition	Each ml contains:- Diminazine Aceturate……..…50mg **Antipyrine**……350mg
	Diary No. Date of R& I & fee	Dy.No 17726 dated 17-06-2022 Rs.30,000/- dated 16-06-2022 (slip No. 474030284960)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Pri-Protocid Plus Injection (50ml) of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 080759)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

218.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketoxay LA Injection
	Composition	Each ml contains:- Oxytetractycline as HCl……..mg **Ketoprofen**……..30mg
	Diary No. Date of R& I & fee	Dy.No 17848 dated 20-06-2022 Rs.30,000/- dated 09-06-2022 (5592698150)
	Pharmacological Group	Antibiotic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 24-09-2021 based on inspection conducted on 02-07-2021.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General) section** confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
219.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Industries, 542-A, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Dicotyl Injection 100ml
	Composition	Each ml contains:- Tylosin Tartrate……..…50mg **Dimetridazole** ……100mg Colistin Sulphate……...10mg
	Diary No. Date of R& I & fee	Dy.No 17850 dated 20-06-2022 Rs.30,000/- dated 09-06-2022 (slip No. 1290915784)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Mettycoli Injection (100ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No.080728)
	GMP status	cGMP certificate dated 24-09-2021 based on inspection conducted on 02-07-2021.
	Remarks of the Evaluator [X]	• **Veterinary Liquid Injection (General) section** confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014. • **Target species:** Pheasants, partridges, turkeys, cattle and sheep • Firm has submitted fee Rs.30000/- for correction in formulation (salt form) vide challan No. 1290915784.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		

220.	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ketonol Injection
	Composition	Each ml contains:- **Ketoprofen**……100mg
	Diary No. Date of R& I & fee	Dy.No 18192 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 99613018)
	Pharmacological Group	Analgesic, anti-inflammatory agent
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Approval of relevant manufacturing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
221.	Name and address of manufacturer / Applicant	M/s. Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Ketonol Injection
	Composition	Each ml contains:- **Ketoprofen**…….100mg
	Diary No. Date of R& I & fee	Dy.No 18193 dated 22-06-2022 Rs.30,000/- dated 22-06-2022 (slip No. 96071888)
	Pharmacological Group	Analgesic, anti-inflammatory agent
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Ketoject Injection (10ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **relevant manufacturing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Approval of relevant manufacturing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use		
222.	Name and address of manufacturer / Applicant	M/s. Symans Pharmaceuticals (Private) Limited, 10km Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	Ketosym Injection
	Composition	Each ml contains:- **Ketoprofen**…….100mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 987 dated 28-04-2017 Rs.20,000/- dated 28-04-2017
	Pharmacological Group	**Anti haematozoan**
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	De-Trox 340 Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113397)
	GMP status	Panel inspection report for renewal of DML dated 28-10-2019 and 02-10-2020 recommends renewal of DML
	Remarks of the Evaluator [x]	• **Liquid Injectable section vial Veterinary (General)** confirmed vide panel inspection report for renewal of DML dated 28-10-2019 and 02-10-2020
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Fee Rs. 7500/- for change of finished product specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
223.	Name and address of manufacturer / Applicant	M/s. Symans Pharmaceuticals (Private) Limited, 10km Sheikhupura Road, Lahore.
	Brand Name +Dosage Form + Strength	SPZ-Plus Oral
	Composition	Each 100gm contains:- **Procaine Penicillin** ……1200mg **Streptomycine Sulphate**……3600mg **Zinc Bacitracin……...**…5200mg **Colistin Sulphate** …….…….500MIU
	Diary No. Date of R& I & fee	Dy. No nil dated 16-08-2010 Rs.8,000/- dated 16-08-2010 & Rs. 12000/- dated 11-03-2013
	Pharmacological Group	Antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	-
	Remarks of the Evaluator	
	Decision of 249th meeting of RB: Registration Board deferred for confirmation of manufacturing facility for penicillin products.	
	Updated status: Firm has now submitted the following: • Letter No. F. 1-25/91-Lic (Vol-III) **dated 30-11-2020** confirming approval of **Oral Dry Powder (Penicillin) section (Veterinary)**	

	• The firm has revised formulation as per following label claim: **Each gram contains:** **Procaine Penicillin** …**12mg** **Streptomycine Sulphate……36mg** **Zinc Bacitracin…52mg** **Colistin Sulphate ……0.06MIU** **Metoo status:** Pro PSZ Powder of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 103888)	
	Remarks of the Evaluator [x]:	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters, and for submission of the following: • **Fee Rs. 30,000/- for revision of formulation prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use.**		
224.	Name and address of manufacturer / Applicant	M/s. Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Parasol-Ce Oral Powder
	Composition	Each 100gm contains:- **Paracetamol……..**…20gm Vitamin C……..……..…5gm Potassium Carbonate…….12.5gm Sodium Bicarbonate……..…12.5gm Vitamin E…1.25gm
	Diary No. Date of R& I & fee	Dy.No 23855 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Antipyretic, Vitamin and Mineral supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5Kg: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings:** Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 326th meeting of RB: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: Firm has now revised the formulation as per following label claim: Each gram contains: **Paracetamol**…200mg Vitamin C…50g Potassium Carbonate…125mg Sodium Bicarbonate…125mg Vitamin E…125mg	

	Me-too status: Parold C Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109123) The firm has submitted Rs. 30,000/- dated 07-09-2023 for revision of formulation vide challan No. 78587344.	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
225.	Name and address of manufacturer / Applicant	M/s. M.A.Kamil Farma Pvt. Ltd., Plot No. H-17, S.I.T.E, Super Highway,Phase II, Karachi.
	Brand Name +Dosage Form + Strength	Lyzomox-G Water Soluble Powder
	Composition	Each gram contains:- Amoxicillin as Trihydrate……500mg **Lysozyme HCl**……100mg Guaifenesin……..…350mg
	Diary No. Date of R& I & fee	Dy.No 19853 dated 10-08-2023 Rs.30,000/- dated 04-08-2023 (slip No. 49086353)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm,25000gm: Decontrolled
	Me-too status	Lyzomox Water Soluble Powder of M/s Decent Pharma, Islamabad. (Reg. No. 079842)
	GMP status	New DML
	Remarks of the Evaluator [x]	Firm has revised formulation as per following label claim along with submission of fee of Rs. 30,000/- for correction in label claim in line with reference product vide challan No. 55260246791 **Each gram contains:** **Amoxicillin as Trihydrate…50mg** **Lysozyme HCl…10mg** **Guaifenesin…35mg**
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
226.	Name and address of manufacturer / Applicant	M/s. Suave Pharmaceuticals Pvt. Ltd. Plot No. 2-C, Value Addition City, Khurianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Hi-Pro Powder
	Composition	Each gram contains:- **Procaine Penicillin**…….12mg **Streptomycin Sulphate**…….36mg **Zinc Bacitracin……..**….52mg **Colistin Sulphate**……...60,000 IU
	Diary No. Date of R& I & fee	Dy.No 21338 dated 29-08-2023 Rs.30,000/- dated 28-08-2023 (slip No. 2043155249)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 10000gm, 25000gm ; Decontrolled

	Me-too status	C-ZPS 100/60 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113454)
	GMP status	**New DML**
	Remarks of the Evaluator [X]	**Oral Powder (Penicillin)-Veterinary** section granted vide letter No. F.1-9/2018 dated 10-11-2022
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
227.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ketozon Injection
	Composition	Each ml contains:- **Ketoprofen** …… 100mg
	Diary No. Date of R& I & fee	Dy. No. 23386 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 1721722586)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Ketoject Injection (10ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
228.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ketozon Injection
	Composition	Each ml contains:- **Ketoprofen** …… 100mg
	Diary No. Date of R& I & fee	Dy. No. 23387 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 4078198612)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	20ml, Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
229.	Name and address of manufacturer / Applicant	M/s Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ketozon Injection

	Composition	Each ml contains:- **Ketoprofen** ……. 100mg
	Diary No. Date of R& I & fee	Dy. No. 23388 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 81146079242)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Ketoject Injection (50ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
230.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Ketozon Injection
	Composition	Each ml contains:- **Ketoprofen** …… 100mg
	Diary No. Date of R& I & fee	Dy. No. 23389 dated 20-09-2023 Rs.30,000/- dated 19-09-2023 (Slip No. 783772489377)
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specification
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Ketoject Injection (100ml) of M/s. Selmore Pharmaceuticals (Reg. No. 043141)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
231.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Floxizon 50% Dry Powder Injection
	Composition	Each vail contains:- Flucloxacillin (as sodium)…… 500mg
	Diary No. Date of R& I & fee	Dy. No. 23165 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 49486076755)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	1x1's, Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:**

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation.**		
232.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Floxizon 25% Dry Powder Injection
	Composition	Each vail contains:- Flucloxacillin (as sodium) … 250mg
	Diary No. Date of R& I & fee	Dy. No. 23164 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 83473318)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	1x1's, Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic/RRA approval.**		
233.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Poly-Cid 1000 Water Soluble Powder
	Composition	Each gram contains: **Procaine Penicillin** …….. 12mg **Streptomycin Sulphate** …..…. 36mg **Colistin Sulphate** ……. 0.060MIU **Zinc Bacitracin** ……... 52mg
	Diary No. Date of R& I & fee	Dy. No. 23228 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 76328844)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, 25000gm; Decontrolled
	Me-too status	Zeptocol of M/s. Selmore Pharma (Reg. No. 080962)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Conversion of Colistin Sulphate from MIU to grams.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
234.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Poly-Cid 2000 Water Soluble Powder
	Composition	Each gram contains:- **Procaine Penicillin** ……. 16mg **Streptomycin Sulphate** …….. 40mg **Colistin Sulphate** ……. 0.080MIU **Zinc Bacitracin 10%**……. 100mg
	Diary No. Date of R& I & fee	Dy. No. 23229 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No.558174721890)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, 25000gm; Decontrolled
	Me-too status	Colibac- SP 160 Powder of M/s. Nawan Laboratories (Reg. No.082488)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Conversion of Colistin Sulphate from MIU to grams.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
235.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Spect Water Soluble Powder
	Composition	Each gram contains:- Amoxicillin as Trihydrate …….... 20mg Lincomycin HCl …….…... 8.8mg Spectinomycin dihydrochloride …….8.8mg
	Diary No. Date of R& I & fee	Dy. No. 23225 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 655313221065)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, 25000gm; Decontrolled
	Me-too status	Licosac-200 Oral Water-Soluble Powder of M/S. Sanna Laboratories (Reg. No. 081696)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Referred to sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
236.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Liso-Best Water Soluble Powder
	Composition	Each gram contains:- Amoxicillin as Trihydrate …….. 50mg Lysozyme HCl ……..…….. 10mg Guaifenesin ……..….. 35mg
	Diary No. Date of R& I & fee	Dy. No. 23214 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 53086969904)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, 25000gm; Decontrolled
	Me-too status	Lyzomox of M/s. Decent Pharma (Reg. No. 079842)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
237.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Liso-Best Water Soluble Powder
	Composition	Each gram contains:- Amoxicillin as Trihydrate …….. 50mg Lysozyme HCl ……..... 10mg Guaifenesin ……. 35mg
	Diary No. Date of R& I & fee	Dy. No. 23214 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 53086969904)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, 25000gm; Decontrolled
	Me-too status	Lyzomox of M/s. Decent Pharma (Reg. No. 079842)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
	Case No. 11: Deferred case of (M-333)	
238.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Amantazon 10% Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl .....** 100mg

	Diary No. Date of R& I & fee	Dy. No. 23332 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 4416505712)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Metadine Powder of Farm Aid Group (Reg. No. 088040)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
239.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Amantazon 98% Water Soluble Powder
	Composition	Each gram contains:- **Amantadine HCl .....** 980mg
	Diary No. Date of R& I & fee	Dy. No. 23333 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 144667034)
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded	20gm, 100gm, 500gm, 1000gm, 5000gm, and 25000gm; Decontrolled
	Me-too status	Vety Amantex 98% Oral Powder of M/s. Leads Pharma (Reg. No. 094402)
	GMP status	New DML
	Remarks of the Evaluator	**Target species:** Calves, goat, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
	Case No. 12: Deferred case of (M-334)	
240.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxyket L.A Injection
	Composition	Each ml contains:- Oxytetracycline as HCl…..…200mg **Ketoprofen**……..30mg
	Diary No. Date of R& I & fee	Dy.No 20537 dated 20-07-2022 Rs.30,000/- dated 18-07-2022 (slip No. 76930089)
	Pharmacological Group	Antibiotic/NSAID

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • **Target species:** Honeybees, livestock, cattle, poultry, fish
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
241.	Name and address of manufacturer / Applicant	M/s. SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Fen Injection 100ml
	Composition	Each ml contains:- **Ketoprofen**……..100mg
	Diary No. Date of R& I & fee	Dy.No 19925 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 3428744475)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Dogs, cats, horses, small animals, other large animals, birds, exotic animals **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.**	

	• **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
242.	Name and address of manufacturer / Applicant	M/s. SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad. **Manufacturer:** M/s Bio-Labs Pvt. Ltd., Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Fen Injection
	Composition	Each ml contains:- **Ketoprofen……**…100mg
	Diary No. Date of R& I & fee	Dy.No 19924 dated 07-07-2022 Rs.75,000/- dated 22-06-2022 (slip No. 61279267300)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	**M/s Bio-Labs:** cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021 **M/s SB pharma:** GMP inspection report dated 26-09-2019 & 07-10-2019 concludes acceptable level of cGMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Target species:** Dogs, cats, horses, small animals, other large animals, birds, exotic animals **Shortcomings:** • Address of the applicant mentioned on DML is Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad while that on form-5 is 48-C, Satellite Town, Chandani Chowk, Rawalpindi, clarify.
	Decision: Deferred for following: • **Review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Clarification regarding address of the applicant** • **DML status of the applicant from Licensing Division, DRAP** •	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
243.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection
	Composition	Each ml contains:- **Ketoprofen**…….100mg

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

	Diary No. Date of R& I & fee	Dy.No 19943 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 97238058)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.043141)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, dairy bulls
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
246.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butafar Injection
	Composition	Each ml contains:- **Phenylbutazone** ……..200mg
	Diary No. Date of R& I & fee	Dy.No 19934 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 9352701106)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Vutazon SS Injectable Solution (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 048280)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horses and ponies
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
247.	Name and address of manufacturer / Applicant	M/s. Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butafar Injection
	Composition	Each ml contains:- **Phenylbutazone** ……200mg
	Diary No. Date of R& I & fee	Dy.No 19935 dated 07-07-2022 Rs.30,000/- dated 06-07-2022 (slip No. 50316143217)

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Vutazon SS Injectable Solution (10ml, 25ml, 50ml, 100ml, 500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 048280)
	GMP status	GMP inspection report dated 29-07-2022 concludes that the firm was GMP compliant on the day of inspection.
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horses and ponies
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
248.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fluoron Injection
	Composition	Each 100ml contains:- **9 Alpha Fluoro Prednisolone**…..…… 0.2gm
	Diary No. Date of R& I & fee	Dy. No. 23257 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 57804401724)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Abicorten Injectable solution (50ml) of M/s Prix Pharma (Reg. No. 020756)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
249.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Fluoron Injection
	Composition	Each ml contains:- **9 Alpha Fluoro Prednisolone** …… 0.2gm
	Diary No. Date of R& I & fee	Dy. No. 23256 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 12645908129)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	I-Alpha Pre-Injection (10ml) of M/s International Pharma Labs (Reg. No. 099032)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:**

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

252.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Dexazon 1 Injection
	Composition	Each ml contains:- **Dexamethasone (as sodium phosphate)** … 1mg
	Diary No. Date of R& I & fee	Dy. No. 23237 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 6831285510)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Dexamethasone 1mg/ml Injection (50ml) of M/s. Venus Pharma (Reg. No. 031511)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
253.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Dexazon 2 Injection
	Composition	Each ml contains:- **Dexamethasone (as sodium phosphate)** … 2mg
	Diary No. Date of R& I & fee	Dy. No. 23238 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 162276861)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Dexamethasone Injection (50ml) of M/s. Elko Organization Karachi (Reg. No. 017071)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
254.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Injection
	Composition	Each ml contains:- **Prednisolone Acetate**……..... 5 mg Tylosin Tartrate .....100mg Oxytetracycline HCl …..... 50mg
	Diary No. Date of R& I & fee	Dy. No. 23247 dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 44785727989)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5

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

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
257.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Forte Injection
	Composition	Each ml contains:- **Prednisolone Acetate** …..... 7.50mg Tylosin Tartrate .....100mg Oxytetracycline HCl..... 50gm
	Diary No. Date of R& I & fee	Dy. No. 23250 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 39998905948)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Tylox-P Injection of M/s. Breeze Pharma (Reg. No. 063789)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
258.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Tyzon-P Forte Injection
	Composition	Each ml contains:- **Prednisolone Acetate** …..... 7.50mg Tylosin Tartrate .....100mg Oxytetracycline HCl.....50gm
	Diary No. Date of R& I & fee	Dy. No. 23251 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 695964687182)
	Pharmacological Group	Steroid/ Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Tylox-P Injection of M/s. Breeze Pharma (Reg. No. 063789)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Horse, cattle, sheep, goat, dog, cat
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
259.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.

	Brand Name +Dosage Form + Strength	Predmin Injection
	Composition	Each ml contains:- **Prednisolone** ……..…… 10mg Chlorpheniramine Maleate …….. 4mg
	Diary No. Date of R& I & fee	Dy. No. 23241 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 868560927301)
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Solomin Injection of M/s. Selmore Pharmaceuticals (Reg. No. 049642)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
260.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predmin Injection
	Composition	Each ml contains:- **Prednisolone**…… 10mg Chlorpheniramine Maleate ……... 4mg
	Diary No. Date of R& I & fee	Dy. No. 23242 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 63785834)
	Pharmacological Group	Steroid, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Solomin Injection of M/s. Selmore Pharmaceuticals (Reg. No. 049642)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
261.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsone Injection
	Composition	Each ml contains:- **Prednisolone (as acetate)**…… 7.5mg **Dexamethasone (as sodium phosphate)** …... 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 23239 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 8069319710)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications

	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Penacort Injection Selmore Pharmaceuticals (Reg. No. 029665)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, horse, sheep, goat, calves, foals, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
262.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsone Injection
	Composition	Each ml contains:- **Prednisolone (as acetate)**……..…… 7.5mg **Dexamethasone (as sodium phosphate)** 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 23240 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 84054518230)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Penacort Injection Selmore Pharmaceuticals (Reg. No. 029665)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, horse, sheep, goat, calves, foals, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
263.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-25 Injection
	Composition	Each ml contains:- **Prednisolone acetate** ……..…… 25mg
	Diary No. Date of R& I & fee	Dy. No. 23233 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 61942942187)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Predison Injection 2.5% of M/s. Manhattan Pharma (Reg. No. 035091)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

264.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-25 Injection
	Composition	Each ml contains:- **Prednisolone acetate** …… 25mg
	Diary No. Date of R& I & fee	Dy. No. 23234 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 7233 161)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Predison Injection 2.5% of M/s. Manhattan Pharma (Reg. No. 035091)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
265.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-10 Injection
	Composition	Each ml contains:- **Prednisolone Acetate** …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 23235 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 1602696860)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	GP-Pred Injection (10ml) of M/s. Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111541)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
266.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Predsol-10 Injection
	Composition	Each ml contains:- **Prednisolone Acetate** …… 10mg
	Diary No. Date of R& I & fee	Dy. No. 23236 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 97933535087)
	Pharmacological Group	Steroid

	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Premsone 10 Injection (50ml) of M/s. Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111333)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
267.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection
	Composition	Each ml contains:- Tylosin Tartrate ……..…….. 150mg Gentamycin Sulphate …….…….…. 60mg **Dexamethasone as Sodium Phosphate** …. 0.265mg Chlorpheniramine (Maleate) … 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23244 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 52975174803)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	10ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
268.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection
	Composition	Each ml contains:- Tylosin Tartrate …….……. 150mg Gentamycin Sulphate …….…….…. 60mg **Dexamethasone as Sodium Phosphate** … 0.265mg Chlorpheniramine (Maleate)…… 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23245 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 30105372808)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)

	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
269.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Genta Combizon Injection 100ml
	Composition	Each ml contains:- Tylosin Tartrate …….……. 150mg Gentamycin Sulphate …….……. 60mg **Dexamethasone as Sodium Phosphate** … 0.265mg Chlorpheniramine (Maleate) … 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 23246 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 6391273819)
	Pharmacological Group	Steroid, Antibiotic, Anti-Histamine
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, Decontrolled
	Me-too status	Genta Combisone Injection of M/s. Leads Pharma (Reg. No. 046696)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
270.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Biodex Injection
	Composition	Each ml contains:- Benzyl Penicillin Procaine ……..… ….125,000IU Benzathine Penicillin G……..……. 125,000IU Dihydrostreptomycin Sulphate …….…….. 0.25g **Dexamethasone Sodium Phosphate …. 0.20mg** **Dexamethasone-21-Isonicotinate**…..**… 0.20mg**
	Diary No. Date of R& I & fee	Dy. No. 23243 Dated 20-09-2023 Rs.30,000/- Dated 19-09-2023 (Slip No. 9946428151)
	Pharmacological Group	Penicillin Antibacterial/ Steroid
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, Decontrolled
	Me-too status	BDEX Liquid Injection of M/s. Selmore Pharmaceuticals (Reg. No. 080952)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Cattle, sheep
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
271.	Name and address of manufacturer / Applicant	M/s. Amazon Pharmaceuticals (Pvt.) Ltd. Plot No. 10/A & 29/B, Small Industrial Estate, Bhimber, AJK.
	Brand Name +Dosage Form + Strength	Parazon WSP
	Composition	Each gram contains:- **Paracetamol** ……..… 200mg Vitamin C ……50mg Potassium Carbonate …… 125mg Sodium Bicarbonate … …….125mg Vitamin E ……..… 125mg
	Diary No. Date of R& I & fee	Dy. No. 23306 Dated 20-09-2023 Rs. 30,000/- Dated 19-09-2023 (Slip No. 794705221568)
	Pharmacological Group	Analgesic, Antipyretic, Antioxidant, Electrolyte, Vitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm, 5000gm, & 25000gm; Decontrolled
	Me-too status	Parascorbic Powder of Baariq Pharmaceuticals (Reg. No. 087140)
	GMP status	New DML
	Remarks of the Evaluator [X]	**Target species:** Calves, goats, sheep, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
272.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Labs (Pvt) Ltd., 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Acemore 2.5% Injection
	Composition	Each ml contains:- **Aceclofenac……**…25mg
	Diary No. Date of R& I & fee	Dy. No. 27420 dated 22-11-2023 Rs 30,000/- dated 16-11-2023 (Slip No. 475994345360)
	Pharmacological Group	Anti-pyretic/ Analgesic/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	I-Acefenac Injection (50ml) of M/s International Pharma Labs. Lahore. (Reg. No. 094437)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Horse, camel, cattle, buffaloes, sheep, goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
273.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad

	Brand Name +Dosage Form + Strength	Prednimin Injection
	Composition	Each ml contains:- **Prednisolone Acetate**…….……10mg Chlorpheniramine Maleate……..…4mg
	Diary No. Date of R& I & fee	Dy.No 26527 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 10866719)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Not mentioned; Decontrolled
	Me-too status	
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, buffalo, horse, sheep, goat, dog, cat **Shortcomings:** • Clarification regarding applied formulation is required since **Prednisolone Acetate**…10mg/ml is mentioned in label claim on form-5 and throughout the dossier while **Prednisolone as Acetate**…10mg/ml is mentioned in master formula; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Demanded pack size
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Demanded pack size**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic/RRA status confirmation**		
274.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lepred Injection
	Composition	Each ml contains:- **Isoflupredon Acetate**…….2mg
	Diary No. Date of R& I & fee	Dy.No 26520 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No.72616960580)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Me-too status	Isopred Suspension Injection (**10ml, 25ml, 50ml, 100ml, 500ml**) of M/s Alina Combine Pharmaceutical Karachi. (Reg. No.063701)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, buffalo, horse, small animals **Shortcomings:**

		• Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier • Clarification regarding applied formulation is required since **Isoflupredon Acetate**…2mg/ml is mentioned in label claim on form-5 and throughout the dossier while **Isoflupredon** …2mg /ml is mentioned in master formula; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Clarification regarding applied formulation** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to keep under review the above formulation for veterinary use**		
275.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Solodex Injection Each ml contains:-
	Composition	Each ml contains: **Prednisolone Acetate……**…7.5mg **Dexamethasone**……2.5mg
	Diary No. Date of R& I & fee	Dy.No 26519 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 77863930)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Me-too status	Predexa Injection (**10ml, 20ml, 30ml**) of M/s Tarobina Corporation Lahore (Reg. No.020762)
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Target species:** Cattle, horse, sheep, goat, dogs, cats **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier • accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status**), in the same pack size/fill volume,** alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following:	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
276.	Name and address of manufacturer / Applicant	M/s. Leads Pharma Pvt Ltd., Plot No. 81, Street No. 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Lecogen Spray
	Composition	Each 60ml contains:- **Chloramphenicol**……7.5gm Cetrimide……..…1.5gm Dimethyl Phthalate……..…1.5gm Crystal Violet……..….0.75gm Isopropyl Alcohol……100ml Dimethyl Ether……100ml
	Diary No. Date of R& I & fee	Dy.No 26522 dated 03-11-2023 Rs 30,000/- dated 02-11-2023 (Slip No. 6147192385)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Additional section
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs decided to reject the above formulation for veterinary use.**		
	Case No. 13: Deferred case of (M-335)	
277.	Name and address of manufacturer / Applicant	M/s. Medpharm Research Lab, 28 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	AR Paramed C Oral Powder
	Composition	Each 100gram contains:- **Paracetamol**..... 20gm **Vitamin C**.....5gm Potassium Carbonate..... 12.5gm Sodium bicarbonate..... 12.5gm Vitamin E..... 12.5gm
	Tracking Id, date & fee	PPT-XZ2-7V28 dated 04-03-2024 Rs 30,000/- dated 28-02-2024 (Slip No. 18074311812)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded	500gm, 1000gm and 5000gm; Decontrolled
	Me-too status	Parold C Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109123)

	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Poultry **Shortcomings:** Firm shall submit Rs.7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
278.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl……..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	P6S-L4W-ZBWZ dated 26-02-2024 Rs 30,000/- dated 22-02-2024 (Slip No. 470625527)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketocin Injection of M/s A & K Pharmaceutical, Faisalabad. (Reg. No.102101)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
279.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl……..…..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	AA3-ZDD-L7QM dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 30271366088)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Oxyfen LA Injection of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore (Reg. No. 071091)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee:		

After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use		
280.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Ketostrep LA Injection
	Composition	Each ml contains:- Oxytetracycline as HCl……..200mg **Ketoprofen**.....30mg
	Tracking Id, date & fee	RH9-5JL-5NG3 dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 95106582745)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pro Cycline Injection of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111328)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
281.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APIPRED Injection
	Composition	Each 100ml contains:- **Prednisolone as Acetate**.....0.75gm **Dexamethasone as Sodium Phosphate**.....0.25gm
	Tracking Id, date & fee	XVB-PZL-4GY6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 75233469)
	Pharmacological Group	Adrenocortical steroid anti-inflammatory drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Prednicort-D Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Ltd., Karachi (Reg. No. 043115)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs, cats **Shortcomings:** State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **role of Creatinine mentioned in master formula.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
282.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.

	Brand Name +Dosage Form + Strength	APIPRED Injection
	Composition	Each 100ml contains: - **Prednisolone as Acetate**.....0.75gm **Dexamethasone as Sodium Phosphate**.....0.25gm
	Tracking Id, date & fee	DR8-LBM-E7P6 dated 28-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 617855393808)
	Pharmacological Group	Adrenocortical steroid anti-inflammatory drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Camocort Injection of M/s Lawrance Pharma (Pvt) Ltd., Lahore. (Reg. No. 043220)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, dogs, cats **Shortcomings:** State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **role of Creatinine mentioned in master formula.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
283.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-14 Injection
	Composition	Each ml contains: - **Prednisolone**.....10mg Chlorpheniramine Maleate.....4mg
	Tracking Id, date & fee	TSG-VLL-WMNG dated 27-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9029153240)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Chlorphen-P Injection of M/s Alina Combine Pharmaceutical (Pvt) Ltd. Karachi (Reg. No. 052354)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • Submit revised master formula since Creatinine is mentioned. • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Submission of revised master formula since Creatinine is mentioned.**	

	• **fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
284.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-14 Injection
	Composition	Each ml contains:- **Prednisolone**.....10mg Chlorpheniramine Maleate….....4mg
	Tracking Id, date & fee	ZYS-QSN-S76E dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 15931938196)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	PC Jet Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No. 106757)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • Submit revised master formula since Creatinine is mentioned. • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Submission of revised master formula since Creatinine is mentioned.** • **fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
285.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-40 Injection
	Composition	Each ml contains:- **Prednisolone Acetate**.....25mg Chlorpheniramine Maleate.....10mg
	Tracking Id, date & fee	ZR9-NS9-GRLX dated 27-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 295607848277)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Laphenra-35 Injection **(20ml)** of M/s International Pharma Labs. Lahore. (Reg. No. 099035)
	GMP status	New Section

	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Role of Creatinine mentioned in master formula.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
286.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Predphen-40 Injection
	Composition	Each ml contains: **Prednisolone Acetate**.....25mg Chlorpheniramine Maleate.....10mg
	Tracking Id, date & fee	Q9Y-3JN-Y389 dated 01-03-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9811226112)
	Pharmacological Group	Steroid and anti-histamine drug
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Chlorprem 35 Injection (10ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 113499)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, horse, sheep, goats, dogs, cats **Shortcomings:** • State role of Creatinine mentioned in master formula.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Role of Creatinine mentioned in master formula.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
287.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAPRED-10 Injection
	Composition	Each ml contains:- **Prednisolone Acetate**.....10mg
	Tracking Id, date & fee	PEJ-Z86-E9AD dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 2161644409)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Premsone 10 Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111333)
	GMP status	New Section

	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Rs. 7500/- for correction in finished product specifications before issuance of registration letter.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
288.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAPRED-10 Injection
	Composition	Each ml contains:- **Prednisolone Acetate**.....10mg
	Tracking Id, date & fee	W79-B9T-95XA dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 97330011971)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	GP-Pred Injection of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 111541)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** Official monograph of the applied formulation is **available in USP**. Firm shall submit Rs. 7500/- for correction in finished product specifications before issuance of registration letter.
	Decision: Deferred for following: • **review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Rs. 7500/- for correction in finished product specifications before issuance of registration letter.**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
289.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection
	Composition	Each ml contains: **Prednisolone**.....25mg
	Tracking Id, date & fee	QE2-4JD-PMP6 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8297734842)
	Pharmacological Group	Steroid
	Type of Form	Form 5

	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Pedison 25 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 114929)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
290.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection
	Composition	Each ml contains: - **Prednisolone**.....25mg
	Tracking Id, date & fee	1N2-UT3-JV55 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 93244892)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Pedison 25 Injection of M/s Farm Aid Group, Haripur. (Reg. No. 114928)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
291.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Aplapred-25 Injection
	Composition	Each ml contains:- **Prednisolone**.....25mg
	Tracking Id, date & fee	GTH-85T-TB2B dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 2924899807)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Prednisolone 2.5 Injectable Solution of M/s Orient Traders International, Karachi. (Reg. No. 020771)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, calves, dogs, cats **Shortcomings:** APLAPRED-25 Injection **10ml** is mentioned on fee challan.

	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
292.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-1 Injection
	Composition	Each ml contains:- **Dexamethasone as Sodium Phosphate**.....1mg
	Tracking Id, date & fee	B2J-8NX-P8UG dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8283006151)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Decaprem 1% Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111334)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
293.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-2 Injection
	Composition	Each ml contains:- **Dexamethasone Sodium Phosphate eq to Dexamethasone Phosphate** 2mg
	Tracking Id, date & fee	Z8E-D71-TM28 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 95279484075)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexacare Injection of M/s Vety Care Islamabad (Reg. No. 026528)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, horse, calves, sheep foals, goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
294.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Apthason-4 Injection

	Composition	Each ml contains: **Dexamethasone Sodium Phosphate eq to Dexamethasone base**……..4mg
	Tracking Id, date & fee	VJN-J5R-3EA1 dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 8424685840)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexamethasone Injection of M/s Amros Pharm Karachi (Reg. No. 020100)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Horse, sheep goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
295.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLA OTD Injection
	Composition	Each 100ml contains:- Oxytetracycline.....15gm Tripelenamine HCl.....1gm **Dexamethasone**.....0.050gm
	Tracking Id, date & fee	VYS-ZMZ-U2BP dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 486847959218)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	OXY-TD Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 029666)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Horse, cattle, sheep goats, dogs, cats
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
296.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	KENA-S Injection
	Composition	Each ml contains:- Kanamycin Sulphate.....50mg Colistin Sulphate.....100000 IU Neomycin Sulphate.....50mg **Dexamethasone 21 Phosphate Sodium Salt**.....0.5mg
	Tracking Id, date & fee	DRA-A2S-DN9Z dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 9136058509)

	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	K.C.N.D. Injection of M/s Tarobina Corp Lahore (Reg. No. 020065)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
297.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Typhendex-G Injection
	Composition	Each ml contains:- Thiamphenicol.....200mg Tylosin.....57.5mg **Prednisolone as Acetate**.....5mg
	Tracking Id, date & fee	8ZA-4EN-BNQD dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 764377478330)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Tylopen Injection of M/s Selmore Agencies (Pvt) Ltd., Lahore (Reg. No. 058815)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, calf, sheep, goats **Shortcomings:** Specify salt form of Tylosin
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and complete salt form of Tylosin.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
298.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Typhendex-G Injection
	Composition	Each ml contains:- Thiamphenicol.....200mg Tylosin.....57.5mg **Prednisolone as Acetate**.....5mg
	Tracking Id, date & fee	4ZA-VRV-J69N dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 855673114)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications

	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Tylopen Injection of M/s Selmore Agencies (Pvt) Ltd., Lahore (Reg. No. 058815)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Cattle, buffaloes, calf, sheep, goats **Shortcomings:** Specify salt form of Tylosin
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and complete salt form of Tylosin.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
299.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection
	Composition	Each 100ml contains:- Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	NX7-G19-DGBJ dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 92478096714)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Tylo-Combisone Injectable Solution of M/s Mustafa Brothers, Faisalabad (Reg. No. 053948)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
300.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection
	Composition	Each 100ml contains:- Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm

	Tracking Id, date & fee	6PV-J4N-EMNR dated 01-03-2024 Rs 30,000/- dated 27-02-2024 (Slip No. 071348776314)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	10ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
301.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection
	Composition	Each 100ml contains:- Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	7RR-5HD-ZAYU dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 8726864866)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

302.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydogen Injection
	Composition	Each 100ml contains:- Tylosin Tartrate.....15gm Gentamycin Sulphate.....6gm **Dexamethasone**.....0.0265gm Chlorpheniramine.....0.750gm
	Tracking Id, date & fee	ZU3-1UJ-WV4W dated 01-03-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 915778667524)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	250ml; Decontrolled
	Me-too status	Genta Combisone Injection of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046696)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry **Shortcomings:** • Tydogen **50ml** Injection is mentioned on fee challan. • Confirmation of **relevant manufacturing facility** • Firm shall submit fee Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of following: • **Rs. 30,000/- for revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.** • Tydogen **50ml** Injection is mentioned on fee challan. • **Confirmation of relevant manufacturing facility**	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
303.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	DICANE Injection
	Composition	Each ml contains:- Procaine Penicillin G.....200000 IU Dihydrostreptomycin Sulfate.....250mg **Dexamethasone**.....1mg
	Tracking Id, date & fee	2ME-JA3-8JMQ dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 228453807)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Dexa-SP Injection of M/s Atzan Pharmaceuticals, Sargodha (Reg. No. 049533)
	GMP status	New Section

	Remarks of the Evaluator	**Target species:** Horse, cattle, sheep goats, dogs, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
304.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	AP-STREP-D Injection
	Composition	Each ml contains:- Ampicillin Trihydrate.....100mg Colistin Sulfate.....250000 IU **Dexamethasone Acetate**.....0.5mg
	Tracking Id, date & fee	7J2-5ML-JL4D dated 28-02-2024 Rs 30,000/- dated 24-02-2024 (Slip No. 80191181)
	Pharmacological Group	Steroid and antimicrobial
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Amcicoli-D Injection of M/s Atzan Pharmaceuticals, Sargodha (Reg. No. 049535)
	GMP status	New Section
	Remarks of the Evaluator	**Target species:** Livestock, poultry
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
305.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- **Ketoprofen**…….....100mg
	Tracking Id, date & fee	ZB1-8UN-L1LA dated 27-02-2024 Rs 30,000/- dated 23-02-2024 (Slip No. 0893442558)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	50ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		

306.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- **Ketoprofen**…….....100mg
	Tracking Id, date & fee	Z91-16X-2WWA dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 33091851175)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
307.	Name and address of manufacturer / Applicant	M/s. Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad.
	Brand Name +Dosage Form + Strength	APLAFENIK Injection
	Composition	Each ml contains:- **Ketoprofen**…….....100mg
	Tracking Id, date & fee	BGU-193-6QQ1 dated 29-02-2024 Rs 30,000/- dated 26-02-2024 (Slip No. 667493224)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded	20ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 043141)
	GMP status	New Section
	Remarks of the Evaluator	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Decision:- Decision: The Registration Board discussed the matter in detail and decided to refer back the matter to the sub committee for further delibrations and recommendations.

3. MPORTED VETERINARY CASES

1.	Name and address of Applicant	M/s. Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan

	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises, Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s. Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s. Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1947 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Preso Suspension for Injection
	Composition	Each ml contains:- Prednisolone Acetate…….10mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Glucocorticoid
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml and 100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied pack size**
	Detail of certificates attached	1. Original legalized FSC Ref. No. 610/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country 2. Validity: 2years 3. Scanned copy of GMP certificate No. 32/18/GCN- GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam 4. Scanned copy of legalized distribution agreement No. i. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.

	Remarks of the Evaluator X	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** 1. Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. 2. Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** 3. Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm. 4. Confirmation of **manufacturing facility**. 5. Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation.**		

2.	Name and address of Applicant	M/s. Vety Care Pvt Ltd., Plot # 77, Street No. 6, I-10/3, Islamabad.
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s. Intervet International B.V. Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands.
	Name and address of marketing authorization holder	M/s. Intervet International B.V. Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands.
	Name of exporting country	**Netherlands**
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6612 Dated 01-03-2021
	Fee including differential fee	Rs : 1,00,000 Dated 26-02-2021
	Brand Name +Dosage Form + Strength	Mastijet Forte Intramammary Suspension
	Composition	Each 8gram contains:- Tetracycline HCl…….……200mg Neomycin Base as Sulphate.....…250mg Bacitracin……..2000 IU Prednisolone…….10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial and Corticosteroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	Not demanded
	International availability	N/A
	Me-too status	MASTIJET Syringe of M/s Progressive Associate, Karachi. (Reg. No. 014162)
	Detail of certificates attached	**1.** Original legalized CoPP BD/2020/No. of Certificate 254273 dated 12-11-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands **does not confirm free sale status of the product in country of origin** **2.** Original legalized GMP certificate No. NL/V 20/0012 based on inspection conducted on 16-07-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands. (**scope of provided GMP certificate does not cover manufacturing lines of steroids**) **3.** Letter of authorization not provided

Remarks of the Evaluator X	4. Provide valid copy of DSL 5. CoPP is provided which **does not confirm free sale status of the product in country of origin;** Submit legalized original valid FSC. 6. The **scope of provided GMP certificate does not cover manufacturing lines of steroids;** Submit legalized original relevant GMP certificate. 7. Provide legalized original valid Letter of authorization/sole agency agreement between product license holder and distributor. 8. In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. 9. Demanded Pack size is not mentioned in form-5A. **1. The initial stability studies of Mastijet Forte were performed at 25ºC/60% RH covering 24 months. However, when a decrease in the content of Bacitracin and Prednisolone was observed the storage conditions were finally changed to "store at 2-8ºC". Consequently, only 24 months study results for storage at 5ºC (±3ºC) are presented.**
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	

Recommendation of Sub-committee:
After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use

3.	Name and address of Applicant	M/s. Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, Malir Halt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s. Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24716 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 68437616724)
	Brand Name +Dosage Form + Strength	Dexabiopen Suspension for Injection
	Composition	Each ml contains:- Benzyl Penicillin (Procaine)…….200mg Dihydrostreptomycin (sulfate)…….200mg **Dexamethasone**……0.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial and corticosteroid
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of CoPP dated 17-12-2020 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution; valid for 5 years
	Remarks of the Evaluator [X]	Provided only **12 months long term** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since already submitted is scanned copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 100ml and 250ml pack sizes of injectable dosage form are demanded in a single

		application. So clarification is required for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
4.	Name and address of Applicant	M/s. Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s. Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25229 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.9085466559)
	Brand Name +Dosage Form + Strength	Solo-P 50ml Injection
	Composition	Each ml contains:- **Prednisolone**……10mg Chlorpheniramine Maleate…….4mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Bacteriostatic/ antihistamine
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Chlorprem 14 Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 113496)
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042904 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy

		• In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
5.	Name and address of Applicant	M/s. Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s. Neovet Pharma Pvt Ltd Address: Plot No. A 12/37, Street No. 6, Commercial Area Landhi, Cattle Colony Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25225 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.40463491104)
	Brand Name +Dosage Form + Strength	Dimipro Plus 2.36gm Granules for Injection
	Composition	Per Unit contains:- Diminazene Aceturate……..1.05g Vitamin B6…….5mg Vitamin B12……1mg **Antipyrine** add to …….....2.36g
	Finished Product Specification	CVP specifications
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	2.36gm bag
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042911 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026 ➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years

	Remarks of the Evaluator [X]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to Generic/RRA confirmation.**		
6.	Name and address of Applicant	M/s. Orion Group, P-97, Usman Block, Muslim Town No.1, Near Lasani Pully, Sargodha Road, Faisalabad
	Detail of Drug Sale License	M/s. Orion Group, Address: 97 Commercial Area, Usman Block, Muslim Town No.1, Sargodha Road, Faisalabad Validity: 22/01/2023 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s O.L. Kar-AgroZooVet -Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name and address of marketing authorization holder	M/s O.L. Kar-AgroZooVet-Service. PC 272B Lenina (Heriyiv Maydanu) St., Shargorod, Vinnytsia Region, Ukraine, 23500
	Name of exporting country	Ukraine
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 25412 Dated 13-09-2021
	Fee including differential fee	Rs : 150,000 Dated 31-07-2021 (slip No. 3543254018)
	Brand Name +Dosage Form + Strength	Mastilong Forte Combined antimicrobial Intramammary syringe tube for livestock
	Composition	1 Syringe (8g) tube contains:- Tetracycline HCl…….200mg Neomycin Sulphate…….250mg Bacitracin…….200 IU **Prednisolone……..**…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic/ steroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	8gm syringe tube
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of FSC No. PK00500S 28/1 dated 29-01-2020 Validity: **28-01-2021**

		➢ Scanned copy of GMP certificate 602-1121-16/3654 of 25-05-2018, certified by the state service of Ukraine on Food safety and Consumer protection Ukraine. ➢ Scanned copy of Distribution agreement between PLH and the applicant dated 01-12-2019**.**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide original legalized valid FSC, since the already submitted FSC is **expired even upon submission**. • Provide original legalized valid GMP certificate, since the **scope of already submitted GMP does not cover hormones** • Notarized original sole agency/distribution agreement between PLH and Applicant since the already submitted is scanned copy. • Confirmation of **dedicated manufacturing facility** • Provide accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic/RRA confirmation.**		
7.	Name and address of Applicant	M/s. Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s. Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 11001 Dated 09-04-2021
	Fee including differential fee	Rs : 100,000 Dated 09-04-2021
	Brand Name +Dosage Form + Strength	Para-Sone Water Soluble Powder
	Composition	Each gram contains:- **Paracetamol**……..45mg Bromhexine HCl……2mg Prednisolone…….0.1mg
	Finished Product Specification	Inhouse
	Pharmacological Group	NSAID/ Mucolytic/ Corticosteroid
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1Kg

	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **(scope does not cover steroid manufacturing lines)** **Validity: 5 Years** ➢ Copy of Free sale certificate No. 618/2019/QLT-CFS dated 17-06-2019 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 2 Years** ➢ Copy of agency agreement concluded on 17-10-2020 between the applicant and PLH
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC), since already submitted are copies. • Provide valid legalized original relevant GMP certificate since the scope of already submitted copy does not cover **steroid manufacturing lines.** • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic/RRA confirmation.**		

8.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	Name: M/s Brand Station, Address: 69 Wocland villas Lahore, near Raiwind road, Lahore. Validity: **10-08-2027** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam
	Name and address of marketing authorization holder	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam North Star Import Export Joint Stock Company, 69 Hung Vuong Road, Thoi Binh Ward, Ninh Kieu District, cantho City, Vietnam. (supplier)
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 8799 Dated 06-04-2022
	Fee including differential fee	Rs: 150,000 Dated 06-04-2022 (slip N0. 5177016)
	Brand Name +Dosage Form + Strength	Para-Sone Water Soluble Powder
	Composition	Each gram contains: **Paracetamol**…45mg Bromhexine HCl…2mg **Prednisolone**…0.1mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Analgesic and antipyretic/ Mucolytic/ Corticosteroid
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	15000gm can; 5gm, 10gm, 20gm, 30gm, 50gm, 100gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm aluminum coated PE bags; 5gm, 10gm, 15gm, 20gm, 30gm, 50gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm aluminum coated plastic can
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	Original legalized valid CoPP/FSC, GMP and sole agency certificate **not provided**
	Remarks of the Evaluator [X]	Firm has provided 06-month accelerated (40±2ºC/ 75±5%) and 36-month real time **(27±2ºC/ 60±5%)** stability studies data of three batches. **The firm had already applied for same formulation of M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam with same brand name** (vide Dy. No. 11001 dated 09-04-2021 Rs. 100,000/- dated 09-04-2021) which was considered and referred to EWG on Veterinary drugs by the Registration Board in its 330th meeting **Shortcomings:**

		• Provide valid legalized original CoPP/FSC, GMP certificate (covering scope of **steroid manufacturing lines)** and sole agency certificate/distributor agreement. • Provide long term stability studies data as per zone IV-A/B conditions upto the claimed shelf life. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic/RRA confirmation.**		
9.	Name and address of Applicant	M/s Orient Traders International, CM-10, Block A, Kazimabad, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Traders International Address: CM-10, Block A, Kazimabad, Model Colony, Karachi Validity: 26th January 2024 Status: Drug License By Way of Wholesale (Form No.07).
	Name and address of manufacturer	M/s Sanochemia Pharmazeutika GmbH Landegger Straβe 7, Neufeld an der Leitha 2491, Austria. (Bulk product, finished product, primary packaging, secondary packaging, lot analysis) M/s V.M.D. N. V. Hoge Mauw 900 2370 Arendonk-Belgium (labelling & batch release)
	Name and address of marketing authorization holder	M/s V.M.D. N. V. Hoge Mauw 900 2370 Arendonk-Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 9916 Dated 19-04-2022
	Fee including differential fee	Rs: 1,50,000/- Dated 01-04-2022 (slip No.49137470987)
	Brand Name +Dosage Form + Strength	Alvegesic vet 10mg/ml Injectable Solution
	Composition	Each ml contains: Butorphanol as Tartrate…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	**Opioid analgesics, morphinan derivatives**
	Shelf life	4 years
	Demanded Price	Decontrolled
	Pack size	10ml
	International availability	Alvegesic Vet. 10mg/ml Solution for injection (10ml) **(approved in France)**
	Me-too status	Not available
	Detail of certificates attached	▪ Original legalized Certificate of Pharmaceutical Product Certificate No. 20211105006 Issued on 05/11/2021, Certified by *Federal Agency for medicines and health products – famhp, Eurostation II, Victor Hortaplein 40/40, 1060 Brussels, Belgium*. The CoPP confirms free sale status of the

		product in exporting country as well as GMP status of the manufacturing site through routine inspection with 2-year periodicity (only for Belgium). ▪ Copy of certificate of GMP compliance of manufacturer is **expired even upon submission**. ▪ Original notarized letter of authorization (LOA) dated 12-06-2023, validity 3 years, is given. (**already submitted with reply No. RAD/06/23-08 dated 06-2023 for Tulinovet 100mg/ml.)**
	Remarks of the Evaluator [x]	➢ 06 months accelerated and 60 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** ➢ Original legalized certificate of GMP compliance of manufacturer since the already submitted copy is **expired even upon submission**.
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs devided to refer the case to Control Division for their comments.**		
10.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Richter Pharma, AG, Durisolstrabe 14, 4600 Wels, Austria
	Name and address of marketing authorization holder	M/s Richter Pharma, AG, Durisolstrabe 14, 4600 Wels, Austria.
	Name of exporting country	Austria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34336 Dated 24-12-2020
	Fee including differential fee	**Rs : 50,000** Dated 24-12-2020
	Brand Name +Dosage Form + Strength	Mitex Ear Drops (Cutaneous Suspension)
	Composition	Strength of Active Ingredient per unit dose: Miconazole Nitrate …23mg (eq. to 19.98mg of Miconazole) **Prednisolone Acetate** …5mg (Eq. to 4.48mg of prednisolone) Polymyxin B Sulphate …0.5293mg (Eq. to 5500 IU Polymyxin B Sulphate)
	Finished Product Specification	Inhouse
	Pharmacological Group	Corticosteroid, anti-infective
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	**Austria approved**
	Me-too status	N/A

	Detail of certificates attached	➢ Original Legalized COPP Certificate No. 12826569 issued by BASG/ AGES Traisengasse 5, A-1200 Wien confirms GMP status of the manufacturer, and that the product is licensed to be placed on market but not actually on the market in the exporting country. (since Austria acts as Reference Member State, the product is marketed only in Concerned Member State) Date of issuance: 04-03-2020 ➢ Scanned copy of Legalized Power of attorney provided.
	Remarks of the Evaluator [X]	06 months accelerated and **18 months** long term stability studies data as per zone-IV-A conditions provided **Target species:** Dogs and cats **Shortcomings:** • Provide original Legalized Power of attorney/sole agency certificate**.**
	Decision of 326th meeting: Deferred for free sale status of applied product in country of origin.	
	Updated status: The firm has submitted the following ➢ Scanned copy of original legalized COPP No. 102027332 issued by BASG/ AGES Traisengasse 5, A-1200 Wien confirms GMP status of the manufacturer, as well as **free sale status in the exporting country.** Date of issuance: 30-05-2023 **Shortcomings:** • Notarized original valid Letter of authorization (LOA)/power of attorney since the already submitted power of attorney is **scanned copy.**	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**		
11.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area,Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Guangzhou Haicheng Pharmaceutical Co., Ltd. 311-312 A Yangming Nongzi Market, No.180-1 TianyuanRoad, Tianhe Area, Ghuangzhou China
	Name and address of marketing authorization holder	M/s Guangzhou Haicheng Pharmaceutical Co., Ltd. 311-312 A Yangming Nongzi Market, No.180-1 TianyuanRoad, Tianhe Area, Ghuangzhou China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 27955 Dated 11-10-2021
	Fee including differential fee	Rs : 1,50,000 Dated 05-10-2021 (slip No. 6505525117)
	Brand Name +Dosage Form + Strength	Halofuginone Hydrobromide 0.6% Powder
	Composition	Each gram Contains: Halofuginone Hydrobromide…6mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anticoccidial
	Shelf life	02 Years
	Demanded Price	N/A
	Pack size	Not demanded

International availability	N/A
Me-too status	Could not be confirmed
Detail of certificates attached	• Original Legalized FSC dated 21-02-2021 issued by the Guangdong institute for Veterinary drug andfeedstuffs inspection of Peoples Republic of Chinaconfirms Free sale status of applied product incountry of origin. • Original Legalized GMP certificate dated 05-09- 2020 issued by the Ministry of Agriculture Peoples Republic of China confirms GMP status of themanufacturer • Original Legalized LOA dated 12-03-2021 Validity: 1 year
Remarks of the Evaluator [X]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-Aconditions. **Shortcomings:** • Notarized original sole agency/distribution agreement between PLH and Applicant since the already submittedis **expired now but valid upon submission.** • In the finished product label the Urdu version of the following namely; (i) Name of drug is missing. Submitlabel in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approvedby DRAP (generic / me-too status) along with registration number, brand name and name of firm.
Decision of 330th meeting: Deferred for following: • valid notarized copy of letter of authorization (LOA)/ distribution agreement • label in accordance with The Drugs (Labelling and Packing) Rules, 1986 • evidence of applied formulation/drug already approved by DRAP (generic / me-toostatus) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.	
Updated status: The firm has submitted the following reply dated 01-11-2023: • Legalized original letter of authorization (LOA)/ distribution agreement dated 21-09-2023 valid for 5 years. • label in accordance with The Drugs (Labelling and Packing) Rules, 1986	
• RRA status: Stenorol (Halofuginone Hydrobromide 0.6% Powder) in National office of Animal Health, UK (NAOH) compendium as **Specified Feed additive** **Shortcomings:** • Generic / RRA approval status of the applied product	
Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
Recommendation of Sub-committee: **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use subject to generic confirmation.**	

12.	Name and address of Applicant	M/s Qualivet Pharma, **Office address:** 1st Floor, B-16, Block A, Kazimabad, NearMasjid-e-Hira, Model Colony, Karachi-75100, Pakistan **Godown Address:** No. 5/15, Golden Town, Survey No. 79,Malir Halt, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Qualivet Pharma Address: No. 5/15, Golden Town, Survey No. 79, MalirHalt, Karachi, Validity: **14-10-2022.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Laboratories SYVA S.A.U
		Avda. Portugal, s/n, Parque technologico de Leon, Parcelas 15-16, Leon 24009 Leon Spain
	Name and address of marketing authorization holder	M/s Laboratories SYVA S.A.U Avda. Parroco Pablo Diez, 49-57 (24010) Leon Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24716 Dated 07-09-2021
	Fee including differential fee	Rs : 150,000 Dated 26-08-2021 (slip No. 68437616724)
	Brand Name +Dosage Form + Strength	Dexabiopen Suspension for Injection
	Composition	Each ml contains: Benzyl Penicillin (Procaine)…200mg Dihydrostreptomycin (sulfate)…200mg **Dexamethasone**…0.5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial and corticosteroid
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, and 250ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Scanned copy of CoPP dated 17-12-2020 issued by Spanish agency of Medicines and Medical Devices, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of declaration dated 09-02-2021 of sole and exclusive distribution; valid for 5 years

	Remarks of the Evaluator [X]	Provided only **12 months long term** stability studies data as per zone-IV-A conditions. **Shortcomings:** • Provide copy of valid DSL • Provide notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is scanned copy. • Provide legalized original valid CoPP since alreadysubmitted is scanned copy. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life as per zone IV-A conditions. • Confirmation of **dedicated manufacturing facility** • Separate registration is granted to separate pack size/fillvolume of injectable dosage form. However, both 100ml and 250ml pack sizes of injectable dosage form are demanded in a single application. So clarification isrequired for which pack size/ fill volume you want to apply this dossier and provide accordingly, evidence ofapplied formulation/drug already approved by DRAP (generic / me-too status) along with registrationnumber, brand name and name of firm.
	Decision of 330th meeting: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
	Updated status: The firm has submitted the following: • legalized original valid CoPP No. 3170003050117 dated 17-12-2020 issued by the Spanish agency of Medicines and Medical Devices, Spain confirming the free sale statusin exporting country as well as GMP status of the manufacturer	
	• copy of DSL valid till **14-10-2024** • Provided 06 months accelerated and 24 months' real time stability studies data as perzone IV-A conditions. • Demanded pack size: **100ml** **Shortcomings:** • Confirmation of dedicated manufacturing facility • original valid Letter of Authorization/ Sole agency certificate since the already submitted is scanned copy • Already referred to EWG on veterinary drugs to review therapeutic requirement keepingin view safety, efficacy and quality parameters	
	Decision: Deferred for review of Sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and with submission ofthe following: • **clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise** • **original valid Letter of Authorization/ Sole agency certificate** **Recommendation of Sub-committee:** **After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use**	

Decision: The Registration Board discussed the matter in detail and decided to refer back the matter to the sub committee for further delibrations and recommendations.

Case No.01 **REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR PERMISSION TO IMPORT INTERNATIONAL PACKS OF REGISTERED PRODUCTS.**

M/s Novartis Pharma (Pakistan) Limited, C-21, S.I.T.E., Karachi has stated that manufacturer of their registered products has informed that due to very specific and limited quantity of products they are unable to provide this medicine in country specific packs. Detail of products is as under:-

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
1.	059068	Exelon 4.6mg Transdermal Patch. Each transdermal patch of 5cm^2 contains:- Rivastigmine 9mg and releases rivastigmine at the rate of 4.6mg/24hours	Dy.No.6653-R&I dated 01-07-2023 Reg. Letter date 05.10.2009 Renewal due date 04.10.2019 Renewal submit date 04.09.2019
2.	059069	Exelon 9.5mg Transdermal Patch. Each transdermal patch of 10cm^2 contains:- Rivastigmine 18mg and releases rivastigmine at the rate of 9.5mg/24hours	
3.	074855	Exelon Transdermal Patch. Each patch of 15 cm^2 contains:- 27mg rivastigmine base, in vivo release rate of 13.3mg/24 hours.	Reg. Letter date 18.08.2015 Renewal due date 17.08.2020 Renewal submit date 21.07.2020
4.	078119	Jakavi 5mg Tablets. Each tablet contains:- Ruxolitinib……5mg.	Reg. Letter date 20.03.2014 Renewal due date 19.03.2024 Renewal submit on 26.01.2014.
5.	078120	Jakavi 15mg Tablets. Each tablet contains:- Ruxolitinib……..15mg.	
6.	078121	Jakavi 20mg Tablets. Each tablet contains:- Ruxolitinib……..20mg.	
7.	090523	Kisqali 200mg Film Coated Tablet. Each Film Coated Tablet Contains: Ribociclib (as succinate)…200mg	Reg. Letter date 25.06.2018 Renewal due date 24.06.2023 Renewal submit on 12.05.2023.
8.	072543	Tasigna Capsules 150mg. Each capsule contains:- Nilotinib……150mg.	Reg. Letter date 20.12.2012 Renewal due date 19.12.2022 Renewal submit on 18.10.2022
9.	052256	Tasigna 200mg Capsules. Each hard gelatin capsule contains:- Nilotinib…..200mg	Reg. Letter date 13.11.2008. Renewal due date 12.11.2023. Renewal submit date 09.10.2023.
10.	033196	Glivec 100mg Film Coated Tablets. Each tablet contains:- Imatinib mesylate 100mg.	Reg. Letter date 14-03-2005. Due date: 13-03-2020 Submit date 10-02-2020
11.	033197	Glivec 400mg Film Coated Tablets. Each tablet contains:- Imatinib mesylate 400mg	Reg. Letter date: 14-03-2005. Due date: 13-03-2020 Submit date: 25-02-2020
12.	023119	Exelon capsules 1.5mg Each capsule contains carbamoylatine as hydrogen tartrate 1.5mg	Reg. Letter date: 10-02-1999 due date: 09-02-2024 Renewal submit on: 25-01-2024.
13.	023120	Exelon capsules 3mg Each capsule contains carbamoylatine as hydrogen tartrate 3mg	

14.	027322	Exelon capsules 4.5mg Each capsule contains carbamoylatine hydrogen tartrate 4.5mg	Reg. Letter date: 22-03-2002 due date: 21-03-2022 Renewal submit on:04-02-2022
15.	027321	Exelon capsules 6.0mg Each capsule contains carbamoylatine hydrogen tartrate 6.0mg	
16.	014961	Sandimmum Neoral -Drink Solution 100mg/ml Each ml contains Ciclosporin 100mg	Reg. Letter date: 19-05-1994. Approval for change of name from Sandoz to Novartis: 23-06-2007 Due date: 22-06-2022 Submit date: 18-05-2022
17.	027324	Sandostatin Lar Injection 20mg Each vial contains:- Octreotide acetate 20mg.	Reg. Letter date: 22-03-2002 due date: 20-03-2022 Renewal submit on:04-02-2022
18.	027325	Sandoslatin Lar Injection 30mg Each vial contains: Octreotide acetate 30mg.	

The firm has requested to allow them to print the following components for a period of 03 Years on outer box of product locally at licensed premises i.e. C-21, SITE, Karachi DML No. 000003 as per labeling and packaging rules 1986.

- Urdu text.
- Registration number.
- Maximum retail price.
- Name and address of sole agent.
- 2D Matrix Barcode
- Other information (as per labeling requirements)

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.10,000/- for each product.
b. Copy of registration letter, PRVC approvals & renewal trail.
c. Copy of valid DML.
d. Agreement between Drug Sale License & Drug Manufacturing License Holders.

Decision:

Registration Board acceded to the request of M/s Novartis Pharma (Pakistan) Limited, Plot No. C-21, S.I.T.E. Manghopir Roard, Karachi to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000003- M/s Novartis Pharma Pakistan Ltd, C-21, SITE, Karachi) to comply with the requirements of Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two years only. The firm shall submit the plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs afterwards.

S. No.	Reg. No.	Name of Product	S. No.	Reg. No.	Name of Product
1.	074855	Exelon Transdermal Patch. Each patch of 15 cm^2 contains:- 27mg rivastigmine base, in vivo release rate of 13.3mg/24 hours.	2.	059069	Exelon 9.5mg Transdermal Patch. Each transdermal patch of 10cm^2 contains:- Rivastigmine 18mg and releases rivastigmine at the rate of 9.5mg/24hours

3.	074855	Exelon Transdermal Patch. Each patch of 15 cm^2 contains:- 27mg rivastigmine base, in vivo release rate of 13.3mg/24 hours.	4.	078119	Jakavi 5mg Tablets. Each tablet contains:- Ruxolitinib……5mg.
5.	078120	Jakavi 15mg Tablets. Each tablet contains:- Ruxolitinib……..15mg.	6.	078121	Jakavi 20mg Tablets. Each tablet contains:- Ruxolitinib……..20mg.
7.	090523	Kisqali 200mg Film Coated Tablet. Each Film Coated Tablet Contains: Ribociclib (as succinate)…200mg	8.	072543	Tasigna Capsules 150mg. Each capsule contains:- Nilotinib……150mg.
9.	052256	Tasigna 200mg Capsules. Each hard gelatin capsule contains:- Nilotinib…..200mg.	10.	033196	Glivec 100mg Film Coated Tablets. Each tablet contains:- Imatinib mesylate 100mg.
11.	033197	Glivec 400mg Film Coated Tablets. Each tablet contains:- Imatinib mesylate 400mg.	12.	023119	Exelon capsules 1.5mg Each capsule contains carbamoylatine as hydrogen tartrate 1.5mg
13.	023120	Exelon capsules 3mg Each capsule contains carbamoylatine as hydrogen tartrate 3mg	14.	027322	Exelon capsules 4.5mg Each capsule contains carbamoylatine hydrogen tartrate 4.5mg
15.	027321	Exelon capsules 6.0mg Each capsule contains carbamoylatine hydrogen tartrate 6.0mg	16.	014961	Sandimmum Neoral -Drink Solution 100mg/ml Each ml contains Ciclosporin 100mg
17.	027324	Sandostatin Lar Injection 20mg Each vial contains:- Octreotide acetate 20mg.	18.	027325	Sandoslatin Lar Injection 30mg Each vial contains: Octreotide acetate 30mg.

Case.No.02: **REQUEST OF M/S FEROZSONS LABORATORIES LIMITED, FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.**

M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera has submitted request for cancellation of registration of imported drug as per following details.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)
1.	Sovaldi Tablet 400mg Each film coated tablet contains: - Sofosbuvir…400mg	078147	Importer informed that their product license holder i.e. M/s Gilead Sciences Inc. 333 Lakeside Drive, Foster City, CA, 94404, USA dated 27th June, 2024 wants to withdraw marketing authorization of Sovaldi Tablet 400mg in Pakistan.

Alternative registered products: -

S. No.	Name of Drug	Name of Firm	S. No.	Name of Drug	Name of Firm
1.	Myhep	AGP Limited, Karachi	2.	C-Off	Atco Labs Limited, Karachi

3.	Hepgard	Barrett Hodgson Pakistan Pvt Ltd	4.	Qvir	Bosch pharmaceuticals
5.	Sofotel	Helix Pharma Pvt Ltd	6.	Fosbu	Highnoon Labortories Ltd
7.	Sovex	Highnoon Labortories Ltd	8.	Sofohil	Hilton Pharma Pvt Ltd
9.	Sofomac	Macter Internation Limited	10.	Ozbir	Martin Dow Limited
11.	Virso	Novartis Pakistan Limited	12.	Zoval	ParmEvo Pvt Ltd
13.	Ocvir	SAMI Pharmaceuticals	14.	Lavie	Schazoo pharmaceutical
15.	Hepaldi	Scotmann Pharmaceuticals	16.	Sobvi	Searle Company Limited
17.	Hepevir	AJM	18.	Sofhep	Aspin Pharma
19.	Lesof	Bio-Labs	20.	Abriva	CCL
21.	Rivofos	Genetics	22.	Sofos	Genix
23.	Sofiget	Getz	24.	Cure-C	Global
25.	Sofonil	High-Q	26.	Sovihep	Jenner pharmaceuticals
27.	Sovir	LCI	28.	Scihop	Scilife Pharma
29.	Vibrenta	Tabros Pharma	30.	Sofida	WelMark Pharmaceuticals
31.	Ziqar	Wilshire	32.	Saferon	Wilsons Pharmaceuticals

SOP Requirement	**Firms Response**
a) Application. b) Copy of registration letter. c) Justification. d) List of alternatives brands/ FPPs available in the country.	a. Application with reason for cancellation. b. Copy of registration letter (Reg. Letter date 12-02-2015) Last Renewal submit on 19-09-2019. c. As mentioned above. d. As mentioned above.

Decision:
The Registration Board did not accede to the firm's request.

Case No.03. <u>REQUEST OF M/S MARTIN DOW LIMITED, KARACHI FOR REGISTRATION OF FEMFERTIL CAPSULE 200MG & 100MG TO THEIR NAME FROM M/S ACUMEN PHARMA (PVT) LTD, RAWALPINDI.</u>

M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi has submitted an application for Registration of following already registered product from M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat to their name. Detail of each proposed product is as under: -

Product: Femfertil Capsule 200mg (approved in 258th RB)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per approval** Fertigest Capsule 200mg. Each soft gelatin capsule contains:- Progesterone …..200mg	**As per CoPP/LOA:** Femfertil Capsule 200mg. Each soft gelatin capsule contains:- Progesterone …..200mg
	Reg. date / renewal status	approved in 258th RB	
	Name and address of Applicant(Transferee)	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.	
	Name of Transferor	M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat	
	Detail of Drug Sale License	**DSL No. DHOKK/(drugs)-69/2024 (valid upto 16-06-2029)** **Address:** M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown addresses:** Plot No.32, Sector 16 K.I.A., Karachi. 1st Floor, Plot NO.211 Sector 23 K.I.A., Karachi. Plot No.116, Sector 15 K.I.A., Karachi	
	Name and address of Manufacturer / Product License Holder	**As per Minutes 258 RB.** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, C/La Vallina s/n, P.INavatejera, 24008 Villaquilambre (Leon) Spain	**As per CoPP (No.36918/2023).** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, S.A. C/La Vallina s/n, Poligono Industrial Navatejera Villaquilambre, 24008 Leon, Spain.
	Name of exporting Country	Spain	
	Diary No. & Date of R& I	Dy. No. 5734 Dated 03/06/2024.	
	Finished Product Specification	As per Innovator's Specifications	
	Shelf life	24 Months	
	MRP/Pack Size	As per DPC, Pack size 15's (as per CTD Doc)	

Product: Femfertil Capsule 100mg (approved in 258th RB)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
2.	Product Name/ Composition	**As per approval** Fertigest Capsule 100mg. Each soft gelatin capsule contains:- Progesterone …..100mg	**As per CoPP/LOA:** Femfertil Capsule100mg. Each soft gelatin capsule contains:- Progesterone …..100mg
	Reg. date / renewal status	approved in 258th RB	
	Name and address of Applicant(Transferee)	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.	
	Name of Transferor	M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat	
	Detail of Drug Sale License	**DSL No. DHOKK/(drugs)-69/2024 (valid upto 16-06-2029)** **Address:** M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown addresses:** Plot No.32, Sector 16 K.I.A., Karachi.	

		1st Floor, Plot NO.211 Sector 23 K.I.A., Karachi. Plot No.116, Sector 15 K.I.A., Karachi	
	Name and address of Manufacturer / Product License Holder	**As per Minutes 258 RB.** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, C/La Vallina s/n, P.INavatejera, 24008 Villaquilambre (Leon) Spain	**As per CoPP (No.36934/2023).** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, S.A. C/La Vallina s/n, Poligono Industrial Navatejera Villaquilambre, 24008 Leon, Spain.
	Name of exporting Country	Spain	
	Diary No. & Date of R& I	Dy. No. 5735 Dated 03/06/2024.	
	Finished Product Specification	As per Innovator's Specifications	
	Shelf life	24 Months	
	MRP/Pack Size	As per DPC, Pack size 30's (as per CTD Doc)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application on form-5F with a fee of Rs.300,000/- for each product.

b) Copy of extract of minutes M-258.

c) Original & Legalized CoPP issued by Spain.

d) Original Legalized of Letter of authorization in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

e) Original Legalized Termination letter from Product License Holder in the name of M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat.

f) Original NOC for transfer of registrations from M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat **(issued on 23-01-2024).**

g) Undertaking.

Decision: -
The Registration Board deferred the case for personal hearing of M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat along with records.

Case No. 04: <u>REGISTRATION OF DRUGS UNDER THE DRUGS ACT, 1976-VIRTUAL INSPECTION REPORT OF MANUFACTURER ABROAD.</u>

It is submitted that Registration Board in its 290th meeting considered and approved the following products of M/s Neutro Healthcare, 22-M, Gulberg-III, District Lahore. Details are as under:-

S. No.	Name of Applicant/ Manufacturer	Name of Drugs & Composition	Panel of Inspector(s)/ Date of inspection
1.	M/s Neutro Healthcare, 22-M, Gulberg-III, District Lahore. **Manufacturer & Product License Holder: -** M/s Getwell Phaarmaceuticals, 474,	(i) I-DOX 50mg/25ml Concentrate for solution for IV infusion Each ml contains: Doxorubicin hydrochloride…….. 2mg (as pegylated liposome)	(i) Mr. Muneeb Ahmed Cheema, Deputy Director (PE&R), Drug Regulatory Authority of Pakistan, Islamabad. (ii)

	Udyog Vihar, Phase-V,Gurgaon-122016, Haryana, India	(ii) I-DOX 20mg/10ml Concentrate for solution for IV infusion Each ml contains: Doxorubicin hydrochloride…….. 2mg (as pegylated liposome)	Mr. Adil Saeed, Deputy Director (PE&R), Drug Regulatory Authority of Pakistan, Islamabad
Decision: Approved as per policy of inspection of manufacturer abroad.			

Accordingly, an inspection was carried out by inspection panel dated 14th & 15th February, 2024 and final remarks of the panel are as under:-

Conclusion:
The following observations were noted during the virtual inspection:

Based on the proceedings of virtual inspection, documents reviewed, videos of the unit seen, discussion with the technical staff, the panel has reached on the conclusion that M/s Getwell Pharmaceuticals situated at 474, Udyog Vihar, Phase-V, Gurgaon-122016, Haryana, India was not operating at acceptable level of cGMP compliance, hence the panel do **not recommend** the grant of registration of I-DOX 20mg & 50mg Injections in name of M/s Neutro Pharma Pvt. Ltd. 9.5km Sheikhupora Road, Lahore. The major observation though recorded above, are reiterated as under:

a) The land of manufacturing unit is 500 square yards and the requirement as per Schedule B of Drug (LRA) Rules 1976 is 2000sq. yards.

b) Due to old design there was no provision of proper HVAC systems for the corridors and ancillary areas.

c) The manufacturing facility was located in commercial & residential area.

d) The material receiving area was an open uncovered area.

e) Primary change rooms and corridors leading to secondary change rooms were not supplied with HVAC system which is mandatory under cGMP guidelines for manufacturing of sterile products.

f) There is no provision of Class A area at any stage of manufacturing of the drug product.

g) Most of the processes involved in the manufacturing of above product were manual and were being performed in Class C area hence posing risk of contamination of product.

h) Space constraints in manufacturing area leading to unnecessary movement of in-process solutions and equipment from one room to another multiple times, posing risk of contamination of product.

i) In process quarantine area was not available, rather stored in finished good cold storage, posing a risk of mix up.

j) Insufficient QC equipment for complete in-house testing of the drug product.

k) Contract agreement and analytical reports for tests conducted on contract testing basis were not submitted though committed to provide the time of inspection.

l) Space constraints in stability chambers.

Decision: -The Board decided to reject the registration application(s) of above mentioned drugs manufactured by M/s Getwell Phaarmaceuticals, 474, Udyog Vihar, Phase-V, Gurgaon-122016, Haryana, India as the inspection panel has not recommended the grant of registration.

Case.No.05: REQUEST OF M/S PFIZER PAKISTAN LIMITED, FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.

M/s Pfizer Pakistan Limited, 12-Dockyard Road, West Wharf, Karachi has submitted request for cancellation of registration of imported drug as per following details.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)
1.	Zeldox IM 20mg Injection. Each vial contains:- Ziprasidone Mesylate Trihydrate 40.93mg eq. to Zipresidone 20mg	062291	This refers to our global asset purchase agreement with OBS Pakistan Private Limited (a subsidiary of AGP Limited) the agreement included divestment of several products including zeldox IM Injection. However, we have been informed by OBS that they will not be pursuing the transfer of registration of referred product.
Alternative registered products: - Not provided			

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter. c) Justification. d) List of alternatives brands/ FPPs available in the country.	a. Application with reason for cancellation. b. Copy of registration letter (Reg. Letter datet 25-06-2010) Last Renewal submit on 19-09-2019. c. As mentioned above. d. As mentioned above.

Decision:
The Registration Board did not accede to the firm request.

Case No.06. REQUEST OF M/S RA HEALTH CARE (SMC-PVT.) LTD FOR EXEMPTION FROM LOCAL LABELING FOR HOSPITAL USE PRODUCT (SEVOFLURANE LIQUID FOR INHALATION).

M/s RA Health Care (SMC-Pvt.) Ltd, 2nd Floor Building No. 50 Mir Arcade, Mini Commercial Phase 7, Bahria Town, Rawalpindi has submitted request with a fee of Rs.10,000/- that to meet local labeling Laws, our global manufacturing and supply chain setups require adjustments in manufacturing flow which will take a considerably long time due to the company's operational complexity. Detail of product is as under:-

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
1.	115751	Sevoflurane Liquid For Inhalation Each aluminium bottle contains:- Sevoflurane……. 250ml (USP Specification)*	E-application No. Reg. Letter date 16th February, 2024

Product License Holder:	M/s Baxter Healthcare Corporation, 1 Baxter Parkway, Deerfield, IL 60015, United States of America.
Manufacturer:-	M/s Baxter Healthcare Corporation, Route 3-Km 144.2, Guayama, Puerto, Rico 00784, United States of America

Now, firm requested for exemption from local labeling for a period of 03 years as product is for hospital use only and will be directly used by qualified anesthesiologists / health care professionals in surgical theater within hospital settings.

Further firm inform that we requested for exemption from local labeling as our product is for hospital use only and will be directly used by qualified anesthesiologists / health care professionals in surgical theater within hospital settings.
Due to quality issues, it is not possible to get the product locally labeled, for the safety of patients we request you to give us exemption from local label requirements for a period of 3 years.
It is requested to please accept our request at your earliest convenience, so we can make the product available for the patient.

Decision:
The Registration Board advised the firm to reapply with a local agreement with a DML holder to comply with the Drugs (Labelling & Packing) Rules, 1986.

Case No.07. **REQUEST OF M/S MULLER & PHIPPS PAKISTAN (PVT) LTD, KARACHI FOR REGISTRATION OF NEPHROSTERIL SOLUTION FOR INFUSION TO THEIR NAME FROM M/S FRESENIUS KABI PAKISTAN, LAHORE.**

M/s Muller & Phipps Pakistan (Pvt) Ltd, Uzma Court, Main Clifton Road, Karachi has submitted an application for Registration of following already registered product from M/s Fresenius Kabi Pakistan (Pvt) Ltd, 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27 C/3, Gulberg-III, Lahore to their name. Detail of each proposed product is as under: -

Product: Zoledronic Acid Fresenius Kabi 4mg/5ml concentrate for solution for IV Infusion (Reg.No. 114208)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. Letter** Zoledronic Acid Fresenius Kabi 4mg/5ml concentrate for solution for IV Infusion Each ml solution for infusion contains: - Zoledronic acid monohydrate 0.853mg (corresponding to 0.8mg anhydrous substance) (As per Innovator's Specification)	**As per CoPP (No.102829702)** -do-
	Reg. date / renewal status	Reg letter, 22nd December, 2022	
	Name and address of Applicant(Transferee)	M/s Muller & Phipps Pakistan (Pvt) Ltd, Uzma Court, Main Clifton Road, Karachi.	
	Name of Transferor	M/s Fresenius Kabi Pakistan (Pvt) Ltd, 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27 C/3, Gulberg-III, Lahore.	
	Detail of Drug Sale License	**DSL No. DHODSK/(drugs)219 (valid upto 08-05-2028)** Uzma Court Main Clifton Road, Karachi. **Godown address:**	

		Plot No.208&208/1, Sector 23 Korangi Industrial Area, Karachi	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder: -** M/s Fresenius Kabi Deutschland GMBH, D-61346 Bad Homburg v.d.H. Germany. **Manufacturer:** M/s Fresenius Kabi Austria GMBH, Hafnerstrabe 36, 8055 Graz, Austria.	**As per CoPP (No. 102829702)** **Product License Holder & Manufacturer:** Fresenius Kabi Austria GmbH HafnersraBe 36 8055 Graz Austria
	Name of exporting Country	Germany	
	Diary No. & Date of R& I	Dy. No.	
	Finished Product Specification	As per Innovator's Specifications (As per Reg. Letter)	
	Shelf life	02 Years	
	MRP/Pack Size	Rs.1500/- 1's (as per Reg. Letter)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.300,000/-.

b) Copy of Reg. letter

c) Original & Legalized CoPP.

d) Original Legalized of Letter of authorization in the name of M/s Muller & Phipps Pakistan (Pvt) Ltd, Uzma Court, Main Clifton Road, Karachi.

e) Original Legalized Termination letter from Product License Holder in the name of M/s Fresenius Kabi Pakistan (Pvt) Ltd, Lahore.

f) Original NOC for transfer of registrations from M/s Fresenius Kabi Pakistan (Pvt) Ltd **(issued on 20-11-2023).**

g) Undertaking.

Decision: -

In light of the above, the Registration Board decided to schedule a personal hearing for M/s Fresenius Kabi Pakistan (Pvt) Ltd, located at 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27 C/3, Gulberg-III, Lahore, during its forthcoming meeting.

RRR section

Case No.1 Mandatory Submission of Risk Management Plan (RMP) as a Part of Registration Application Dossier

Pharmacy Services division has informed vide letter dated 10.07.2024 and 12.07.2024 that Drug Regulatory Authority of Pakistan (DRAP) has notified the Pharmacovigilance Rules, 2022, vide S.R.O 540 (I) /2022, dated 22nd of April 2022. Rule 11 (11) of said rules requires the mandatory submission of Risk Management Plans (RMPs) as a part of the registration dossier to the Registration Board for all new drug products. Moreover, the World Health Organization (WHO) team at the time of benchmarking of the DRAP developed the following Institutional Development Plans (IDPs):

Indicator **Institutional Development Plans (IDP)**

Sub-Indicator

VL 04.01:	Implement active surveillance activities. e.g. through the marketing authorization holders, through alliances with universities, with a network of sentinel hospitals, etc., especially define the criteria which would motivate the conduction of an active PV study *(e.g. introduction of new biological, monoclonal or vaccine, a serious event with an unknown occurrence, rare events, events affecting specific populations, etc).*
VL 04.05:	*"Identify high-risk products* that received marketing authorization before the RMP norm entered into effect, and request ad-hoc submission of such plans"
VL 04.07:	"Develop mechanisms (guidelines and/or SOPs) to systematically review the growing body of evidence on efficacy (or lack of) that is published permanently - *particularly with new high-risk products* - that may affect their risk-benefit ratio.

In order to streamline the procedure with the aforementioned rules and IDPs, Divisions of Pharmaceutical Evaluation & Registration and Biological Evaluation & Research has been requested by Pharmacy Services Division to take the necessary measures as per the following details:

a. The RMP should be made a mandatory part of the CTD (Form-5F) application dossier for new drug products including biological and vaccines as per Pharmacovigilance Rules, 2022;

b. Submission of approved RMP by registration holders for new drug products, biologicals and vaccines to the National Pharmacovigilance Centre (NPC) before the sale of drug product should be kept as a condition of registration;

c. Provision of registration letter of new drugs products, biologicals and vaccines to NPC, Pharmacy Services Division for further coordination with registration holders related to pharmacovigilance activities such as submission of Periodic Benefit-Risk Evaluation Report (PBRER) and RMPs etc; and

d. Share a list of new drug products including biological and vaccines registered since 1st January 2022, so that NPC can identify high-risk products for submission of RMP and implementation of active surveillance and benefit-risk assessment.

The division is expecting that necessary action may be taken at the earliest for the timely implementation of IDPs for confirmation by WHO in the upcoming review expected in September / October 2024.

Decision: **Registration Board considered the proposal of Pharmacy Services Division, DRAP regarding mandatory submission of Risk Management Plan (RMP) as part of registration dossier for all new drug products. The Board deliberated that submission of RMP by the registration holders needs to be in line with the requirements laid down by the Reference Regulatory Authorities. Therefore, the Board decided that PE&R Disvion shall frame a guidance document in consultation with Pharmacy Services Division regarding submission of RMP by registration holders for new drug/ biological products.**

Case No. 2 **M/s Himmel Pharmaceuticals (Pvt) Ltd Ground Floor 6-Judcicail Colony Phase 1 Ext. Shahrah-e-Nazria Pakistan Lahore.**

M/s Himmel Pharmaceuticals (Pvt) Ltd located at Ground Floor 6-Judcicail Colony Phase 1 Ext. Shahrah-e-Nazria Pakistan Lahore has requested for renewal of registration of below mentioned anticancer drugs based on following reasons:

a. Request from their principal company.
b. Requirement for participation in tenders in institutions across Pakistan.

Sr. No.	Reg. No.	Brand Name, Composition & Specifications	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	093929	BORTEZOMIB PHARMIDEA 3.5MG (Powder for Solution for Injection) Each vial contains: Bortezomib….3.5mg (as Mannitol Boronic Ester) (As per Innovator's Specifications) **Manufacturer:** M/s. Pharmidea SIA, 4 Rupnicu Street., Olaine, LV-2114, Latvia.	11.12.2018	Rs.30000/- Dy No.11056 Dated.03.05.2023	Renewal is granted w.e.f. 11.12.2023 to 10.12.2028 as per import policy for finished drugs.

Remarks:

CoPP issued by State Agency of Medicines, Republic of Latvia vide No. 1-41/876 dated 20.12.2022.

Shortcomings:

A–pproval of change address of importer as per DSL submitted (Ground Floor 6-Judcicail Colony Phase 1 Ext. Shahrah-e-Nazria Pakistan Lahore.

2.	084811	DOCETAXEL AQVIDA 20MG/ML (Concentrate for solution for IV infusion) Each ml contains: Docetaxel….20 mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany	22.06.2017 Change of Mfg site: 30.09.2019	Rs.30000/- Dy No.6611 Dated.09.03.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027 as per import policy for finished drugs.

		Manufacturer: M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.			
3.	084812	Docetaxel AqVida 80mg/4ml Concentrate for Solution for IV Infusion Each ml contains: Docetaxel …..20 mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:** M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.	22.06.2017 Change of Mfg site: 30.09.2019	Rs.30000/- Dy No.6611 Dated.09.03.2022	Renewal is granted w.e.f. 22.06.2022 to 21.06.2027 as per import policy for finished drugs.

CoPP issued by regulatory Authority of Germany vide No. AQV/05052/13 dated 05.05.2021

4.	085251	OXALIPLATIN AQVIDA 50MG/10ML (Concentrate for solution for IV Infusion) Each ml contains: Oxaliplatin……...5mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:** M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.	31.10.2017 Change of Mfg site: 07.05.2019	Rs.30000/- Dy No.6612 Dated.09.03.2022	Renewal is granted w.e.f. 31.10.2022 to 30.10.2027 as per import policy for finished drugs.
5.	084810	Oxaliplatin AqVida 100mg/20ml Concentrate for solution for IV Infusion	31.10.2017 Change of Mfg site: 07.05.2019	Rs.30000/- Dy No.6612 dated.09.03.2022	Renewal is granted w.e.f. 31.10.2022 to 30.10.2027 as per

		Each ml contains: Oxaliplatin……..5mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:** M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.			import policy for finished drugs.

CoPP issued by regulatory Authority of Germany vide No. AQV/05052/14 dated 05.05.2021

6.	084630	Paclitaxel AqVida 300mg/50ml Concentrate for solution for infusion Each 50ml contains: Paclitaxel…….300mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:** M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.	06.06.2017 Change of Mfg site: 26.06.2019	Rs.30000/- Dy No.6610 Dated.09.03.2022	Renewal is granted w.e.f. 06.06.2022 to 05.06.2027 as per import policy for finished drugs.
7.	084631	Paclitaxel AqVida 100mg/16.7ml Concentrate for solution for infusion Each 16.7ml contains: Paclitaxel…….100mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:**	06.06.2017 Change of Mfg site: 26.06.2019	Rs.30000/- Dy No.6610 Dated.09.03.2022	Renewal is granted w.e.f. 06.06.2022 to 05.06.2027 as per import policy for finished drugs.

		M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.			
8.	084632	Paclitaxel AqVida 30mg/5ml Concentrate for solution for infusion Each 5ml contains: Paclitaxel…….30mg (USP Specifications) **Product License Holder:** M/s. AqVida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany **Manufacturer:** M/s. AqVida GmbH, WerkstraBe, 21 23942 Dassow Germany.	06.06.2017	Rs.30000/- Dy No.6610 Dated.09.03.2022	Renewal is granted w.e.f. 06.06.2022 to 05.06.2027 as per import policy for finished drugs.

CoPP issued by regulatory Authority of Germany vide No. AQV/05051/15 dated 05.05.2021

Case No. 3 M/s Shazeb Pharmaceuticals Industries Limited, Hazara Trunk Road, Sarai Gadaee District Haripur.

The firm has requested for issuance of renewal of registration because for following reasons:

a. Bank LC's
b. Export purpose
c. Government Tenders
d. Defense institutions supplies

Sr. No.	Reg. No.	Brand Name & Composition	Date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	073339	Zee Inject Contains: Water for injection……...10ml (BP Specifications)	06.09.2012	Rs.15000/- Dy No.19206 Dated.30.06.2022	Renewal is granted w.e.f. 06.09.2022 to 05.09.2027

2.	019752	Zeesol H Intravenous Infusion Each 1000ml contains: Calcium Chloride $2H_2O$….0.27gm Potassium Chloride…0.40gm Sodium Chloride….6 gm Sodium Lactate…….2.5 gm	17.07.2007	Rs.15000/- Dy No.19213 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
3.	016610	Zeesol DS Intravenous Infusion Each 1000ml contains: Sodium Chloride……9gm Dextrose Anhydrous…..50gm	17.07.2007	Rs.15000/- Dy No.19212 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
4.	017738	Zeesol DR IV Infusion Each 1000ml contains: Dextrose Anhydrous…...50gm Sodium Lactate…….2.5gm Sodium Chloride….6gm Calcium Chloride $2H_2O$….0.27gm	17.07.2007	Rs.15000/- Dy No.19219 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
5.	017736	Zeesol R IV Infusion Each 1000ml contains: Calcium Chloride….0.33gm Potassium Chloride ….0.30gm Sodium Chloride….8.60gm	17.07.2007	Rs.15000/- Dy No.19208 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
6.	016609	Zeesol NS Intravenous Infusion Each 1000ml contains: Sodium Chloride B.P…..9gm	17.07.2007	Rs.15000/- Dy No.19210 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
7.	016612	Zeesol 10 Intravenous Infusion Each 1000ml contains:	17.07.2007	Rs.15000/- Dy No.19208 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027

		Dextrose anhydrous…..100gm			
8.	016611	Zeesol 5 Intravenous Infusion Each 1000ml contains: Dextrose Anhydrous…..50gm	17.07.2007	Rs.15000/- Dy No.19208 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
9.	017737	Zeelyte-M IV Infusion Each 1000ml contains: Dextrose Anhydrous…...50gm Sodium Acetate …….3.13gm Sodium Chloride…....2.16gm Potassium Chloride....1.50gm Calcium Chloride $2H_2O$…...0.27gm	17.07.2007 Change of BN: 11.06.2014	Rs.15000/- Dy No.19205 Dated.30.06.2022	Renewal is granted w.e.f. 17.07.2022 to 16.07.2027
10.	077458	Zeesol-5% I.V Infusion Each 100 ml contains: Dextrose Anhydrous…...5gm (BP Specifications)	11.10.2013	Rs.15000/- Dy No.23444 Dated.21.09.2023	Renewal is granted w.e.f. 11.10.2023 to 10.10.2028
11.	077459	Zeesol-NS I.V Solution Each 100 ml contains: Sodium chloride…….0.9 gm (BP Specifications)	11.10.2013	Rs.15000/- Dy No.23445 Dated.21.09.2023	Renewal is granted w.e.f. 11.10.2023 to 10.10.2028
12.	076872	Zeelox I.V Infusion Each 100ml contains: Ofloxacin …… 200mg (Manufacturer Specifications)	23.04.2013	Rs.15000/- Dy No.8034 Dated.21.03.2023	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028
13.	076874	Zeelevo I.V Infusion Each 100ml contains: Levofloxacin Hemihydrate eq. to Levofloxacin ….500mg (Manufacturer Specifications)	23.04.2013	Rs.15000/- Dy No.8036 Dated.21.03.2023	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028
14.	076877	Zeesol Paed I.V Infusion Each 100ml contains:	23.04.2013	Rs.15000/- Dy No.8039	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028

		Dextrose (Anhydrous)……..4.30g Sodium Chloride …. 0.18g (BP Specifications)		Dated.21.03.2023	
15.	076873	Zee-Met I.V Infusion Each 100ml contains: Metronidazole …. 500mg (BP Specifications)	23.04.2013	Rs.15000/- Dy No.8035 Dated.21.03.2023	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028
16.	076875	Zeecipro I.V Infusion Each 100ml contains: Ciprofloxacin Lactate eq. to Ciprofloxacin ….. 200mg (BP Specifications)	23.04.2013	Rs.15000/- Dy No.8037 Dated.21.03.2023	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028
17.	76876	Zeesol-1/2 I.V Infusion Each 100ml contains: Dextrose (Anhydrous) …. 5g Sodium Chloride …. 0.45g	23.04.2013	Rs.15000/- Dy No.8038 Dated.21.03.2023	Renewal is granted w.e.f. 23.04.2023 to 22.04.2028
18.	029810	Potassium Chloride Injection Each 20ml contains: Potassium Chloride…...1.492gm Water for injection……q. s	09-06-2009	Rs. 15000/- dated 08.06.2024 vide Tracking ID: N1B-QB3-SD1R	Renewal is granted w.e.f. 09.06.2024 to 08.06.2029
19.	029811	Dextrose-25% Injection Each 20ml contains: Dextrose Anhydrous…..5.00gm Water for injection q.s	09-06-2009	Rs. 15000/- dated 08.06.2024 vide Tracking ID: 3UE-RQ2-QR68	Renewal is granted w.e.f. 09.06.2024 to 08.06.2029
20.	029812	Zee-Inject Injection Each ampoule contains: Water for injection……20ml	09-06-2009	Rs. 15000/- dated 08.06.2024 vide Tracking ID: RVH-EGZ-VB5P	Renewal is granted w.e.f. 09.06.2024 to 08.06.2029
21.	029813	Zeelon-84 Injection Each 20ml contains: Sodium Bicarbonate….1.68gm Water for injection…...q. s	09-06-2009	Rs. 15000/- dated 08.06.2024 vide Tracking ID: ZHB-S19-RSZE	Renewal is granted w.e.f. 09.06.2024 to 08.06.2029

Case No: 4 Submission of new/fresh registration applications after cancellation of registration due to non-submission/ submission of renewal after the prescribed time period as per decision of DRAP Authority in its 180th meeting

The DRAP Authority in its180th meeting held on 07th March 2024 while considering the application of M/s Gray's Pharmaceuticals Rawat decided as under:

> *"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:*
>
> *i) Shall be considered out-of-queue and*
> *ii) Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1) /2018 dated 08th June, 2018.*
>
> *2. No such cases shall be forwarded to the Authority and shall be decided on the same analogy by the Division of PE&R and BE&R.*

Keeping in view the above decision of the following new registration applications have been submitted on Form-5:

i) M/s. Shazal's Pharmaceuticals, Plot No. 41/1-A-1 Phase-I Industrial Estate Hattar.

1.	Brand Name + Dosage Form and Strength	Ebison Tablet 10mg
	Composition	Each tablet contains:- Ebastine… 10mg
	Dairy No. date of R &I fee	6534 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	JP Specifications
	Pack size and Demand Price	As per SRO, 10x1s
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Ebison Tablet 10mg (043798) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved	
2.	Brand Name + Dosage Form and Strength	Cehrin Suspension 250mg/5ml
	Composition	Each 5ml contains:- Cephradine (as dihydrate)… 250mg
	Dairy No. date of R &I fee	6533 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, pack if 1's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Cehrin Suspension 250mg/5ml (043796) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Reference formulation is approved in RRA as base.	
	Decision: Approved with following label:	

	Each 5ml contains: **Cephradine…...125mg** **The firm shall submit Rs. 30000/- for correction in salt form as pre-registration variation.**	
3.	Brand Name + Dosage Form and Strength	Cehrin Suspension 125mg/5ml
	Composition	Each 5ml contains:- Cephradine… 125mg
	Dairy No. date of R &I fee	6532 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Cehrin Suspension 125mg/5ml (043795) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Remarks: Formulation is not registered in RRA. **Decision:** Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. a. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. b. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. c. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.	
4.	Brand Name + Dosage Form and Strength	Cehrin Capsule 250mg
	Composition	Each capsule contains: Cephradine… 250mg
	Dairy No. date of R &I fee	6531 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Not provided
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Cehrin Capsule 250mg (043794) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved with following label: **Each capsule contains:** **Cephradine…...250mg** **The firm shall submit Rs. 30000/- for correction in salt form as pre-registration variation.**	
	Decision: Approved	
	Brand Name + Dosage Form and	Cehrin Capsule 500mg

5.	Strength	
	Composition	Each capsule contains:- Cephradine as dihydrate… 500mg
	Dairy No. date of R &I fee	6530 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, not provided
	GMP Status	
	Remark of the Renewal section	Registration of Cehrin Capsule 250mg (043793) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Reference formulation is approved in RRA as base or monohydrate.	
	Decision: Approved with following label: **Each capsule contains:** **Cephradine…...500mg** **The firm shall submit Rs. 30000/- for correction in salt form as pre-registration variation**	
6.	Brand Name + Dosage Form and Strength	Famocin Tablet 20mg
	Composition	Each film coated tablet contains:- Famotidine… 20mg
	Dairy No. date of R &I fee	6529 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 20,s
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Famocin Tablet 20mg (043792) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved	
7.	Brand Name + Dosage Form and Strength	Famocin Tablet 40mg
	Composition	Each film coated tablet contains:- Famotidine… 40mg
	Dairy No. date of R &I fee	6528 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 20,s
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Famocin Tablet 40mg (043791) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
8.	Brand Name + Dosage Form and Strength	Zelprox-550 Tablet
	Composition	Each film coated tablet contains:- Naproxen Sodium eq.to Naproxen sodium…..500mg
	Dairy No. date of R &I fee	6527 dated 28.06.2024

		Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10,s
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Zelprox-550 Tablet (043789) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
9.	Brand Name + Dosage Form and Strength	Frogesic Tablet 100mg
	Composition	Each film coated tablet contains:- Flubiprofen… 100mg
	Dairy No. date of R &I fee	6526 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10,s
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Frogisic Tablet 100mg (043790) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
10.	Brand Name + Dosage Form and Strength	Biocox Tablet 7.5mg
	Composition	Each tablet contains:- Meloxicam… 7.5mg
	Dairy No. date of R &I fee	6525 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Biocox Tablet 7.5mg (043788) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved	
11.	Brand Name + Dosage Form and Strength	Biocox Tablet 15mg
	Composition	Each tablet contains: Meloxicam… 15mg
	Dairy No. date of R &I fee	6524 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Biocox Tablet 155mg (043787) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.

	Decision: Approved	
12.	Brand Name + Dosage Form and Strength	Dikan-50 Tablet
	Composition	Each film coated tablet contains:- Diclofenac Potassium… 50mg
	Dairy No. date of R &I fee	6523 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Dikan-50 Tablet (043785) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
13.	Brand Name + Dosage Form and Strength	Klarid Tablet 500mg
	Composition	Each film coated tablet contains:- Clarithromycin … 500mg
	Dairy No. date of R &I fee	6522 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Klarid Tablet 500mg (043782) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
14.	Brand Name + Dosage Form and Strength	Klarid Tablet 250mg
	Composition	Each film coated tablet contains: Clarithromycin … 250mg
	Dairy No. date of R &I fee	6521 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Klarid Tablet 250mg (043781) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
15.	Brand Name + Dosage Form and Strength	Dic-50 Tablet
	Composition	Each enteric coated tablet contains: Diclofenac Sodium… 50mg
	Dairy No. date of R &I fee	6520 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications

	Pack size and Demand Price	As per SRO, Pack of 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Dic-50 Tablet (043784) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved	
16.	Brand Name + Dosage Form and Strength	Ometon Capsules 20mg
	Composition	Each capsule contains:- Omeprazole (as enteric coated pellets)...20mg
	Dairy No. date of R &I fee	6518 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 2x7's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Ometon cap 20mg (044541) cancelled vide DRAP letter No. 3-5/2021-RRR (M-312) dated 10.12.2021 due to non-submission of renewal in prescribed time period.
	Remarks: Source of pellets is not submitted.	
	Decision: Approved. The firm shall submit the source of pellets before issuance of registration letter.	
17.	Brand Name + Dosage Form and Strength	Zyacef Capsule 400mg
	Composition	Each capsule contains: Cefixime as trihydrate…400mg
	Dairy No. date of R &I fee	6511 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Zyacef Capsule 400mg (043814) cancelled vide DRAP letter No. 3-5/2021-RRR (M-312) dated 10.12.2021 due to non-submission of renewal in prescribed time period.
	Decision: Approved with manufacturer specifications as per decision of registration Board in its 313rd meeting.	
18.	Brand Name + Dosage Form and Strength	Folicose Tablet 100mg
	Composition	Each chewable tablet contains: Iron Polymaltose Complex eq. to Elemental Iron…100mg Folic Acid…0.35mg
	Dairy No. date of R &I fee	6516 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacture Specifications
	Pack size and Demand Price	As per SRO,
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Folicose Tablet 100mg (043804) cancelled vide DRAP letter No. 3-5/2021-RRR (M-312) dated

		10.12.2021 due to non-submission of renewal in prescribed time period.
	Decision: Approved	
19.	Brand Name + Dosage Form and Strength	Zyacef 100mg/5ml Suspension
	Composition	Each 5ml contains:- Cefixime as Trihydrate….100mg.
	Dairy No. date of R &I fee	6515 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s
	GMP Status	
	Remark of the Renewal section	Registration of Zyacef 100mg/5ml Suspension (043797) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
20.	Brand Name + Dosage Form and Strength	Deslorate 5mg tablet
	Composition	Each tablet contains: Desloratadine… 5mg
	Dairy No. date of R &I fee	6514 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Deslorate 40mg tab (044542) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
21.	Brand Name + Dosage Form and Strength	Esozole Capsule 20mg
	Composition	Each capsule contains: Esomeprazole Pellets (as Magnesium Trihydrate… 20mg
	Dairy No. date of R &I fee	6513 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 2x7's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Esozole Capsule 20mg (044539) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Source of pellets not submitted.	
	Decision: Approved. The firm shall submit the source of pellets before issuance of registration letter.	
22.	Brand Name + Dosage Form and Strength	Esozole Capsule 40mg
	Composition	Each capsule contains: Esomeprazole Pellets (as Magnesium Trihydrate… 40mg

	Dairy No. date of R &I fee	6512 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 2x7's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Esozole Capsule 40mg (044538) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Remarks: Source of pellets not submitted.	
	Decision: Approved. The firm shall submit the source of pellets before issuance of registration letter.	
23.	Brand Name + Dosage Form and Strength	Azimal Tablet 250mg
	Composition	Each film coated tablet contains: Azithromycin as Dehydrate… 250mg
	Dairy No. date of R &I fee	6511 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Azimal Tablet 250mg (043812) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
24.	Brand Name + Dosage Form and Strength	Zytizine Tablet 10mg
	Composition	Each film coated tablet contains: Cetirizine Dihydrochloride… 10mg
	Dairy No. date of R &I fee	6510 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10 & 14's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Zytizine Tablet 10mg (043811) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
25.	Brand Name + Dosage Form and Strength	Tinic Tablet 4mg
	Composition	Each tablet contains: Tizanidine as HCl… 4mg
	Dairy No. date of R &I fee	6509 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 1s Vial
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP

		letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Tinic Tablet 4mg (043810) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
26.	Brand Name + Dosage Form and Strength	Tinic Tablet 2mg
	Composition	Each tablet contains: Tizanidine as HCl… 2mg
	Dairy No. date of R &I fee	6508 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Tinic Tablet 2mg (043809) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
27.	Brand Name + Dosage Form and Strength	Estram Tablet 10mg
	Composition	Each film coated tablet contains: Escitalopram as oxalate…10mg
	Dairy No. date of R &I fee	6507 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 10 & 14's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Estram Tablet 10mg (043808) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
28.	Brand Name + Dosage Form and Strength	Esocare Tablet 20mg
	Composition	Each enteric coated tablet contains:- Esomeprazole (as Magnesium Trihydrate)… 20mg
	Dairy No. date of R &I fee	6505 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	As per SRO, 2x7's
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Esocare Tablet 20mg (043799) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
29.	Brand Name + Dosage Form and Strength	Esocare Tablet 40mg
	Composition	Each enteric coated tablet contains:- Esomeprazole (as Magnesium Trihydrate)… 40mg

	Dairy No. date of R &I fee	6504 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 2x7'ss
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Esocare Tablet 40mg (043800) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Decision: Approved	
30.	Brand Name + Dosage Form and Strength	Voltrec Capsule 50mg
	Composition	Each capsule contains: Diclofenac Sodium… 50mg
	Dairy No. date of R &I fee	6506 dated 28.06.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	As per SRO, 1s Vial
	GMP Status	Panel inspection report for renewal of DML w.r.t DRAP letter dated 17.11.2022 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Voltrec Capsule 50mg (043806) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2014 in prescribed time period.
	Remarks: Source of pellets is required.	
	Decision: Approved. The firm shall submit the source of pellets before issuance of registration letter.	

ii) M/s. Sarco Chemical Industries 17th KM Peerwala Morr Qader Pur Ran, Khanewal Road District Multan.

31.	**Brand Name + Dosage Form and Strength**	**Tincture Iodine Mitis**
	Composition	Each 1000ml contains:- Iodine……25gm Potassium Iodide……..25gm Water……100ml Alcohol (90%) to produce 1000ml
	Dairy No. date of R &I fee	Dy No.7275 dated 19.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	50ml, 450ml As per SRO,
	GMP Status	Panel inspection report dated 01.06.2022 recommends the renewal of DML
	Remark of the Renewal section	Registration of Tincture Iodine Mitis (006888) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 as renewal applied after prescribed time period for year 2014.
	Decision: Approved.	
32.	**Brand Name + Dosage Form and Strength**	**Lugol's Iodine Solution**

	Composition	Each ml contains: Potassium Iodide …10gm
	Dairy No. date of R &I fee	7274 dated 19.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 25ml
	GMP Status	Panel inspection report dated 01.06.2022 recommends the renewal of DML
	Remark of the Renewal section	Registration of Lugol's Iodine Lotion (021674) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to renewal application was submitted after prescribed time period
	Decision: Approved.	
33.	**Brand Name + Dosage Form and Strength**	**Tincture Bezoin Co.**
	Composition	Each 1000ml contains: Bezoin crushed ….100gm Prepared Storax…...75gm Tolu Balsam …...75gm Aloes……20gm Alcohol 90% to produce 1000ml
	Dairy No. date of R &I fee	7204 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 50ml and 450ml
	GMP Status	Panel inspection report dated 01.06.2022 recommends the renewal of DML
	Remark of the Renewal section	Registration of Tincture Bezoin Co. (006887) was invalid due to late submission of renewal of 2014. Date of Registration: 12.12.1983 Renewal Trail: 03.03.2014, 12.03.2019, 08.12.2023
	Decision: Approved.	
34.	**Brand Name + Dosage Form and Strength**	**Hydrogen Peroxide Solution 6%**
	Composition	Each 1000ml contains: Hydrogen Peroxide …6% Purified water to produce…1000ml
	Dairy No. date of R &I fee	7202 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 120ml and 450ml
	GMP Status	Panel inspection report dated 01.06.2022 recommends the renewal of DML
	Remark of the Renewal section	Registration of Hydrogen Peroxide Solution 6% (006886) was invalid due to late submission of renewal of 2014. Date of Registration: 12.12.1983 Renewal Trail: 03.03.2014, 12.03.2019, 08.12.2023

	Decision: Approved.	
35.	**Brand Name + Dosage Form and Strength**	**Icthamol Glycerin**
	Composition	Each 100gm contains: Icthahmol……10gm Glycerin…..90gm
	Dairy No. date of R &I fee	7203 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BPC Specifications
	Pack size and Demand Price	As per SRO, 50gm & 450gm
	GMP Status	Panel inspection report dated 01.06.2022 recommends the renewal of DML
	Remark of the Renewal section	Registration of **Icthamol Gycerin** (006885) was invalid due to late submission of renewal of 2014. Date of Registration: 12.12.1983 Renewal Trail: 03.03.2014, 12.03.2019, 08.12.2023
	Decision: Approved.	

iii) M/s. Sharex Laboratories (Pvt) Ltd., KLP Road Sharex Colony Sadiqabad District Rahim Yar Khan

36.	Brand Name + Dosage Form and Strength	Hepa Wel Syrup
	Composition	Each 5ml contains: L-Ornithine L Aspartate… 300mg Riboflavin 5 Phosphate … 0.76mg Nicotinamide… 24mg
	Dairy No. date of R &I fee	Dy No.7368 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	120ml, Rs. 475/-
	GMP Status	Panel inspection report dated 13.04.2021 & 14.04.2021 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Hepa Wel Syrup (019741) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 due to non-submission of renewal of 2016 in prescribed time period.
	Decision: Approved.	

iv) M/s. Leama Chemi Pharma (Pvt) Ltd.37-A, Industrial Estate Jamrud Road, Peshawar.

37.	Brand Name + Dosage Form and Strength	Leket Syrup
	Composition	Each 5ml contains: Ketotifen (as Hydrogen Fumarate) …...1mg
	Dairy No. date of R &I fee	Dy No.7369 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specifications

	Pack size and Demand Price	60ml glass bottle, As per SRO,
	GMP Status	
	Remark of the Renewal section	Registration of Leket Syrup (020946) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 01.06.2022 due to renewal application was submitted after prescribed time period
	Remarks: GMP and section approvals not submitted.	
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate.	
38.	Brand Name + Dosage Form and Strength	Medile Suspension
	Composition	Each 10ml contains: Metronidazole as benzoate…...200mg Diloxanide Furoate...…..250mg
	Dairy No. date of R &I fee	7371 dated 19.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	60ml glass vial, As per SRO,
	GMP Status	
	Remark of the Renewal section	Registration of Medile Suspension (031189) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 01.06.2022 due to renewal application was submitted after prescribed time period
	Remarks: Formulation is not available in RRA. GMP and section approvals not submitted. Evidence of testing facilities for EG/PG for glycerin.	
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate.	
39.	Brand Name + Dosage Form and Strength	Lemazole Suspension
	Composition	Each 5 ml of suspension contains: Metronidazole benzoate equivalent to metronidazole 200 mg.
	Dairy No. date of R &I fee	7370 dated 23.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO, 60ml glass bottle
	GMP Status	Not provided
	Remark of the Renewal section	Registration of Lemazole Suspension (031188) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 01.06.2022 due to non-submission of renewal application of year 2018.
	Remarks: GMP and section approvals not submitted. Evidence of testing facilities for EG/PG for glycerin.	
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate.	

v) M/s. Fozan Pharmaceuticals Industries, 36-A Industrial Estate Hayatabad, Peshawar.

40.	Brand Name + Dosage Form and Strength	Pedia Fresh Liquid 500ml
	Composition	Sodium Chloride…1.75gm. Trisodium Citrate Dihydrate…1.45gm Potassium Chloride…0.75gm. Dextrose Anhydrous..…10gm.
	Dairy No. date of R &I fee	Dy No.7482 dated 25.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	500ml bottle, As per SRO
	GMP Status	Not submitted
	Remark of the Renewal section	Registration of Pedia Fresh Liquid 500ml (064266) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 due to renewal application was submitted after prescribed time period
	Decision: Approved. Registration letter shall be issued after submission of valid GMP certificate.	

vi) M/s. Crystolite Pharmaceuticals, Plot # 1&2, S-2, National industrial Zone Rawat, Islamabad.

41.	Brand Name + Dosage Form and Strength	Folligro 2% (w/v) Solution
	Composition	Each ml contains:- Minoxidil… 20mg
	Dairy No. date of R &I fee	3816 dated 05.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	60ml, As per SRO
	GMP Status	Panel inspection report dated 14.12.2023 recommended the renewal of DML including topical lotion section.
	Remark of the Renewal section	Registration of Folligro 2% Solution (80815) is invalid due to non-submission of renewal for year 2021
	Decision: Approved.	

vii) M/s Novartana pharmaceuticals of **87- B Sunder Industrial Estate Raiwind Lahore**

42.	Brand Name + Dosage Form and Strength	AVANIC 500MG TABLET
	Composition	Each film coated tablet contains Levofloxacin as hemihydrate….500mg
	Dairy No. date of R &I fee	Dy No.7585 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10s, As per SRO

	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Registration of Avanic 500mg tablet (074106) is invalid due to non-submission of renewal of 2022.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
43.	Brand Name + Dosage Form and Strength	AVANIC 250MG TABLET
	Composition	Each film coated tablet contains Levofloxacin as hemihydrate….250mg
	Dairy No. date of R &I fee	Dy No.7588 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Avanic 500mg tablet (074105) is invalid** due to non-submission of renewal of 2022
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
44.	Brand Name + Dosage Form and Strength	NOVAFER SYRUP
	Composition	Each 5ml contains: Iron (III) Hydroxide Polymaltose Complex Eq. to Elemental Iron……50mg
	Dairy No. date of R &I fee	Dy No.7577 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	60ml, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Novafer syrup (074102)** due to non-submission of renewal of 2022 in prescribed time period.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
45.	Brand Name + Dosage Form and Strength	PARACETAMOL SYRUP
	Composition	Each 5ml contains: Paracetamol……120mg
	Dairy No. date of R &I fee	Dy No.7584 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP specifications

	Pack size and Demand Price	60ml, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: Not available in database Registration of **Paracetamol syrup (074103)** due to non-submission of renewal of 2022 in prescribed time period.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
46.	Brand Name + Dosage Form and Strength	NOVAMAX 250MG CAPSULE
	Composition	Each capsule contains: Azithromycin (as dihydrate) ……250mg
	Dairy No. date of R &I fee	Dy No.7578 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	10s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Novamax 250mg capsule (074104) is invalid** due to non-submission of renewal of 2022
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
47.	Brand Name + Dosage Form and Strength	CIPRON TABLET 500MG
	Composition	Each film coated tablet contains: Ciprofloxacin (as HCl)…...500mg
	Dairy No. date of R &I fee	Dy No.7576 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	10s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Cipron tablet (074107)** is invalid due to non-submission of renewal of 2022.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
48.	Brand Name + Dosage Form and Strength	DICLONOV TABLET 50MG
	Composition	Each enteric coated tablet contains: Diclofenac sodium….50mg
	Dairy No. date of R &I fee	Dy No.7579 dated 26.07.2024 Rs.30000/-

	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	2x10s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Diclonov tablet (074108) is invalid** due to non-submission of renewal of 2022.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
49.	Brand Name + Dosage Form and Strength	INE-ZONE TABLET 0.5MCG
	Composition	Each tablet contains Alfacalcidol….0.5mcg
	Dairy No. date of R &I fee	Dy No.7580 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	10s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of reg:17.09.2012 Renewal: 09.01.2018 Registration of **Ine-zone tablet (074109)** due to non-submission of renewal of 2022 in prescribed time period.
	Decision: Approved subject to submission of valid GMP certificate or panel GMP inspection report.	
50.	Brand Name + Dosage Form and Strength	ESPOLE CAPSULE 40MG
	Composition	Each Capsule contains Esomeprazole as magnesium trihydrate (pallets)…..40mg
	Source of Pellets	M/s Spansules Formulations, Plot No. 154/A4 IDA Bollaram Medak District Hyderabad India
	Dairy No. date of R &I fee	Dy No.7583 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Novartana specifications
	Pack size and Demand Price	2.7s, As per SRO
	GMP Status	
	Remark of the Renewal section	Date of Reg: 19.12.2012 Renewal: 09.01.2018 Registration of Espole capsule (074219) is invalid due to non-submission of renewal of 2022.
	Remarks: Differential fee Rs. 270000 as imported source mentioned above was fixed at the time of registration. GMP certificate of source of pellets by regulatory authority of Austria.	
	Approved. The firm shall submit following before issuance of registration letter. **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration**	

	letter. **b. Valid legalized GMP certificate issued by regulatory authority of India to M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.** **c. Valid GMP certificate or panel inspection report.**	
51.	Brand Name + Dosage Form and Strength	ESPOLE CAPSULE 20MG
	Composition	Each capsule contains Esomeprazole as magnesium trihydrate (Pellets)…..20mg **Source of pellets:** M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.
	Dairy No. date of R &I fee	Dy No.7582 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	2x7s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML
	Remark of the Renewal section	Date of Reg: 19.12.2012 Renewal: 09.01.2018 Registration of **Espole capsule (074220) is invalid** due to non-submission of renewal of 2022.
	Remarks: Differential fee Rs. 270000 as imported source mentioned above was fixed at the time of registration. GMP certificate of source of pellets by regulatory authority of India.	
	Approved. The firm shall submit following before issuance of registration letter. **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration letter.** **b. Valid legalized GMP certificate issued by regulatory authority of India to M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.** **c. Valid GMP certificate or panel inspection report.**	
52.	Brand Name + Dosage Form and Strength	OPOLE CAPSULE 40MG
	Composition	Each Capsule contains Omeprazole as enteric coated (Pellets)…...40mg **Source of pellets:** M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.
	Dairy No. date of R &I fee	Dy No.7586 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	2x7s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of Reg: 19.12.2012 Renewal: 09.01.2018 Registration of Opole capsule (074221) is invalid due to

		non-submission of renewal of 2022.
	Remarks: Differential fee Rs. 270000 as imported source mentioned above was fixed at the time of registration. GMP certificate of source of pellets by regulatory authority of India.	
	Approved. The firm shall submit following before issuance of registration letter. **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration letter.** **b. Valid legalized GMP certificate issued by regulatory authority of India to M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.** **c. Valid GMP certificate or panel inspection report.**	
53.	Brand Name + Dosage Form and Strength	OPOLE CAPSULE 20MG
	Composition	Each Capsule contains Omeprazole As enteric coated (pellets)…..20mg **Source of pellets:** M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.
	Dairy No. date of R &I fee	Dy No.7581 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	14s, As per SRO
	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of Reg: 19.12.2012 Renewal: 09.01.2018 Registration of Opole capsule (074222) is in valid due to non-submission of renewal of 2022.
	Remarks: Differential fee Rs. 270000 as imported source mentioned above was fixed at the time of registration. GMP certificate of source of pellets by regulatory authority of India.	
	Approved. The firm shall submit following before issuance of registration letter. **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration letter.** **b. Valid legalized GMP certificate issued by regulatory authority of India to M/s Spansules Formulations, Plot No. 154/A4, IDA, Bollram Medak District, Hyderabad India.** **c. Valid GMP certificate or panel inspection report.**	
54.	Brand Name + Dosage Form and Strength	FABLAC SYRUP
	Composition	Each 5ml contains Lactulose…3.35gm **Source of bulk:** M/s Fresenuis Kabi Austria GmbH
	Dairy No. date of R &I fee	Dy No.7587 dated 26.07.2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP specifications
	Pack size and Demand Price	120ml, As per SRO

	GMP Status	Panel inspection report dated 24.08.2023 recommends the renewal of DML.
	Remark of the Renewal section	Date of Reg: 19.12.2012 Renewal: 09.01.2018 Registration of **Fablac syrup (074223)** due to non-submission of renewal of 2022 in prescribed time period.
	Remarks: Differential fee Rs. 270000 as imported source mentioned above was fixed at the time of registration. GMP certificate of source of pellets by regulatory authority of Austria.	
	Approved. The firm shall submit following before issuance of registration letter. **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration letter.** **b. Valid legalized GMP certificate issued by regulatory authority of Austria to M/s Fresenius Kabi Austria GmbH.** **c. Valid GMP certificate or panel inspection report.**	

vii) M/s. Roryan Pharmaceuticals, Industries (Pvt) Ltd, 85/B Hayatabad Industrial Estate Peshawar.

55.	Brand Name + Dosage Form and Strength	Paracetol 500mg Tablet
	Composition	Each tablet contains: Paracetamol…500mg
	Dairy No. date of R &I fee	Dy No.7505 dated 25-07-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	BP Specification
	Pack size and Demand Price	As per SRO,
	GMP Status	GMP Certificate issued by DRAP Peshawar on 17.06.2022.
	Remark of the Renewal section	Registration of Paracetol 500mg Tablet(059421) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 as application was submitted after prescribed time period
	Decision: Approved.	
56.	Brand Name + Dosage Form and Strength	Rovidol Tablet
	Composition	Each tablet contains: Paracetamol……..500mg Caffeine……65mg Chlorpheniramine Maleate…2mg
	Dairy No. date of R &I fee	Dy No.7506 dated 25-07-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer Specifications
	Pack size and Demand Price	As per SRO, 10x10's and 10x20's
	GMP Status	GMP Certificate issued by DRAP Peshawar on 17.06.2022.
	Remark of the Renewal section	Registration of Rovidol Tablet (059422) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 as application was submitted after prescribed time period
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance	

	of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. d. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. e. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. f. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. g. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.	
57.	Brand Name + Dosage Form and Strength	Esoyan-40mg Capsule
	Composition	Each Capsule Contains: Esomeprazole Magnesium Trihydrate eq. to coated pellets)…40mg **Source of pellets:** M/s Smilax Laboratories Ltd., Plot No. 88/A, Flat 401, Sarala Niwas, Street No. 1 Sagar Society, R. No.02, Banjra Hills Hyderabad.
	Dairy No. date of R &I fee	Dy No.7699 dated 30-07-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO, 14's
	GMP Status	GMP Certificate issued by DRAP Peshawar on 17.06.2022.
	Remark of the Renewal section	Registration of Esoyan-40mg Capsule (060088) cancelled vide DRAP letter No. 3-8/2022-RRR (M-317) dated 05.07.2022 as application was submitted after prescribed time period
Remarks: Differential fee as imported source approved as per registration letter. GMP certificate of M/s Smilax Laboratories Ltd issued by regulatory authority of India.		
Decision: **Approved. The firm shall submit following before issuance of registration letter.** **a. Differential fee of Rs. 270000/- being imported source of pellets as per initial registration letter.** **b. Valid legalized GMP certificate issued by regulatory authority of India for M/s Smilax Laboratories Ltd., Plot No. 88/A, Flat 401, Sarala Niwas, Street No. 1 Sagar Society, R. No.02, Banjra Hills Hyderabad.** **c. Valid GMP certificate or panel inspection report.**		
58.	Brand Name + Dosage Form and Strength	Mospro DS Tablet
	Composition	Each tablet contains:- Artemether…40mg Lumefantrine….240mg
	Dairy No. date of R &I fee	Dy No.7698 dated 30-07-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Mospro DS Tablet (059420) cancelled vide DRAP letter No. 3-5/2022-RRR (M-312) dated 10.12.2021 as application was submitted after prescribed time period
Decision:		

Approved with International Pharmacopeia Specifications. The firm shall submit 7500/- fee as pre-registration variation before issuance of registration letter.

viii) M/s. Gray's Pharmaceuticals Plot #.2, Street # N3, National industrial Zone Rawat, Islamabad.

59.	Brand Name + Dosage Form and Strength	**Cephagray 250gm suspension**
	Composition	Each 5ml after reconstitution contains: Cephradine……250mg
	Dairy No. date of R &I fee	Dy No.7949 dated:02-08-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO,
	GMP Status	
	Remark of the Renewal section	Registration of Cephagray 250gm suspension (041703) is invalid due to non-submission of renewal application in year 2020.
	Decision: Approved	
60.	Brand Name + Dosage Form and Strength	**Cephagray 125gm suspension**
	Composition	Each 5ml after reconstitution contains: Cephradine……125mg
	Dairy No. date of R &I fee	Dy No.7948 dated:02-08-2024 Rs.30000/-
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO,
	GMP Status	
	Remark of the Renewal section	Registration of Cephagray 125gm suspension (041702) is valid due to non- submission of renewal application in year 2020
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. a) Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. b) Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. c) Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. d) Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.	

As per facts mentioned in minutes of 313rd and 316th 327th meeting of Registration Board, it is submitted that the firm on 10.10.2011 requested for transfer of registration of their registered products from existing facility i.e. M/s Grays Pharmaceuticals Plot No. 442 Street No. 7 Sect I-9/s2 Industrial Area Islamabad to their new licensed manufacturing facility i.e. M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National

Industrial Zone Rawat, which was granted DML vide approval No. 1-7/2008-Lic dated 22.06.2008. Accordingly, the request of the firm was considered in 233rd meeting of Registration Board held on 15.06.2012 wherein the Board decided to accede the request of for transfer of registrations to M/s Grays Pharmaceuticals Rawat from M/s Grays Pharmaceuticals Islamabad subject to fulfillment of latest fee requirements and confirmation of sections. As per decision of the Board the firm submitted the requisite fee. However, the letter of transfer of registration to new facility couldn't be issued. The registration letters of other products based on approval of 233rd meeting of Registration Board had been issued after approval by the Board in above mentioned meetings but these above products were deferred for confirmation of renewal submission and PRV approvals if any. Now the firm has submitted above applications in light the decision of the Authority in its 180th meeting.

Case No: 5 Renewal application submitted after due date but within sixty days under Rule 27 of Drug (LR&A) Rules 1976 by M/s Liven Pharmaceuticals (Pvt) Ltd.49-km, Multan Road, Lahore

Sr. No.	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	091546	Oma 40mg capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……40mg (USP Specification) **Source of Pellets:** M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
2.	091545	Oma 20mg capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole…20mg (USP Specification) **Source of Pellets:** M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
3.	091544	Livocetamol 1g/100ml infusion Each ml contains Paracetamol…...10mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
4.	091543	Livgyl 500mg/100ml Infusion Each ml contains: Metronidazole….5mg (BP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
5.	091542	Defung 100mg/50ml Infusion Each ml contains: Fluconazole….2mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
6.	091541	Ofon 200mg/100ml Infusion Each ml contains: Ofloxacin…2mg	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

		(As per innovators Specification)			
7.	091540	Levon 500mg/100ml infusion Each ml contains: Levofloxacin (as hemihydrate) ….5mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
8.	091539	Renoval 400mg/250ml infusion Each ml contains: Moxifloxacin (as hydrochloride) ….1.6mg (As per innovator's Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
9.	091538	Diclosed 75mg/3ml Injection Each ml contains: Diclofenac sodium….25mg (As per Innovator's Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
10.	091537	L-D3 5mg/ml Injection Each ml contains: Cholecalciferol…5mg (BP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
11.	091536	Nalax 0.4mg/ml Injection Each ml contains: Naloxone as HCl…0.4mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
12.	091535	Ondaset 2mg/ml Injection Each ml contains: Ondansetron…2mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
13.	091534	Ketoliv 30mg/ml Injection Each ml contains: Ketorolac Tromethamine…30mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
14.	091533	Ketolive 10mg/ml Injection Each ml contains: Ketorolac Tromethamine….10mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
15.	091532	N-Bin 10mg/ml Injection Each ml contains: Nalbuphine HCl….10mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
16.	091531	N-Bin 20mg/ml Injection Each ml contains: Nalbuphine HCl…20mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
17.	091530	Ondaset 4mg/2ml Injection IM/IV Each ml contains Ondansetron as hydrochloride…2mg	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

		(USP Specification)			
18.	091529	Livobal 500mcg/ml Injection Each ml contains: Mecobalamin..500mcg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
19.	091527	Daizelive 10mg/2ml Injection Each ml contains: Diazepam…5mg (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
20.	091526	Topas Sachet 135mg/3.5gm Each sachet contains; Mebeverine…….135 mg Psyllium Husk….3.5 g	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
21.	091525	Stran Sachet 2gm Each sachet contains: Strontium ranelate…2gm (As per innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
22.	091524	Livair Sachet 4mg Each sachet contains: Montelukast sodium granules eq. to Montelukast….4mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
23.	091523	Lenvir 1mg Tablets Each film coated tablet contains: Entecavir (as monohydrate)…1mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
24.	091522	Lenvir 0.5mg Tablets Each film coated tablet contains: Entecavir (as monohydrate) …0.5mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
25.	091521	Napolive 500mg Tablets Each film coated tablet contains: Naproxen……500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
26.	091520	Napolive 250mg Tablets Each film coated tablet contains: Naproxen…….250mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
27.	091519	Ciprotab 500mg tablet Each film coated tablet contains: Ciprofloxacin (as HCl)…….500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
28.	091518	Ciprotap 250mg Tablet Each film coated tablet contains: Ciprofloxacin (as HCl) ….250mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
29.	091517	Aril 10mg Tablets	24.07.2018	Dy No.19276	

		Each film coated tablet contains: Cetirizine 2HCl eq. to Cetirizine….10mg (BP Specification)		Rs.15000/- dated 02.08.2023	
30.	091516	Livazole 2.5mg Tablets Each film coated tablet contains: Letrozole…2.5mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
31.	091515	Atavast 40mg Tablets: Each film coated tablet contains: Atorvastatin (as calcium trihydrate)….40mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
32.	091514	Atavast 20mg Tablets Each film coated tablet contains: Atorvastatin (as calcium trihydrate) … 20mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
33.	091513	Atavast 10mg Tablets Each film coated tablet contains: Atorvastatin (as calcium trihydrate)10mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
34.	091512	Rvastine 20mg Tablets Each film coated tablet contains: Rosuvastatin (as Rosuvastatin calcium) … 20mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
35.	091511	Rvastine 10mg Tablets Each film coated tablet contains: Rosuvastatin (as Rosuvastatin calcium) ….10mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
36.	091510	Rvastine 5mg Tablets Each film coated tablet contains Rosuvastatin (as Rosuvastatin calcium)……5mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
37.	091509	Renoval 400mg Tablets Each film coated tablet contains: Moxifloxacin (as hydrochloride) …400mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
38.	091508	Levon 500mg Tablet Each film coated tablet contains: Levofloxacin (as hemihydrate) …500mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
39.	091507	Levon 250mg Tablet	24.07.2018	Dy No.19276	

		Each film coated tablet contains: Levofloxacin (as hemihydrate) …250mg (USP Specification)		Rs.15000/- dated 02.08.2023	
40.	091506	Livadine 60mg capsule Each capsule contains: Fexofenadine…60mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
41.	091505	Livoxetine 20mg capsule Each capsule contains: Fluoxetine hydrochloride….20mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
42.	091504	Grepalin 50mg capsule Each capsule contains: Pregabalin….50mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
43.	091503	Grepalin 100mg capsule Each capsule contains: Pregabalin….100mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
44.	091502	Grepalin 75mg capsule Each capsule contains: Pregabalin…..75mg (As per Innovators Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
45.	091501	Pentilive 300mg capsule Each capsule contains: Gabapentin...300 mg (USP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	
46.	091500	Defung 150mg capsule Each capsule contains: Fluconazole…150mg (JP Specification)	24.07.2018	Dy No.19276 Rs.15000/- dated 02.08.2023	

Shortcomings (F. No.3-1/2023 (Renewal) dated 15.08.2023)	**Reply Dy No.21650 dated 01.09.2023**
i. Differential fee of Rs. 15000/- each is required under DRAP Notification No. F.7-11/2012 B&A/DRAP dated 07.05.2021 as renewal applications for year 2023 was submitted after due date. ii. Evidence of purchase, IQ, OQ & PQ of Liquid Particle Counter and TOC Analyser as per condition of registration. Testing details need to be submitted as evidence. iii. Copy of valid DML. iv. Copy of section approval letters issued by Licensing Disvion.	The firm has submitted the copy of request letter to CEO DRAP dated 02.08.2023 for justification of 3days delay due in accessibility to www.fee.dra.gov.pk and in ability to generate fee challans for submission, and it was neither in our power nor approach to use any alternate method. The detail of the letter is as under: *"There were holidays for Ashura and then Islamabad local holidays due to a visit of his Excellency Deputy Prime minister of People's Republic of china and we are submitting on the first working day after the debatable date of registration letter. The date of registration letter is 24th of July 2018 but letter signed and received by us was on dated 12th August, 2018".*

v. Brief details of last batches manufactured. vi. Copies of post registration variation approvals (if any). vii. Undertaking that applied products granted "As per Innovators specifcations" are not yet included in any of the reference pharmacopeia, however in case of inclusion submit evidence of submission of application for grant of pharmacopeial specs or copy of approval if any. viii. Latest GMP inspection report.	ii. The firm has submitted the copy of delivery challan dated 10.10.2018 LPC and 14.11.2018 for TOC Analyzer. However, the IQ, OQ and PQ report was generated on 24.01.2023 which was completed on 15.08.2023. Testing details have not been submitted. iii. Firm has submitted copy of application submitted for renewal of DML dated 12.12.2022. iv. The firm has submitted copy of section approval letter. v. The firm has submitted copies of approval of change of specs and copies of request submitted for grant of pharmacopeial specs. vi. The firm has submitted copy of request dated 19.07.2022 to DRAP Lahore for GMP inspection/ certificate.

Proceedings:

The Board was apprised as per date of registration the renewal due date was 23.07.2023. and on the due date was Sunday which is an official holiday hence the firm can submit the fee on 24th July 2023. However, it was submitted on 02.08.2023 with single fee in DRAP R&I. Moreover, the Ashura holidays were notified by the Government 28-29th July 2023 (Friday & Saturday). Moreover, the Chinese Premier arrived in Islamabad on 31st July 2023 and remained here till 2nd July 2023 and there no local holiday announcement for Government Offices including DRAP. Hence the stance of the firm is not justified. The RRR section has checked from the B&A Division regarding the submission of fee specifically renewal submission fee/ challan generation from and it was found that challan were created and even the fee was submitted in the month of July till the due date i.e. 24.07.2023.

Decision in 331st meeting of Registration Board:

Keeping in view the position narrated above. Registration Board directed the firm to submit differential fee before next meeting. In case of non-compliance, proceedings for suspension of registration shall be initiated under Rule 27 of Drug (LR&A) Rules 1976 and under section 42 of Drug Act 1976.

Accordingly, above decision of the Board was communicated to the firm vide letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023.The reply of the firm with reference to the aforesaid letter is reproduced verbatim.

Now firm reply as under:

Reference to the letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023 reached to us on 14th December, 2023 on our address 49-Km Multan Road Lahore the firm has requested as under: I am writing to appeal against the decision mad regarding renewal of registration of drugs Act 1976 and rules framed there under, The decision, as it stands appears to be disproportionately harsh and fails to align with the principles of justice due to the absence of a fair hearing and inadequate representation of our case. Upon careful consideration of the circumstances it is evident that our side of the case was not effectively presented or advocated for during the proceedings. We believe that key aspects of our situation were not adequately communicated leading to an unfair and unjust conclusion. Moreover, I which to emphasize that we have diligently fulfilled our obligations by depositing the standard fee hence indication our compliance with the prescribed regulations. As such the intimation of section 42, pertaining to non-compliance, appears to be erroneous in our case. Our primary plea is to request a waiver of the fine imposed which we firmly believe is unjustified and disproportionate given our adherence to the prescribed standards and regulations the imposition of the this fine under the circumstances appears to be arbitrary and not in line with the intended purpose of the regulations. We respectfully request a reconsideration of the decision, emphasizing our commitment to complying with all regulations and providing any necessary documentation or evidence to support our position. Furthermore, we seek and opportunity for a fair and comprehensive hearing where our case can be properly presented allowing for adjust and informed decisions to be made. I trust that your esteemed office/ board will carefully review the details provided and grant us the opportunity to present our case in a fair and unbiased setting your understanding and reconsideration in this matter will be highly appreciated.

Decision in 336th meeting:
Keeping in view the response of the firm as recorded above with reference to DRAP letter No.F.3-11/2023-RRR (M-331) dated 11th December, 2023, Registration Board decided to give opportunity of personal hearing to the firm under section 42 of the Drug Act 1976. Accordingly letter of personal hearing was issued vide DRAP letter No. F.No.3-4/2024-RRR(M-336) dated 24.07.2024.

Proceedings of the Board:

In compliance to DRAP letter DRAP letter No. F.No.3-4/2024-RRR(M-336) dated 24.07.2024 for personal hearing, Mr. Kashif Hussain, CEO of M/s Liven Pharmaceuticals (Pvt) Ltd.49-km, Multan Road, Lahore appeared before the Registration Board on behalf of the firm but could not produce any evidence that they have submitted they have submitted renewal application within time.

Decision:

Keeping in view the submitted documents and personnel hearing to the firm, Registration Board after detailed deliberation suspended the registration of above products under rule 27 of Drug (Licensing, Registering & Advertising) Rules 1976 read with section 42 of the Drug Act 1976, due to non-submission of required fee for renewal of registration as the renewal of registration applications were submitted after the due date but within sixty days.

In case the firm submits the required fee, the case shall be placed before the Registration Board for consideration and till then the registrations of above products shall remain suspended.

Case No. 6 **USE OF METHYLENE CHLORIDE IN FORMULATIONS OF PHARMACEUTICAL PRODUCTS**

Secretary, Provincial Quality Control Board (PQCB), Primary & Secondary Healthcare Department, Government of the Punjab Lahore, has requested to clarify that either the use of methylene chloride is permissible as solvent in coating material of tablets. In this regard he has referred DRAP Circular No. F-286-DRB/ 2018 (PE&R) dated 28.05.2019 which was issued to all pharmaceutical manufacturers to refrain from using banned excipients and solvents in the formulations of pharmaceutical products to avoid any public health risk. He further informed that PQCB in its 281st meeting dated 06.06.2024 discussed the matter and decided to take clarification from DRAP regrading use of methylene chloride and other solvents in the coating material in tablets or in formulation of pharmaceutical products. As per tables and list, guidance for industry, ICH Q3C, Revision 3, the methylene chloride/ dichloromethane is included in class 2 of solvents and its use in pharmaceutical products is limited because of its inherent toxicity.

It is submitted that Registration Board in its 286th meeting held on 14th -16th November 2018, deliberated that methylene chloride and sodium cyclamate (sweetener) are banned excipients as per USFDA regulations 21 CFR 700.19 and thus the Board decided the prohibit the use of both excipients in the formulations of pharmaceutical products. Accordingly, a circular was issued on 28.05.2019 vide No. F-286-DRB/ 2018 (PE&R) to comply with aforesaid directions of Registration Board to refrain from to refrain from using banned excipients and solvents in the formulations of pharmaceutical products to avoid any public health risk.
As the reliance of above decision of the Registration Board for banning the use of methylene chloride, was on USFDA regulations 21 CFR 700.19, hence the same is reproduced as under:

§ 700.19 Use of methylene chloride as an ingredient of cosmetic products.

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

[54 FR 27342, June 29, 1989]

Therefore, the above regulation of USFDA bans the use the methylene in cosmetic products only. That, in accordance with ICH Guideline for Residual Solvents Q3C(R9) and USFDA Guidance for Industry Q3C - Tables and List, residual solvents have been classified into 3 classes based on risk assessment and their possible risk to human health:

- Class 1 solvents: Solvents to be avoided
- Class 2 solvents: Solvents to be limited
- Class 3 solvents: Solvents with low toxic potential

As per above classification, Methylene Chloride (also known as Dichloromethane) is a Class 2 solvent and the permitted daily exposure of Methylene Chloride is 6mg/day (600ppm). That Organic volatile chemicals have been used widely in the manufacture of drug substances or excipients, or in the preparation of drug products. Methylene chloride is one of the volatile organic solvent which is used as an effective reaction and re-crystallization solvent in the extraction of several pharmaceutical compounds especially in the production of antibiotics and vitamins also been used as a **carrier for tablet coatings**. Since there is no therapeutic benefit from residual solvents, all residual solvents should be removed to the extent possible to meet product specifications, good manufacturing practices, or other quality-based requirements. Drug products should contain no higher levels of residual solvents than can be supported by safety data. Residual solvents have been classified by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) based on their possible risk to human health with their residual limits in Q3C (R9) Guideline (Impurities: Guideline for Residual Solvents) https://database.ich.org/sites/default/files/ICH_Q3C%28R9%29_Guideline_MinorRevision_2024_2024_Approved.pdf and said guidelines, methylene chloride/ dichloromethane is classified as Class 2 solvent with permitted daily exposure of 6mg/day (600ppm).

That same clarification was being requested by Ms Getz Pharma Karachi regarding the use of methylene chloride for coating of tablet, and as reference they had submitted approvals of TGA and MHRA wherein methylene chloride is part of approved formulation as excipient of Co-amoxiclav Tablets. They had also referred decision of Registration Board in its 331st meeting held on 31st October to 2nd November 2023 wherein the Board approved registration of fortecin tablets range containing amoxicillin sodium and clavulanic acid in the name of M/s The Searle Company Ltd. by way of Contract Manufacturing at M/s CSH Pharmaceuticals (Pvt) Ltd. Lahore wherein methylene chloride was being used as solvent for final coating based on approval of Therapeutic Goods Administration(TGA) Australia. The Board further imposed a condition that test for residual solvents will be integral part of finished product specifications and there will be no residue of methylene chloride in the finished pharmaceutical product.

That The Medicine and Healthcare Products Regulatory Agency (MHRA) of United Kingdom has also allowed use of methylene chloride as an ingredient in film coating material for amoxicillin sodium and clavulanic acid tablets (https://mhraproducts4853.blob.core.windows.net/docs/edde90a55360b361538948427048d38e68ab093a) .It is noteworthy that MHRA UK is regulatory member of ICH and TGA Australia is included as observer and both of the regulatory agencies have been declared as the one of the Reference Regulatory Authorities (RRA) by the Registration Board for the purpose of determination the safety and efficacy of drug product formulations applied for registration.

Hence, keeping in view the request of Secretary, Provincial Quality Control Board (PQCB), Primary & Secondary Healthcare Department, Government of the Punjab Lahore, matter is placed before the Registration Board for discussion in light of ICH Q3C guideline (Impurities: Guidelines for Residual Solvents) and practices of Reference Regulatory Authorities regarding use of methylene chloride in pharmaceuticals products especially for coating of tablets.

Decision:

Registration deliberated the matter at length regarding the use of organic solvents in manufacturing of drugs products constituted following committee which will give recommendation in light of International guidelines including ICH Q3C (Impurities: Guidelines for Residual Solvents):

i. **Mr. Muneeb Ahmed Cheema, Secretary, Registration Board, DRAP Islamabad.**
ii. **Directors of Drug Testing Laboratories of Punjab, Sindh, KPK and Baluchistan, AJK and Gilgit Baltistan.**
iii. **Representative from division of PE&R as coordinator**

The above committee shall convene a meeting at the earliest and present its recommendations before the forthcoming meeting of Registration Board.

Case No. 1 M/s Punjab Medical Services, 1st Floor, 6 - Judicial Colony (Extension) Shahrah Nazria e Pakistan Lahore

The firm has requested for issuance of renewal of registration through CMS Tracking ID: NM5-W9E-3VD7. Details are as under:

Sr. No.	Tracking ID	Reg. No.	Brand Name, Composition & Specifications	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
1	H5G-Y8A-Q3WE	097360	Kopaq 350 I mg/ml IV Solution for Injection Iohexol....755mg USP Specifcations **Product License Holder:** M/s Kocsel Ilac Snanyi ve Ticaret A.s.Gebze OSB2 Mah. 1700 Sk. No: 1703/2 Cayirova/ Kocacli Turkey. **Manufacturer:** Onko Ilac Sanayi Ve Ticaret A.S. GOSB, 1700 Sk. NO: 1703 Cayirova/ Kocaeli, Turkey	16-07-2019	08-05-2024 Rs. 30000/-	Renewal is granted w.e.f. 16.07.2024 to 15.07.2029

2	XSP-PM4-QP3R	097359	Kopaq 350 I mg/ml IV Solution for Injection Iohexol....755mg USP Specifcations **Product License Holder:** M/s Kocsel Ilac Snanyi ve Ticaret A.s.Gebze OSB2 Mah. 1700 Sk. No: 1703/2 Cayirova/ Kocacli Turkey**.** **Manufacturer:** Onko Ilac Sanayi Ve Ticaret A.S. GOSB, 1700 Sk. NO: 1703 Cayirova/ Kocaeli, Turkey	16-07-2019	07-05-2024 Rs. 30000/-	Renewal is granted w.e.f. 16.07.2024 to 15.07.2029

Case No. 2 Request of M/s Helix Pharma Pvt Limited, A-56. SITE Mangopir Karachi for issuance of renewal letter for HIPRO HC Ear Drops (055817).

M/s Helix Pharma Pvt Limited, A-56. SITE Mangopir Karachi has requested for issuance of renewal of registration for subject mentioned product for registration in Mongolia being the regulatory requirement of the of the importing country because they are not accepting the DRAP receiving copy of DRAP. Details of the product are as under:

Sr.No.	**Reg. No.**	**Brand Name, Composition & Specifications**	**Initial date of Registration** **PRV (If any)**	**Date of application (R&I)** **Fee submitted**	**Decision**
1.	055817	HIPRO HC Ear Drops Each ml contains: Ciprofloxacin as HCl ….2mg Hydrocortisone ….10mg (Manufacturer's Specifications)	25.04.2009	20.02.2024 Rs. 15000/-	Renewal is granted w.e.f. 25.04.2024 to 24.05.2029

Registration Board 339 Meeting Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (112-RU7-S8TA, 2024-05-15) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Azocare 250mg** Each Capsule contains: Azithromycin (as dihydrate) = 250 mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Azomax 250mg Capsule by AGP Pharma Pack Size(s): 10's-As per SRO,12's-As per SRO,6's-As per SRO
	Evaluation Remarks:	
	Decision: Approved Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
2	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (1U9-XJ2-YDUJ, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Omcare 40mg** Each Capsule contains: Omeprazole (as Omeprazole Enteric Coated Pellets) = 40 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Risek 40mg Capsule by Getz Pharma Pack Size(s): 10's-As per SRO,14's-As per SRO
	Evaluation Remarks: Omeprazole 22.5% EC pellets Source: M/s Vision Pharma Islamabad.	
	Decision: Approved	
3	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (2NP-9EE-299Y, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **Nifzole 100mg Capsule** Each Capsule contains: Immediate release Itraconazole pellets Eq. to Itraconazole.....100mg Capsule. (USP Specification) United States Pharmacopeia RRA Status: SPORANOX 100 mg Capsule (USFDA Approved) Janssen Ortho LLC, Gurabo, Puerto Rico,USA By Jassen pharmaceuticals Me Too Status: Rolac by Sami Pharmaceuticals, Pakistan Pack Size(s): Ix8’s, 2x8's, 3x8's,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of Pellets: M/s Vision Pharma. Pellets: Itraconazole 22% IR Pellets.	
	Decision: Approved	
4	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (2SR-PRY-VSDB, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **Asomp 20mg Capsule** Each Capsule contains: Enteric coated Omeprazole pellets Eq. to Omeprazole 20mg Capsule. (USP Specification). United States Pharmacopeia RRA Status: Omeprazole 20 mg Capsule By Sandoz Limited Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, UK. Me Too Status: Risek 20 mg Capsule by Getz Pharma Karachi Pakistan Pack Size(s): Ix7’s, 2x7's, 3x7's,-As per SRO
	Evaluation Remarks: Source of pellets: M/s Vision Pharma	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
5	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (36M-TNZ-WN83, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Omcare 20mg** Each Capsule contains: Omeprazole (as Omeprazole Enteric Coated Pellets) = 20 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Risek 20mg Capsule by Getz Pharma Pack Size(s): 10's-As per SRO,14's-As per SRO
	Evaluation Remarks: Omeprazole 8.5% EC pellets Source: M/s Vision Pharma Islamabad.	
	Decision: Approved	
6	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (4XG-341-8TH3, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-04-19 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Lenzocare 30mg** Each Capsule contains: Enteric coated pellets of Lansoprazole equivalent to Lansoprazole ..... 30 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Selanz Capsule 30mg by Searle Pharma Pack Size(s): 14's-As per SRO
	Evaluation Remarks: Pellets: Lansoprazole Enteric Coated Pellets 8.5%, Source: M/s Pharma Zone Chemicals (Pvt.) Ltd. Plot No.37 Sunder, Industrial Estate, Lahore	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
7	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (51X-YNN-NESU, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Loxicare 60mg** Each Capsule contains: Enteric Coated Pellets of Duloxetine HCl equivalent to Duloxetine …… 60 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Hapibar 60mg capsules by Barret Hodgson Pharma Pack Size(s): 14's-As per SRO
	Evaluation Remarks: Source of Pellets: M/s Vision Pharma Islamabad.	
	Decision: Approved	
8	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (5AR-NPL-NSNH, 2024-05-23) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Itracare 100mg** Each Capsule contains: Itraconazole (as IR Pellets) = 100 mg British Pharmacopeia RRA Status: Health Canada Me Too Status: Fewnol 100mg by Dew Max Pharma Pack Size(s): 4's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Pellets: Itraconazole 22% IR pellets Source: M/s Vision Pharma Islamabad.	
	Decision: Approved	
9	**Air Pharmaceuticals(Pvt.)Ltd** Plot No’s 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (5G7-MVJ-3BRA, 2024-07-05) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **Appetifin** Each 5ml contains: Pizotifen (as hydrogen Malate) ……. 0.25mg Manufacturer Specification RRA Status: Sanomigran BY Novartis Pharmaceuticals UK Ltd Me Too Status: Mosegar Syrup by Novartis Pharma (Pakistan) Ltd Pack Size(s): 1's (60ml)-De-Controlled,1's(120ml)-De-Controlled
	Evaluation Remarks: Firm was asked to submit data for claiming Manufacturer specifications. Firm has replied that innovator specifications may be given.	
	Decision: Approved Approved with innovator specifications. The firm shall submit fee of Rs. 30,000/- before issuance of letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
10	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (5RH-5RW-GP9A, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **Pirospec 20mg Tablet** Each tablet contains: Piroxicam (as Beta Cyclodextrin) …...20mg (Innovator's Specification) As per Innovators Specification RRA Status: BREXIN 20 mg tablets (Piroxicam-beta cyclodextrin) AIFA approved Me Too Status: Woxicam 20mg Tablet (Warafana Pharmaceuticals) Reg. 072300 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
11	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi (**000333**) Tracking ID: (6AS-D5H-3317, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-02-15 Case Category: New Section **(Adil Saeed)**	Proposed Name: **HYDRA Sachet** Each sachet contains: sodium chloride.....1.3gm potassium chloride.....0.75gm sodium citrate.....1.45gm dextrose anhydrous.....6.75gm equivalent to sodium 37.5mmol potassium.....10mmol citrate.....5mmol glucose....37.5mmol As per Innovators Specification RRA Status: WHO recommended ORS formulation Me Too Status: osmolar ors atco laboratories Pack Size(s): 10's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Following Deficiencies are communicated. REPLY IS AWAITED 1. Give tabulated comparison of your formulation with WHO recommended formulation indicating their similarity. 2. The WHO formulation recommends use of Trisodium citrate whereas you have used sodium citrate in your formulation. 3. As per Section 1.5.1, why USP or BP specifications are not adopted, although ORS formulation is same as mentioned in BP. 4. Clearance certificates of each drug substance (KCl, NaCl, Glucose & Sodium Citrate) are required 5. S- part of each drug substance is required	
	Decision: Deferred Deferred for submission of reply	
12	**Pearl Pharmaceuticals** 204, Street No. 1, I-10/3 Industrial Area, Islamabad (**000479**) Tracking ID: (7EB-QAN-PJDD, 2024-05-09) Fee Paid: 30000.0 Paid Date: 2024-03-19 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Tevoflox 100ml Infusion** Tevoflox 100ml Infusion each ml contain Levofloxacin .....5mg (JP Specification) Any Other RRA Status: Approved by MHRA(Gov UK): http://www.mhra.gov.uk/spc-pil/ Attached below Me Too Status: Leflox 100ml infusion Getz Pharma Pack Size(s): 1x100ml Infusion-As per SRO
	Evaluation Remarks: The firm was asked to revise label as firm has not mentioned "as hemihydrate" in it. The firm has submitted fee of Rs. 7500/- for revision of label.	
	Decision: Approved Letter shall be issued after submission of fee of Rs. 22500/- for preregistration vriation.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
13	**Air Pharmaceuticals(Pvt.)Ltd** Plot No’s 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (7TH-TGD-ESVG, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **Pairmol** Each 5ml contains: Paracetamol……. 120mg British Pharmacopeia RRA Status: Paracetamol 120mg/5ml Suspension BY Rosemont Pharmaceuticals Limited,Uk Me Too Status: Febrol Susp 120mg/5ml 60ml by BARRETT HODGSON PAKISTAN (PVT) LTD Pack Size(s): 1's (60ml)-As per SRO,1's(120ml)-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
14	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (963-D6R-JE87, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **ACZI 250mg Tablet** Each Film Coated Tablet Contains: - Azithromycin Dihydrate eq. to Azithromycin……...250mg (USP Specification) United States Pharmacopeia RRA Status: Azithromycin 250 mg Film-coated Tablets (USFDA Approved) Me Too Status: Azitma Tablet (Sami Pharma) Reg. No. 074899 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
15	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha (**000609**) Tracking ID: (9YD-XN3-W3AZ, 2024-04-30) Fee Paid: 30000.0 Paid Date: 2024-04-09 Case Category: New Section **(Adil Saeed)**	Proposed Name: **QUAPRIDE 1MG** Each film coated tablet contains: Prucalopride as succinate.....1mg As per Innovators Specification RRA Status: USFDA Me Too Status: P PRIDE TABLET 1MG Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Following deficiencies are communicated. REPLY IS AWAITED. 1. 3.2.S.4.4. Batch analysis of batch of drug substance used in manufacturing of drug product is required. 2. Batch analysis submitted is of Batch No. PCS-P/22007 and clearance certificate of batch No. PCS-P/23017. Clarification is also required regarding clearance of batch that is mentioned in analysis. 3. 3.2.P.8. Complete stability studies data of 6 months is required. 4. Executed BMR of Trial batches are required. Reply submitted on 06.08.2024. Reply found satisfactory.	
	Decision: Approved	
16	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (AYJ-33Q-7G6Y, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-22 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Tamcare 0.4mg** Each Capsule contains: Tamsulosin HCl (as Sustained Release Pellets) = 0.4 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Maxflow 0.4 mg capsule by CCL Pharma Pack Size(s): 20's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Tamsulosin HCl 0.2% Pellets SR Pellets. Source: M/s Vision Pharma Islamabad.	
	Decision: Approved	
17	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha (**000609**) Tracking ID: (BBJ-EB9-TRTT, 2024-04-24) Fee Paid: 30000.0 Paid Date: 2024-04-09 Case Category: New Section **(Adil Saeed)**	Proposed Name: **QUAPRIDE 2MG** Each film coated tablet contains: Prucalopride as succinate.....2mg As per Innovators Specification RRA Status: USFDA Me Too Status: P PRIDE TABLET 2MG Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Following deficiencies are communicated. REPLY IS AWAITED. 1. 3.2.S.4.4. Batch analysis of batch of drug substance used in manufacturing of drug product is required. 2. Batch analysis submitted is of Batch No. PCS-P/22007 and clearance certificate of batch No. PCS-P/23017. Clarification is also required regarding clearance of batch that is mentioned in analysis. 3. 3.2.P.8. Complete stability studies data of 6 months is required. 4. Executed BMR of Trial batches are required. Reply submitted on 06.08.2024. Reply found satisfactory.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
18	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (DEW-27Z-5P58, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **ESOPAR 40mg Capsules** Each Capsule Contains: Enteric coated pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole……..40mg United States Pharmacopeia RRA Status: Nexium 40 mg Capsule By AstraZeneca Pharmaceuticals LP.2 Pancras Square, 8th Floor,London, N1C 4AG, UK Me Too Status: ESSO 40 Capsule by Shaigan Pharmaceuticals Pack Size(s): Ix7’s, 2x7's, 3x7's,-As per SRO
	Evaluation Remarks: The firm was assked to revise the label claim as per RRA approved product. The firm has revised the label claim along with submission of Fee of Rs. 7500/- Pellets: Esomeprazole Magnesium EC pellets 22.5%. Source: M/s Vision Pharma Islamabad	
	Decision: Approved The firm shall submit differential fee of Rs. 22500/- for preregistration variation before issuance of letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
19	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (DTT-SSW-N9R5, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-04-22 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Neucare 150 mg** Each Capsule contains: Pregabalin ..... 150 mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zeegap Capsules 150 mg by Hilton Pharma Pack Size(s): 14's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
20	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (E3B-LAD-DQAP, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-19 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Esocare 20 mg** Each Capsule contains: Enteric- Coated Pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole = 20 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Nexum 20 mg capsule by Getz Pharma Pack Size(s): 10's-As per SRO,14's-As per SRO
	Evaluation Remarks: Pellets: Esomeprazole magnesium 8.5% EC pellets. Source: M/s Vision Pharma Islamabad.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
21	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha (**000609**) Tracking ID: (DG8-XRV-UTBY, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New Section **(Adil Saeed)**	Proposed Name: **TOFANI 5 MG** Each film coated tablet contains: Tofacitinib citrate eq.to tofacitinib.....5mg As per Innovators Specification RRA Status: USFDA Me Too Status: TOFACNET 5 MG TABLET Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Following deficiencies are communicated to the firm. and REPLY IS AWAITED. 1. 3.2.S.4.4. Batch analysis of batch of drug substance used in manufacturing of drug product is required. 2. Batch analysis submitted is of Batch No. PAR-P/22010 and clearance certificate of batch No. TOF-P/23001. Clarification is also required regarding clearance of batch that is mentioned in analysis. 3. 3.2.P.8. Complete stability studies data of 6 months is required. 4. Executed BMR of Trial batches are required. Reply submitted on 06.08.2024. Reply found satisfactory.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
22	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (J5D-446-9S1T, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-04-19 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Esocare 40 mg** Each Capsule contains: Enteric- Coated Pellets of Esomeprazole Magnesium Trihydrate equivalent to Esomeprazole = 40 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Nexum 40 mg capsule by Getz Pharma Pack Size(s): 10's-As per SRO,14's-As per SRO
	Evaluation Remarks: Source of pellets: M/s Vision Pharma Islamabad. Pellets: 22.5% Esomeprazole magnesium EC pellets.	
	Decision: Approved	
23	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (J6B-1M8-2ZJY, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Diclocare SR 100mg** Each Capsule contains: Diclofenac Sodium (as Sustained Released Pellets) ..... 100 mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Phlogin SR Capsules 100mg by Brookes Pharma Pack Size(s): 20's-As per SRO,30's-As per SRO
	Evaluation Remarks: Diclofenac 32% SR pellets. Source: M/s Vision Pharma Islamabad	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
24	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (JGL-Q1R-PWA8, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-06-13 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Cefimaf DS 200mg/ 5ml Powder for Oral Suspension** Each 5ml contains Cefixime as Trihydrate.....200mg United States Pharmacopeia RRA Status: Spanish agency for Medicines and Health Products Me Too Status: Cefiget DS powder for oral suspension Manufactured by Getz Pharma Pack Size(s): 30ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
25	**Air Pharmaceuticals(Pvt.)Ltd** Plot No’s 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (JLD-3Y6-9ND9, 2024-06-27) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **Adan** Each 5ml contains: Ondansetron HCL dihydrate eq to Ondansetron ……4mg United States Pharmacopeia RRA Status: Zofran Oral solution 4mg/5ml MHRA Approved Me Too Status: Onseron by Indus Pharma Pack Size(s): 1's (100ml)-As per SRO,1's (50ml)-As per SRO,1's(25ml)-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks: Drug substance is taken loan from M/s Novamed Pharma.	
	Decision: Approved	
26	**Quaper pvt Ltd** 26-A small industrial estate Lahore road Sargodha (**000609**) Tracking ID: (JXH-P3Z-672L, 2024-04-29) Fee Paid: 30000.0 Paid Date: 2024-04-09 Case Category: New Section **(Adil Saeed)**	Proposed Name: **TOFANI 10 MG** Each film coated tablet contains: tofacitinib citrate eq.to tofacitinib.....10 mg As per Innovators Specification RRA Status: USFDA Me Too Status: TOFACNET 10 MG TABLET Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Following deficiencies are communicated. REPLY IS AWAITED 1. 3.2.S.4.4. Batch analysis of batch of drug substance used in manufacturing of drug product is required. 2. Batch analysis submitted is of Batch No. PAR-P/22010 and clearance certificate of batch No. TOF-P/23001. Clarification is also required regarding clearance of batch that is mentioned in analysis. 3. 3.2.P.8. Complete stability studies data of 6 months is required. 4. Executed BMR of Trial batches are required. Reply submitted on 06.08.2024. Reply found satisfactory	
	Decision: Approved	
27	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi (**000924**) Tracking ID: (L5S-PYQ-47WP, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2022-08-15 Case Category: New License **(Adil Saeed)**	Proposed Name: **RELIEF** Each 1ml Ampoule Contains: Nalbuphine Hydrochloride.....20mg As per Innovators Specification RRA Status: NUBAIN INJECTION Me Too Status: NALBIN 20mg INJECTION Pack Size(s): 5's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Following deficiency is communicated to the firm. REPLY IS AWAITED. Valid RRA reference is required. The RRA reference of USFDA is discontinued and of Health Canada is also cancelled.	
	Decision: Deferred deferred for reply	
28	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (MQZ-JH6-RB28, 2024-07-12) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Vita-D3** Each 1ml Ampoule Contains: Cholecalciferol (Vitamin D3).....5mg As per Innovators Specification RRA Status: ANSM France Approved Me Too Status: Indrop D Injection by Neutro Pharma Lahore Pack Size(s): 1mlx1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
29	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi (**000924**) Tracking ID: (NRQ-521-ME8G, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-06-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **PARIDON** Each 5ml Suspension Contains: Domperidone.....5mg As per Innovators Specification RRA Status: DOMPERIDONE 1mg/ml SUSPENSION BY M/S. WOCKHARDT UK LTD. Me Too Status: MOTILIUM SUSPENSION Pack Size(s): 120ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
30	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (P4Q-4SS-M9SN, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-04-22 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Lomidcare 2mg** Each Capsule Contains : Loperamide Hydrochloride .....2mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Imodium Capsule 2mg by Aspin Pharma Pack Size(s): 60's-As per SRO
	Evaluation Remarks: Drug substance taken loan from M/s Fynk Pharma	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
31	**Pearl Pharmaceuticals** 204, Street No. 1, I-10/3 Industrial Area, Islamabad (**000479**) Tracking ID: (QR5-A51-YQMA, 2024-05-20) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Metacobal 500µg Injection** Metacobal 500mcg Each ampoule contain; Mecobalamin J.P ……500 µg (MFG. INNOVATER'S SPECIFICATIONS) As per Innovators Specification RRA Status: Methycobal Injection PMDA (Japan) approved Me Too Status: Methycobal (by Hilton pharma Karachi) 500mcg/ml Registration Number: 010313. Pack Size(s): 1mlx10injection-As per SRO
	Evaluation Remarks: Drug substance is taken loan from M/s Biolabs.	
	Decision: Approved	
32	**Care Pharmaceuticals** 8-Km Main Thokar Raiwind Road Lahore (**000563**) Tracking ID: (UZM-3JV-H3AL, 2024-05-30) Fee Paid: 30000.0 Paid Date: 2024-04-22 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Neucare 75mg** Each Capsule contains: Pregabalin ..... 75 mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zeegap Capsules 75mg by Hilton Pharma Pack Size(s): 14's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
33	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (V8D-VT8-9M5A, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **Molpec Forte 250mg/5ml Suspension** Each 5ml suspension contains: Paracetamol……...250mg British Pharmacopeia RRA Status: Calpol Six Plus Suspension 250mg/5ml Oral Suspension of McNeil Products Limited UK, (MHRA Approved). Me Too Status: Calpol 6 Plus 250mg/5ml Suspension (GSK) Reg. No. 012427 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
34	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (X3Z-1RZ-1AM6, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **Cipo-Z Dry Suspension 250mg/5ml** Each reconstituted 5ml suspension contains Ciprofloxacin as HCl……250 mg (USP Specification) United States Pharmacopeia RRA Status: MHRA approved Brand Name: Ciproxin 250mg/5ml (PL 00010/0211) Manufacturer: Bayer Me Too Status: Novidat 250mg Dry Powder for Suspension (Sami Pharma) Reg. No. 047142 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Following deficiencies are communicated to the firm. REPLY IS AWAITED. 1. 1.5.2: Label is of ciprofloxacin as HCl, whereas innovator product uses Ciprofloxacin base. 2. No details of diluent are mentioned in the dossier. 3. The specifications claimed are USP, as per USP monograph the active substance shall be ciprofloxacin base. In section 3.2.P.1 specifications claimed are innovator. 4. RRA reference submitted contains ciprofloxacin base, whereas applied product contains ciprofloxacin HCl. 5. 3.2.P.2.1: Description of product is mentioned as White to off white free flowing powder with banana flavour, whereas 25% taste masked granules are being used to manufacture the product. 6. 3.2.P.5 Testing method is of UV instead of HPLC.	
	Decision: Deferred reply awaited	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
35	**Air Pharmaceuticals(Pvt.)Ltd** Plot No’s 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (XLS-MQ8-LNNH, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-02-28 Case Category: New License **(Adil Saeed)**	Proposed Name: **Feril** Each 5ml contains: Iron (III) hydroxide polymaltose complex equivalent to elemental iron ..... 50mg Manufacturer Specification RRA Status: Maltofer Syrup by Vifor (International) Switzerland Me Too Status: Bisleri Syrup by SAMI Pharmaceuticals (Pvt) Limited Pack Size(s): 1’s (120ml)-De-Controlled,1’s(60ml) -De-Controlled
	Evaluation Remarks: The firm had applied for Manufacturers Specifications. So was asked to submit the following in light of guidance issued vide letter No. 9-2/2022-PEC dated 18.12.2023; 1. Analytical method development and validation report including performance of accuracy, precision, specificity, linearity, ruggedness and robustness parameters as per ICH Q2 (R2) guidelines for assay and impurities against innovator product. 2. Evidence that proposed analytical method is based upon similar principles as declared by the innovator drug product litrature. 3. Evidence that proposed drug product specifications and available innovators specifications are either equivalent or stringent than the innovator. The firm has now replied that although they have applied for manufacturer specifications, but product is tested as per Innovator specifications, so they may be given the Innovator specifications after submission of requisite fee fir preregistration variation.	
	Decision: Approved Approved with innovator specifications. Lette shall be issued after submission of fee of Rs. 30,000/- for preregistration variation	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
36	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. (**000964**) Tracking ID: (YTJ-P9D-G985, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Adil Saeed)**	Proposed Name: **ACZI 500mg Tablet** Each Film Coated Tablet Contains:- Azithromycin Dihydrate eq. to Azithromycin……..500mg (USP Specification) United States Pharmacopeia RRA Status: Azithromycin 500 mg Film-coated Tablets (USFDA Approved) Me Too Status: Zetro 500mg Tablet (Getz Pharma) Reg. No. 053120 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
37	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (Z33-ZU5-GSXZ, 2024-07-12) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Cefimaf 100mg/ 5ml Powder for Oral Suspension** Each 5ml Contains: Cefixime as Trihydrate.....100mg United States Pharmacopeia RRA Status: Spanish agency for Medicines and Health Products Me Too Status: Cefiget powder for oral suspension Manufactured by Getz Pharma Pack Size(s): 30ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
38	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (1AH-AG8-3MS3, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Glyda 110mcg/50mcg** Each capsule contains: 143mcg Indacaterol maleate eq. to indacaterol…110mcg 63mcg Glycopyrronium bromide eq. to glycopyrronium….50mcg Each delivered dose contains 110mcg of Indacaterol maleate eq. to indacaterol…85mcg 54mcg of Glycopyrronium bromide eq. to Glycopyrronium….43mcg (As per Innovator's specs.) As per Innovators Specification RRA Status: Registered drug by Therapeutic Good Administration (TGA) of Australia "ULTIBROO BREEZHALER 110/50 Indacaterol/glycopyrronium Inhalation Powder" Me Too Status: Indibro 110mcg/50mcg DPI capsules Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
39	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (1EB-LRA-1REE, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Indabron 150mcg DPI Capsule** Each Capsule contains 194mcg Indacaterol maleate equivalent to Indacaterol … 150mcg The delivered dose leaving the mouthpiece of the inhaler is Indacaterol maleate equivalent to indacaterol....120 mcg (As per Innovator's Specs.) As per Innovators Specification RRA Status: Registered drug by EMA European Medicine Agency (Onbrez 150mcg), Inhalation powder, hard capsule. Me Too Status: Onbrez 150mcg DPI Capsule Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
40	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (1R2-SGH-6RJ9, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-06-13 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **QDEX** Each Capsule contains: Dexlansoprazole DDR pellets eq. to Dexlansoprazole ..... 60mg Manufacturer Specification RRA Status: USFDA/MHRA Me Too Status: DELANZO Pack Size(s): 30's-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.S.4</td><td>Drug substance specifications, analytical procedure, method verification studies and COA shall be submitted from drug product manufacturer.</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>41</td><td>Horizon Healthcare (pvt.) ltd.
35-A Small Industrial Estate - Taxila (000856)
Tracking ID: (1Y5-XHZ-285Z, 2024-07-13)
Fee Paid: 75000.0
Paid Date: 2024-06-25
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: UMEROL 62.5mcg/25mcg DPI Capsule
Each capsule contains: Umeclidinium (as bromide) …. 62.5mcg Vilanterol (as trifenatate) … 25mcg Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 65 micrograms umeclidinium bromide equivalent to 55 micrograms of umeclidinium and 22 micrograms of vilanterol (as trifenatate). (As per Innovators specs.)
As per Innovators Specification
RRA Status: Registered drug by EMA “ANORO ELLIPTA (umeclidinium and vilanterol inhalation powder) FOR ORAL INHALATION USE”
Me Too Status: N/A
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
42	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (27T-AAZ-5UXS, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-20 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Glymoro DPI Capsule** Each capsule contains: Indacaterol (as acetate) ……..…...150 mcg Glycopyrronium (as bromide) ……50 mcg Mometasone Furoate ……...……160 mcg Each delivered dose contains: Indacaterol (as acetate) ……..…...114 mcg Glycopyrronium (as bromide) ……46 mcg Mometasone Furoate ……...……136mcg (As per Innovator's Specifications) As per Innovators Specification RRA Status: Registered drug by EMA "Enerzair Breezhaler (Indacaterol Acetate, Glycopyrronium Bromide, and Mometasone inhalation powder) FOR ORAL INHALATION USE" Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: •€€€€€€€€€Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". Firm has submitted Specificity parameter with performance of peak purity feature	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
43	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (**000914**) Tracking ID: (2SD-BZ9-7BU6, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **V-COBAL 500mcg injection** Each ml ampoule contains Mecobalamin = 500mcg (As per innovators specs) As per Innovators Specification RRA Status: METHYCOBAL INJECTION, EISAI CO., LTD, PMDA Approved Me Too Status: Methycobal Injection 500µg, by Hilton pharma (Pvt.) Ltd, Registration Number 010313 Pack Size(s): 5-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

1.6.5	Submit valid GMP certificate/DML of the drug substance manufacturer
3.2.S.4	Submit drug substance specifications, analytical procedure and analytical method verification studies form M/s Variant
3.2.S.5	Submit drug substance reference/working standard used for analysis of drug substance by M/s Variant since the submitted COA declares the
3.2.P.2.2.1	The conclusion statement declares the performance of dissolution profile, clarification shall be submitted in this regard.
3.2.P.3.3	Clarification shall be submitted whether ampoule filling was done along with nitrogen purging or not.
3.2.P.5.1	justification shall be submitted for the acceptance range of pH test, since it differs for that recommended by the innovator drug product literature. Justification shall be submitted for applying user limit of Assay test as "120%"
3.2.P.5.3	Justification shall be submitted that how the “specificity” of the applied method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”. Analytical record for the performance of analytical method validation studies shall be submitted.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of reply to shortcomings communicated to firm.	
44	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (2MT-UWB-RZZM, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Ciprocin 500mg Tablets (Film Coated)** Each Film coated tablet contains: Ciprofloxacin Hydrochloride (equivalent to Ciprofloxacin).....500mg (USP Spec's) United States Pharmacopeia RRA Status: CIPROBAY 500mg Tablet, Manufacturer: Bayer (Pty) Ltd. (Registered in Italy) Me Too Status: Novidate Tablets 500mg, Manufacturer: SAMI Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
45	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (31V-M1P-ZG9A, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-A 10mg Tablets** Each Uncoated Tablet Contains:Amlodipine besylate (equivalent to Amlodipine).....10mg(USP Spec's) RRA Status: Norvasc 10mg tabletsManufacturer:M/s Pfizer Laboratories Limited (USFDA Approved) Me Too Status: Norvasc 10mg tablets Manufacturer:M/s Pfizer Laboratories Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has submitted complete 6th month stability data of drug product	
	Decision: Approved	
46	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (369-BSD-1ZQM, 2024-03-13) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Sizor** Each ml Contains:Desloratadine …..……0.5mg Manufacturer Specification RRA Status: Actavis Oral solution 0.5mg/ml by Caduceus Pharma Ltd UK Me Too Status: Jardin-D Syrup by HIGH-Q Pack Size(s): 1's(120ml)-De-Controlled,1's(30ml)-De-Controlled,1's(60ml)-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>47</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (33G-NER-3688, 2024-06-13)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Montes 4mg Tablets (Chewable)
Each chewable tablet contains. Montelukast Sodium (equivalent to Montelukast).....4mg (USP Spec’s)
United States Pharmacopeia
RRA Status: Singulair 4mg Tablets, Manufacturer: MERCK & CO., INC. (Registered in USA)
Me Too Status: Myteka 4mg Tablets, Manufacturer: Hilton Pharma (Private) Limited
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Sr. No</th><th>Shortcomings</th></tr>
<tr><td>1.</td><td>Submitted drug product analytical method declares use of Montelukast Dicyclohexylamine reference standard for Assay test, while COA of “Montelukast sodium” working standard has been submitted in section 3.2.P.6. Justification shall be submitted in this regard.</td></tr>
<tr><td>Firm reply</td><td>Montelukast sodium working standard is used for routine testing of drug substance. The working standard of montelukast sodium is already standardized with USP reference standard of montelukast Dicyclohexylamine. The USP reference standard having minimum quantity and cannot be used or routine analysis of drug product</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration Board directed he firm to use reference standard as per USP monograph for analysis of commercial batches.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
48	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (37V-BA9-LGZ1, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cetzin 10mg Tablets (Film Coated)** Each Film Coated Tablet Contains;Cetirizine dihydrochloride.....10mg(USP Spec's) United States Pharmacopeia RRA Status: Zyrtec 10mg Tablets, Manufacturer: Aesica Pharmaceuticals S.r.l. (Registered in Itlay) Me Too Status: Zyrtec 10mg Tablets, Manufacturer: GlaxoSmithKline Pakistan Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
49	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (3UV-A37-GZ77, 2024-05-06) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-A 5mg Tablets** Each Uncoated Tablet contains: Amlodipine besylate (equivalent to Amlodipine).....5mg (USP Spec's) United States Pharmacopeia RRA Status: Norvasc 5mg tablets (USFDA Approved) Me Too Status: Norvasc 5mg tablets Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
50	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur (**000920**) Tracking ID: (3WV-L9L-SAPP, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Jasotilium tablet 10mg** Each Tablet Contains:DOMPERIDONE ……..10mg(Product Specifications BP specs.) RRA Status: TGA of Australia Me Too Status: Motilium Tablet Pack Size(s): 05x10’s Tablets -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	

tion#	Observations
1.5.2	Submitted label claim shall declare the dosage form as “Film coated”, along with submission of relevant fee.
1.5.6	Justification shall be submitted for claiming BP specifications for applied formulation, since no BP monograph is available for applied formulation.
3.2.S.7.3	Long term stability data of drug substance shall be submitted as per Zone IV conditions.
3.2.P.1	• €€€€€€€€€Justification shall be submitted for variation in qualitative formulation form that of the innovator. • €€€€€€€€€Justification shall be used for not including any surfactant and hydrogenated oil in the applied composition as used by the innovator.
3.2.P.5.2	• €€€€€€€€€Justification shall be submitted for referring to BP for the specifications and method for test for Assay and Dissolution since no BP monograph is available for applied formulation.
3.2.P.8.3	• €€€€€€€€€Clearance certificate issued by DRAP I&E office shall be submitted for evidence of import of Domperidone.

Decision: Deferred

for submission of reply to shortcomings communicated to firm.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
51	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (44P-9YR-8EZ6, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Defros 400mg Tablets (Uncoated dispersible)** Each uncoated dispersible tablet contains: Deferasirox.....400mg (BP Spec's) British Pharmacopeia RRA Status: Asunra 400mg dispersible tablets, Manufacturer: Novartis (Bangladesh) Limited (Registered in Bangladesh) Me Too Status: Arefed 400mg Tablets (Dispersible), Manufacturer: M/s Novartis Pharma Pakistan Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

ection#	Observations	
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Details of the dissolution media preparation shall be submitted for each buffer used in performance of comparative dissolution profile.	Defros 400mg Tablets are Uncoated Dispersible ta guidelines(available online) for dispersible tablets (Tablet time points for sampling are 10, 20, 30 and 45, The drug substance i.e. Deferasirox has low solubility dissolution of tablets cannot be achieved till 85% i Dissolution of product can only be achieved above 8 medium i.e. (Phosphate Buffer pH 6.8 with 0.5% Tween mentioned in submitted data Dissolution medium was prepared as per FDA guidelines 4.5 and Phosphate buffer pH6.8 with 0.5% Tween included in revised 3.2.P.2.2.1, submitted for your kind co
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted • €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.	Stability of 6 month time point shall be submitted as per as completed The drug substance i.e. Deferasirox is borrowed fron DRAP R&I cop[y of agreement and other details docur certificate, GMP, DML are enclosed Submitted

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
52	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (6JG-S5D-37S2, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Etoroxib 60mg Film coated Tablets** Each Film Coated Tablet Contains; Etoricoxib.....60mg (Innovator Spec's) As per Innovators Specification RRA Status: Arcoxia 60mg Tablets, Manufacturer: MERCK SHARP & DOHME (UK) LIMITED (MHRA Approved) Me Too Status: tarcox 60mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
53	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (**000860**) Tracking ID: (77D-LL7-HB5Y, 2024-06-10) Fee Paid: 30000.0 Paid Date: 2024-05-14 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Nyston Oral Suspension 100,000I.U** Each ml contains: Nystatin……..100,000I.U United States Pharmacopeia RRA Status: MHRA approved drug Me Too Status: Nystanil 100,000 I.U Oral Suspension by Winthrox Laboratories Pvt. Ltd Pack Size(s): 1 x 30ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
54	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (7DW-HA5-2YWR, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Defros 500mg Tablets (Uncoated dispersible)** Each uncoated dispersible tablet contains: Deferasirox.....500mg (BP Spec's) British Pharmacopeia RRA Status: EXJADE 500mg dispersible tablets, Manufacturer: Novartis Pharma Stein AG (Registered in Switzerland) Me Too Status: Arefed 500mg Tablets (Dispersible), Manufacturer: M/s Genome Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Reply
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Details of the dissolution media preparation shall be submitted for each buffer used in performance of comparative dissolution profile.	Defros 500mg Tablets are Uncoated Dispersible ta guidelines(available online) for dispersible tablets (Tablet time points for sampling are 10, 20, 30 and 45, The drug substance i.e. Deferasirox has low solubility dissolution of tablets cannot be achieved till 85% i Dissolution of product can only be achieved above 8 medium i.e. (Phosphate Buffer pH 6.8 with 0.5% Tween mentioned in submitted data Dissolution medium was prepared as per FDA guidelines 4.5 and Phosphate buffer pH6.8 with 0.5% Tween included in revised 3.2.P.2.2.1, submitted for your kind co Stability of 6 month time point shall be submitted as per as completed The drug substance i.e. Deferasirox is borrowed fron DRAP R&I cop[y of agreement and other details docur certificate, GMP, DML are enclosed
		Submitted

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
55	**Genix pharma** 44-45 B korangi creek road. karachi (**000351**) Tracking ID: (6UU-261-EMYW, 2024-03-01) Fee Paid: 30000.0 Paid Date: 2024-01-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Dimis** Each suppository contains Diclofenac Sodium…….12.5mg As per Innovators Specification RRA Status: Voltarol Suppository 12.5mg, UK Me Too Status: Voltral-12.5, Novartis Pakistan Pvt Ltd., Reg # 078140 Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
56	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (6X8-XTR-TTLJ, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Etoroxib 90mg Film coated Tablets** Each Film Coated Tablet Contains; Etoricoxib.....90mg (Innovator Spec’s) As per Innovators Specification RRA Status: Arcoxia 90mg Tablets, Manufacturer: MERCK SHARP & DOHME (UK) LIMITED (MHRA Approved) Me Too Status: Starcox 90mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
57	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (7YR-BMW-D9E5, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Liznisol l00mg/ 5ml Suspension** Each 5ml contains;Linezolid .....100mg(Innovator Spec's) As per Innovators Specification RRA Status: Zyvox 100mg/ 5ml Suspension, Manufacturer: Pfizer Service Company Me Too Status: Nezolid Suspension 100mg/5ml Manufacturer: M/s Searle Pakistan Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>58</td><td>Q. Track Pharma
Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
Tracking ID: (869-2VE-VJYB, 2024-06-13)
Fee Paid: 30000.0
Paid Date: 2024-06-10
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: QPRAZOLE
Each Hard Gelatin capsule contains: Esomeprazole Magnesium Trihydrate enteric coated pellets E.q Esomeprazole 40mg

RRA Status: USFDA/MHRA
Me Too Status: AXESOM
Pack Size(s): Alu Alu Blister 2x7s-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>1.5.1</td><td>Relevant information shall be submitted for the applied formulation i.e., Esomeprazole</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>59</td><td>Variant Pharmaceuticals (Pvt.) Ltd
Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (000914)
Tracking ID: (A98-US4-J5UV, 2024-04-22)
Fee Paid: 30000.0
Paid Date: 2024-03-13
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: NALBO 10MG INJECTION
Each ampoule contains Nalbuphine HCl 10mg
As per Innovators Specification
RRA Status: Nalbuphine Hydrochloride by HOSPIRA USFDA Approved
Me Too Status: Kinz 10mg Injection by Sami pharmaceuticals Pvt Registration Number 018686Ltd
Pack Size(s): 5s-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations
1.6.5	• €€€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.
3.2.S.1	Submitted CAS number and molecular weight for drug substance shall be justified since it varies from that of Nalbuphine HCl.
3.2.S.1.3	Justification shall be submitted for the declared description of water solubility against the reference product literature.
3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer.
3.2.P.1	Submitted master formulation declares the content of Nalbuphine injection instead of the salt form of Nalbuphine. Revision of master formulation shall be submitted along with applicable fee.
3.2.P.5.1	Justification shall be submitted for the declared limits of pH test in variation to that recommended by the innovator drug product literature.
3.2.P.5.3	Sample concentrations used for performance of accuracy parameter are not as per those applied in Assay method.
3.2.P.5.4	COAs of drug product stability batches shall be submitted.
3.2.P.7	Justification shall be submitted for use of Type II glass ampoule, since reference product has used Type I glass ampoule.
3.2.P.8.3	• €€€€€€€€€Documents confirming procurement of drug substance with approval of DRAP I&E office shall be submitted. • €€€€€€€€€Evidence of availability of "Liquid Particle Counter. Required for the performance of "particulate matter" test, shall be submitted. • €€€€€€€€€As evident form submitted raw data sheets the sample and

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of reply to shortcomings communicated to firm.	
60	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (B75-QQ4-7X42, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Dpsyl 50mg Tablets (Film Coated)** Each Film Coated Tablet Contains;Diclofenac Potassium.....50mg(USP Spec's) United States Pharmacopeia RRA Status: Cataflam tablet approved by US FDA Me Too Status: Maxit 50mg Tablets, Manufacturer: Hilton Pharma Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
61	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (BLU-5S5-HS31, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-V 80mg Tablets** Each film coated tablet contain; Valsartan.....80mg (USP Specs.) United States Pharmacopeia RRA Status: Diovan 80mg Tablets, Manufacturer:Novartis Pharmaceuticals UK Ltd.(UK Approved) Me Too Status: Valtec 80mg Tablets, Manufacturer: Tabros Pharma (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
62	**Genix pharma** 44-45 B korangi creek road. karachi (**000351**) Tracking ID: (BQ3-NU6-BBW7, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2024-01-31 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Ondestory** Each suppository contain:Ondansetron as hydrochloride dihydrate ..... 16mg As per Innovators Specification RRA Status: Zofran 16 mg Suppositories, Novartis Ireland Limited Me Too Status: Not Applicable Pack Size(s): 1s, 5s, 10s, 14s, 20-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
63	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (BTP-PYB-HR4D, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-V 40mg Tablets** Each film coated tablet contains; Valsartan.....40mg (USP Specs.) United States Pharmacopeia RRA Status: Diovan 40mg Tablets, Manufacturer:Novartis Pharmaceuticals UK Ltd.(UK Approved) Me Too Status: Valtec 40mg Tablets, Manufacturer: Tabros Pharma (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
64	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (BV7-97P-ZH6Y, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Ciprocin 250mg Tablets (Film Coated)** Each Film Coated Tablet Contains; Ciprofloxacin Hydrochloride(equivalent to ciprofloxacin).....250mg (USP Spec's) United States Pharmacopeia RRA Status: CIPROBAY 250mg Tablet Manufacturer:Bayer (Pty) Ltd. (Registered in Italy) Me Too Status: Novidate Tablets 250mg, Manufacturer: SAMI Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th></th></tr>
<tr><td>3.2.S.7.3</td><td>Submitted drug substance stability studies shall be signed and stamped from the drug substance manufacturer.</td><td>Submitted</td></tr>
<tr><td>3.2.P.8.3</td><td>Stability studies of 6th month time point shall be submitted.

Documents confirming procurement of drug substance shall be submitted.</td><td>Stability of 6 month time point shall be submitted as per s completed

The drug substance i.e. ciprofloxacin is locally purcha Karachi, procurement document i.e. Invoice, GMP, DM module 3.2.P.8.3</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>65</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (GWJ-X3G-58UN, 2024-06-20)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Pirox 20mg Tablets
Each Uncoated Tablet Contains; Piroxicam-Beta-Cyclodextrin 191.2mg (eq. to Piroxicam 20mg) (Innovator Spec’s)
As per Innovators Specification
RRA Status: Cycladol 20 mg Tablet, Manufacturer: Chiesi Farmaceutici Pharmaceutical company (Registered in US)
Me Too Status: Brexin 20mg Tablet, Manufacturer: Chiesi Pharmaceuticals
Pack Size(s): As per SRO-As per SRO</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:

Firm has submitted stability data till 3rd month time point only.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
<tr><td>66</td><td>Horizon Healthcare (pvt.) ltd.
35-A Small Industrial Estate - Taxila (000856)
Tracking ID: (EGQ-WAY-PGW5, 2024-06-13)
Fee Paid: 75000.0
Paid Date: 2024-05-20
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: Budepules Nebuliser Suspension
Each 2 mL vial contains:Budesonide……0.25 mg(As per BP Specs.)
British Pharmacopeia
RRA Status: Registered drug by US FDA as PULMICORT RESPULES (BUDESONIDE) Inhalation suspension, for oral Inhalation use.
Me Too Status: N/A
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.P.5.1</td><td>• €€€€€€€€€Reference for the acceptance limit for delivered dose shall be submitted</td><td>Firm has referred to USP monograph for the limit of delivered d</td></tr>
<tr><td>3.2.P.8.3</td><td>Stability studies of 6th month time point shall be submitted.</td><td></td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>67</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (H2H-TGH-UHAH, 2024-06-03)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Suvasta 10mg Tablets
Each Film Coated Tablet Contains; Rosuvastatin Calcium (equivalent to Rosuvastatin).....10mg (USP Spec’s)
United States Pharmacopeia
RRA Status: Crestor 10mg Tablets, Manufacturer: Astra Zeneca Pharmaceuticals (Registered in UK)
Me Too Status: Rovista 10mg Tablets, Manufacturer: Getz Pharmaceuticals (Pvt.) Ltd.
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th></th></tr>
<tr><td>3.2.P.8.3</td><td>• €€€€€€€€€Stability studies of 6th month time point shall be submitted.
• €€€€€€€€€Documents confirming procurement of drug substance shall be submitted
• €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.</td><td>Stability of 6 month time point shall be submitted as per as completed.

Submitted

Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
<tr><td>68</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (HEW-58G-JGRP, 2024-07-22)
Fee Paid: 30000.0
Paid Date: 2024-06-27
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Flocinol Lotion 0.01%
Each ml Contains; Fluocinolone Acetonide.....0.1mg (USP Spec’s)
United States Pharmacopeia
RRA Status: SYNALAR® Lotion, Manufacturer: IGI Laboratories, Inc.(Registered in United state)
Me Too Status: Synalar Lotion, Manufacturer: Pharma Health Pakistran (Pvt). Ltd.
Pack Size(s): As per SRO-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only. USP monograph describes the dosage form as Topical solution, while firm has declared it as Lotion, while the composition is same as that of innovator.	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
69	**Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. (**000939**) Tracking ID: (JGQ-SNQ-NVJ3, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Gerdmax 40mg Capsules** Each Capsules contains:Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole.....40mg United States Pharmacopeia RRA Status: Nexium 40mg Capsules by AstraZeneca UK approved by MHRA of UK Limited Me Too Status: Nexum 40mg Capsules by Getz Pharma Pvt. Ltd. Pack Size(s): 14s Tablets -As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
70	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (JXB-769-YHVX, 2024-07-17) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **TRACKCIN** Each Tablet Contains Ciprofloxacin (as Hydrochloride).....500mg United States Pharmacopeia RRA Status: USFDA/MHRA Me Too Status: CIPROQUINE Pack Size(s): 10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
71	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (M5R-939-PR7S, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Q-ZOLE** Each Hard gelatin capsule contains Omeprazole enteric coated pellets eq. to Omeprazole.....20mg RRA Status: USFDA/MHRA Me Too Status: Risek Pack Size(s): 2x7s'-As per SRO
	Evaluation Remarks:	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>72</td><td>Q. Track Pharma
Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
Tracking ID: (LPM-3G2-GWVH, 2024-06-24)
Fee Paid: 30000.0
Paid Date: 2024-06-13
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: QDEX
Each Capsule containsDexlansoprazole DDR pellets eq. to Dexlansoprazole.....30mg
Manufacturer Specification
RRA Status: USFDA/MHRA
Me Too Status: DELANZO
Pack Size(s): 3x10's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.S.4</td><td>Drug substance specifications, analytical procedure, method verification studies and COA shall be submitted from drug product manufacturer.</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
73	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (M6T-R4W-7MWL, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-AV 5mg/ 80mg Tablets** Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine)..... 5mg and Valsartan.....80mg United States Pharmacopeia RRA Status: Exforge® 5 mg/80 mg film-coated tablets Manufacturered by Novartis Pharmaceuticals UK Ltd (MHRA approved) Me Too Status: Exforge 5 mg/80 mg film-coated tablets Manufacturered by Novartis Pharma (Pakistan) Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
74	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (MTP-4DP-SYVH, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Dolo Biz Capsule 50mg** Each Capsule contains:- Tramadol hydrochloride ……50mg (BP Specifications) British Pharmacopeia RRA Status: Tramadol 50mg capsule by Milpharm Ltd Approved in MHRA (EMC) Me Too Status: Tramal Capsule 50mg Reg. No. 010170 (The Searle Company Limited Karachi) Pack Size(s): 1's, 5's, 10s, 14, 2-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Firm's response
1.6.5	• €€€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
3.2.S.4	• €€€€€€€€€Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. • €€€€€€€€€Reference of drug substance specifications adopted by drug substance manufacturer shall be submitted. • €€€€€€€€€Drug substance specifications form drug substance manufacturer declare performance of Assay test by potentiometric method, while the analytical method submitted is by way of HPLC. Clarification shall be submitted in this regard. • €€€€€€€€€Drug substance analytical procedure for Assay test submitted by M/s World Biz, does not include details of performance of System suitability. Justification shall be submitted in this regard. • €€€€€€€€€Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter shall be submitted.	. Submitted 1. The specification and test procedures adopt manufacturer from the basis of USP/European Pha Drug substance specifications from drug substanc performance of Assay test by potentiometric method as w Firm has referred to the COA, while analytical method potentiometric titration has not been submitted As material was loaned from DeMont Laboratories Compound A was not available so system suitability skipped. Once the product gets registered, we will perfor USP specifications on API Details of standard and sample concentrations in performance of accuracy parameter is mentioned and rev submitted.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
75	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (NSA-2SM-TP1N, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-06-14 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **QRACONE** Each Capsule contains Itraconazole (as IR Pallets).....100mg United States Pharmacopeia RRA Status: USFDA/MHRA Me Too Status: Itrajen capsule of M/s Jenner Pack Size(s): 4's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
76	**Air Pharmaceuticals(Pvt.)Ltd** Plot No’s 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (P6P-7LD-DP8Z, 2024-03-15) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Levam** Each ml Contains:Levetiracetam…….100mg United States Pharmacopeia RRA Status: Keppra Oral solution 100mg/ml by UCB, Inc. Smyrna, GA 30080 , USA Me Too Status: Lerace Syrup by Hilton Pharma Pack Size(s): 1’s (30ml)-De-Controlled,1’s(60ml) -De-Controlled

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>77</td><td>Horizon Healthcare (pvt.) ltd.
35-A Small Industrial Estate - Taxila (000856)
Tracking ID: (N64-Q52-UWV2, 2024-06-13)
Fee Paid: 75000.0
Paid Date: 2024-05-20
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: Budepules Nebuliser Suspension
Each 2 mL vial containsBudesonide……0.5mg(As per BP Specs.)
British Pharmacopeia
RRA Status: Registered drug by US FDA as PULMICORT RESPULES (BUDESONIDE) Inhalation suspension, for oral Inhalation use.
Me Too Status: N/A
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.P.5.1</td><td>• €€€€€€€€€Reference for the acceptance limit for delivered dose shall be submitted</td><td>Firm has referred to USP monograph for the limit of delive</td></tr>
<tr><td>3.2.P.8.3</td><td>Stability studies of 6th month time point shall be submitted.</td><td></td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>78</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (NR9-DNB-WV3P, 2024-07-18)
Fee Paid: 30000.0
Paid Date: 2024-07-02
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Betapro-F Cream
Each gram cream contains; Fusidic acid ……20mg Betamethasone dipropionate (equivalent to betamethasone)……1mg (Innovator Specifications)
As per Innovators Specification
RRA Status: Fucibet Cream, Manufacturer: Leo laboratories limited UK (MHRA-UK Approved)
Me Too Status: Fosedic B Cream, Manufacturer: Pearl pharmaceuticals (Pvt.) Limited
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th></tr>
<tr><td>1.5.9</td><td>Reference product submitted by frim contains Betamethasone valerate, while firm has applied with betamethasone dipropionate. Justification shall be submitted in this regard.</td></tr>
<tr><td>3.2.P.8.3</td><td>Stability studies of 6th month time point shall be submitted.

Documents confirming procurement of drug substance shall be submitted.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Deferred

for submission of reply to shortcomings communicated to firm.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
79	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (P34-R5U-3AYJ, 2024-07-17) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Indabron 300mcg DPI Capsule** Each Capsule contains 389mcg Indacaterol maleate equivalent to Indacaterol … 300mcg The delivered dose leaving the mouthpiece of the inhaler is Indacaterol maleate equivalent to indacaterol....240 mcg (As per Innovator's Specs.) As per Innovators Specification RRA Status: Registered drug by EMA European Medicine Agency (Onbrez 300mcg), Inhalation powder, hard capsule. Me Too Status: Onbrez 300mcg DPI Capsule Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
80	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (P4T-RGB-9912, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-05-20 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Budepules 1mg/2ml** Each 2 mL vial contains: Budesonide……1.0 mg (As per BP Specs.) British Pharmacopeia RRA Status: Registered drug by US FDA as PULMICORT RESPULES (BUDESONIDE) Inhalation suspension, for oral Inhalation use. Me Too Status: N/A Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><td>3.2.P.5.1</td><td>• €€€€€€€€€Reference for the acceptance limit for delivered dose shall be submitted</td><td>Firm has referred to the USPmonograph for the range of c</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
<tr><td>81</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (PDW-QLV-64MZ, 2024-07-22)
Fee Paid: 30000.0
Paid Date: 2024-07-02
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Pirox 20mg Capsules
Each capsule contains;Piroxicam……..20mg(USP Specifications)
United States Pharmacopeia
RRA Status: Feldene 20 mg capsule approved by US FDAufacturer: Pfizer Pharmaceutical industry company
Me Too Status: Pcam 20mg Capsules, Manufacturer: Martin Dow Pharmaceutical company
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:

Firm has submitted stability data till 3rd month time point only.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
82	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (PWP-XRQ-MTRD, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-AV 5mg/ 160mg Tabletss** Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine).....5mg Valsartan.....160mg United States Pharmacopeia RRA Status: Exforge® 5mg/160mg film-coated tablets Manufacturer:Novartis Pharmaceuticals UK Ltd.(MHRA Approved) Me Too Status: Exforge 5mg/160mg film-coated tablets Manufacturer:Novartis Pharma(Pakistan)Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
83	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (QGY-PV1-H61E, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-02-15 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Deslo Biz Tablet 5mg** Each film coated Tablet Contain:- Desloratadine 5mg (USP Specifications) United States Pharmacopeia RRA Status: Desloratadine Tablet 5mg by Accord Healthcare Limited, United Kingdom (Approved in MHRA) Me Too Status: Neo-Antial Tablet 5mg Reg No. 061440 (SAMI Pharmaceuticals) Pack Size(s): 1’s, 5’s, 10’s,20’s,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations
1.6.5	• €€€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.
3.2.S.4	• €€€€€€€€€Reference of drug substance specifications adopted by drug substance manufacturer shall be submitted. • €€€€€€€€€Drug substance analytical procedure for Assay test submitted by M/s World Biz, does not include details of performance of System suitability. Justification shall be submitted in this regard. • €€€€€€€€€Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter shall be submitted. • €€€€€€€€€Submitted COA from drug substance manufacturer claims “In-House” specifications, while Pharmacopoeial monograph is available for Desloaratadine. Justification shall be submitted on this regard.
3.2.S.5	Clarification shall be submitted for use of “In-House” grade working standard for the analysis of USP grade drug substance.
3.2.S.7	Justification shall be submitted for not performing test of related substances in stability studies.
3.2.P.5	Justification shall be submitted for not including test of “Uniformity of Dosage units” by way of content uniformity, in drug product specifications.
3.2.P.8.3	• €€€€€€€€€Complete raw data sheets for the Dissolution test performed during stability studies shall be submitted declaring the details of sample and standard solution preparation. • €€€€€€€€€As evident form the submitted HPLC chromatograms, the run time for the performance of Assay test by HPLC is not as per the recommendations of USP monograph. Justification shall be submitted in this regard.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred For the shortcomings communicated earlier	
84	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. (**000860**) Tracking ID: (QMT-5X7-1HZA, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-03-21 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Levace 100mg/ml Oral Solution** Each ml contains: Levetiracetam ……100mg United States Pharmacopeia RRA Status: FDA approved drug Me Too Status: Epian 100mg/ml Oral SolutionEpian 100mg/ml Oral Solution by Pharmasol (Pvt) Ltd Plot No. 549, Sundar Industrial Estate, Lahore, Pakistan Pack Size(s): 1x1s-As per SRO
	Evaluation Remarks: Firm has submitted stability data till 3rd month time point only. Firm has also submitted as under: "This product is already vide DRAP reg. letter F. 5-5/2021 -Reg-II (M-312) dated 29-12-2021 as contract manufacturing with Swiss Pharmaceuticals. Sir now our own syrup section is approved, and we want to shift the contract manufacturing from Swiss Pharmaceutical to our own plant. We mistakenly applied this transfer case in Evaluation cell instead of Post Registration Variation Cell. You are requested to consider our case as post registration variation.	
	Decision: Approved Registration Board decided to accede to the request of the firm and considered the instant application as Post registration variation and approved the application with change of manufacturing site of previously registered product i.e, Levac Injection 100mg/ml (Reg.# 110934) from M/s Swiss Pharmaceutical to M/s Seraph Pharmaceuticals. Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
85	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (S7M-LA4-3DYX, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-05-20 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Indabron 75mcg DPI Capsule** Each Capsule contains 97mcg Indacaterol maleate equivalent to Indacaterol ……75mcg Each delivered dose – the dose that leaves the mouth piece of the inhaler) contains 64mcg of Indacaterol (as Maleate) (As per Innovator's Specs.) As per Innovators Specification RRA Status: Registered drug by US FDA (ARCAPTA NEOHALER) Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
86	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (RAU-4E7-RH8D, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Suvasta 20mg Tablets** Each Film Coated Tablet Contains; Rosuvastatin Calcium (equivalent to Rosuvastatin).....20mg (USP Spec's) United States Pharmacopeia RRA Status: Crestor 20mg Tablet, Manufacturer: Astra Zeneca Pharmaceuticals (Registered in UK) Me Too Status: Rovista 20mg Tablets, Manufacturer: Getz Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Reply</th></tr>
<tr><td>3.2.P.8.3</td><td>• €€€€€€€€€Stability studies of 6th month time point shall be submitted.
• €€€€€€€€€Documents confirming procurement of drug substance shall be submitted
• €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.</td><td>Stability of 6 month time point shall be submitted as per as completed

The drug substance i.e. Rosuvastatin is borrowed from DRAP R&I copy of agreement and other details docur certificate, GMP, DML are enclosed

Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>87</td><td>Variant Pharmaceuticals (Pvt.) Ltd
Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (000914)
Tracking ID: (RH2-RRE-2T3W, 2024-05-21)
Fee Paid: 30000.0
Paid Date: 2024-04-19
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: VARI-D INJECTION
Each ml contains Cholecalciferol.....5mg (eq.to 200000 IU)
As per Innovators Specification
RRA Status: VITAMIN D3 GOOD 200000 IU/ML IM by BOUCHARA-RECORDATI by ANSM Approved
Me Too Status: Miura-D 5mg per ml by Getz pharma Pvt Ltd, Registration Number 067547
Pack Size(s): 1'-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations
1.5.7	Justification shall be submitted for claiming both IM & Oral route of administration for the applied formulation against the literary reference of the innovator drug product.
1.6.5	• €€€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.
3.2.S.4	• €€€€€€€€€Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer. • €€€€€€€€€Reference of drug substance specifications shall be submitted. • €€€€€€€€€Submitted drug substance specifications from drug substance manufacturer shall be signed and stamped.
3.2.S.4.4	Submitted COA of drug substance form M/s Variant pharmaceutical does not include performance of bacterial endotoxin test. Justification shall be submitted in this regard.
3.2.P.1	Selection of excipients for the applied drug product shall be justified against the innovator drug product. Justification shall be submitted for use of “Butylated hydroxy anisole” as reference product, against the innovator drug product literature.
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.
3.2.P.3.3	Reference shall be submitted for performance of terminal sterilization of the applied formulation.
3.2.P.5.1	Justification shall be submitted for the declared upper limit of Assay test as

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Deferred

for submission of reply to shortcomings communicated to firm.</td></tr>
<tr><td>88</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (RMH-LDN-ZY1M, 2024-06-14)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Montes 10mg Tablets (Film coated)
Each Film coated tablet contains. Montelukast sodium(equivalent to Montelukast).....10mg (USP Spec’s)
United States Pharmacopeia
RRA Status: Singulair 10mg Tablets, Manufacturer: MERCK & CO., INC. (Registered in USA)
Me Too Status: Montiget 10mg Tablets, Manufacturer: Getz Pharma (Private) Limited
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Sr. No</th><th>Shortcomings</th><th>Reply</th></tr>
<tr><td>1.</td><td>Submitted drug product analytical method declares use of Montelukast Dicyclohexylamine reference standard for Assay test, while COA of “Montelukast sodium” working standard has been submitted in section 3.2.P.6. Justification shall be submitted in this regard.</td><td>Montelukast sodium working standard is used for routine
The working standard of montelukast sodium is already
reference standard of montelukast Dicyclohexylamine.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration Board directed the firm to use reference/working standard as per USP monograph for batch analysis of commercial batches.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
89	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (T99-41U-1A2V, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Zolan 5mg Tablets** Each Film Coated Tablet Contains; Olanzapine (as citrate).....5mg (USP Spec's) United States Pharmacopeia RRA Status: Zyprexa 5mg Tablets, Manufacturer: Eli Lilly and Company (Registered in United State) Me Too Status: Olanzia 5mg Tablets, Manufacturer: Werrick Pharmaceuticals Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Reply
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	Zolan 5mg Tablets are Film coated tablets, and the performed as per FDA guidelinesat same dissolution tim test product i.e 10, 20, 30 and 45 The drug substance i.e. Olanzapine has low solubilit dissolution of tablets cannot be achieved till 85% in buffer Dissolution of product can only be achieved above 85% u medium i.e. (0.1 M HCl solution. The dissolution of achieved at 30 minutes above 85% i.e. 90.08 and 88.73 % product respectively. As per guidelines one additional p 85% dissolution As the innovator product was not available in the loca profile of test product is compared with reverence pr Registration No. 054720 Manufactured by Werrick Ph already approved from DRAP
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted • €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.	Stability of 6 month time point shall be submitted as per s completed The drug substance i.e. Olanzapine is borrowed from Glo R&I cop[y of agreement and other details documents i.e.

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>90</td><td>World Biz Pharmaceuticals Company, Multan
340, Phase-II, Industrial Estate, Multan (000942)
Tracking ID: (RZM-TX9-TZP1, 2024-04-18)
Fee Paid: 30000.0
Paid Date: 2024-02-15
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: Levo Biz Tablet 250mg
Each film coated tablet contains:- Levofloxacin as hemihydrate..250mg (USP Specifications) United States Pharmacopeia
RRA Status: Levofloxacin 250 mg film-coated tablets, MHRA Approved
Me Too Status: Leflox Tablet 250mg Reg No. 026164 (Getz Pharma)
Pack Size(s): 1's, 5's, 10s, 20s, -As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.P.8.3</td><td>• €€€€€€€€€Documents confirming procurement of drug substance in name of M/s De Mont Research Laboratories, issued by DRAP I&E Office shall be submitted.</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>91</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (TGA-X34-T6AN, 2024-06-05)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Zolan 10mg Tablets
Each Film Coated Tablet Contains; Olanzapine (as citrate).....10mg (USP Spec’s) United States Pharmacopeia
RRA Status: Zyprexa 10mg Tablets, Manufacturer: Eli Lilly and Company (Registered in United State)
Me Too Status: Olanzia 10mg Tablets: Manufacturer: Werrick Pharmaceuticals
Pack Size(s): As per SRO-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Reply
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	Zolan10 mg Tabletsare Film coated tablets, and the performed as per FDA guidelinesat same dissolution tim test product i.e 10, 20, 30 and 45. The drug substance i.e. Olanzapine has low solubility dissolution of tablets cannot be achieved till 85% in buffer Dissolution of product can only be achieved above 85% u medium i.e. (0.1 M HCl solution. The dissolution of achieved at 30 minutes above 85% i.e. 90.08 and 88.73 % product respectively. As per guidelines one additional p 85% dissolution. As the innovator product was not available in the loca profile of test product is compared with reverence pr Registration No. 054721 Manufactured by Werrick Ph already approved from DRAP.
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted.	Stability of 6 month time point shall be submitted as per

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
92	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (TSL-31N-DPE1, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-02-15 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Linzo Biz Tablet 600mg** Each Film Coated Tablet Contains:- Linezolid 600mg (USP Specifications) United States Pharmacopeia RRA Status: Zyvox 600mg Tablet (Pfizer Limited) Approved in USFDA Me Too Status: Ecasil Tablet 600mg (SAMI Pharmaceuticals) Reg. No. 067162 Pack Size(s): 1's, 6's,10’s, 12’s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Firm's response
1.6.5	• €€€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
3.2.S.4	• €€€€€€€€€Reference of drug substance specifications adopted by drug substance manufacturer shall be submitted.	Revised Drug substance specifications by drug sul submitted as per Indian Pharmacopoeia.
	• €€€€€€€€€Drug substance analytical procedure for Assay test submitted by drug substance manufacturer, is not as per USP monograph of "Linezolid". Justification shall be submitted din this regard.	Drug substance manufacturer follow the Indian Phar specification for performance of assay test.
	• €€€€€€€€€Justification shall be submitted for the declared limit of Water content by the drug substance manufacturer.	As Drug substance manufacturer follow the Indian Pharm Loss on drying test and adopted limit mentioned in the IP
	• €€€€€€€€€Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter shall be submitted.	Details of standard and sample concentrations in te performance of accuracy parameter is mentioned and rev submitted
	• €€€€€€€€€System suitability has not been performed as per USP monograph, in the analytical method verification studies.	As material was loaned from DeMont Laboratories Compound D was not available so system suitability skipped. Once the product gets registered, we will perform USP specifications
	• €€€€€€€€€Justification shall be submitted for varied limits of water content test between the COAs form drug substance manufacturer and drug product manufacture.	Drug substance manufacturer follow IP procedure and pe product manufacturer follow USP and
	• €€€€€€€€€Submitted COA from drug substance manufacturer claims "In-House" specifications, while Pharmacopoeial monograph is available for Linezolid. Justification shall be submitted on this regard.	When Linezolid API production was started, USP monog company adopted inhouse procedure as per the pharma for API. We drug product manufacturer perform the ana

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of following: Drug substance specifications and analytical method as per the USP monograph, from drug substance manufacturer and drug product manufacturer. • Drug substance analytical method verification studies as per the USP monograph, from drug product manufacturer • Documents confirming import of drug substance approved by DRAP I&E Office in name of M.s Demont research Laboratories, from which firm has claimed to borrow API.	
93	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (SE1-ESE-DMZU, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Clovagizol Lotion (1%w/v)** Each ml Contains; Clotrimazole.....10mg (USP Spec's) United States Pharmacopeia RRA Status: Stiemazol 1% w/v lotion, Manufacturer: Stiefel Laboratories (Registered in United Kingdom) Me Too Status: Canix 1% Lotion, Manufacturer: Crystollite Pharmaceuticals Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Reply</th></tr>
<tr><td>3.2.P.8.3</td><td>• €€€€€€€€€Stability studies of 6th month time point shall be submitted.
• €€€€€€€€€Documents confirming procurement of drug substance shall be submitted.
• €€€€€€€€€Justification shall be submitted for not performing test of pH and Microbial Enumeration test during stability studies, as recommended by claimed USP monograph.</td><td>Stability of 6 month time point shall be submitted as per s completed
The drug substance i.e. Clotrimazole is borrowed from DRAP R&I copy of agreement and other details docur certificate, GMP, DML are enclosed
Performance test i.e. pH is performed during stability individual test report and calculation data sheet, howev stability summery report. The microbial enumeration test product and shall be included in 6month time point</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>94</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (SL4-SNZ-JVEU, 2024-06-13)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Montes 5mg Tablets (Chewable)
Each chewable tablet contains: Montelukast sodium eq. to Montelukast ……..5mg (USP Specifications)
United States Pharmacopeia
RRA Status: Singulair 5mg chewable Tablets, Manufacturer: MERCK & CO., INC. (Registered in USA)
Me Too Status: Montiget 5mg chewable Tablets, Manufacturer: Getz Pharma(Private) Limited
Pack Size(s): As per SRO-As per SRO</td></tr>
</table>

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Sr. No</th><th>Shortcomings</th><th>Reply</th></tr>
<tr><td>1.</td><td>Submitted drug product analytical method declares use of Montelukast Dicyclohexylamine reference standard for Assay test, while COA of “Montelukast sodium” working standard has been submitted in section 3.2.P.6. Justification shall be submitted in this regard.</td><td>Montelukast sodium working standard is used for routine
The working standard of montelukast sodium is already
reference standard of montelukast Dicyclohexylamine.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Registration Board directed the firm to use reference/working standard as per USP monograph for batch analysis of commercial batches.</td></tr>
<tr><td>95</td><td>Polyfine Chempharma
51 Industrial Estate Hayatabad Peshawar, Pakistan (000216)
Tracking ID: (SV7-J2D-G5AS, 2024-03-28)
Fee Paid: 30000.0
Paid Date: 2024-03-18
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: FROMORE OPHTHALMIC OINTMENT 0.1%w/w
Each gram of ointment contains: Fluorometholone. ……1mg (0.1%w/w)

RRA Status: FML 0.1%w/w Ointment (FDA approved)
Me Too Status: Eyefem 0.1% ointment by M/s Kobec Pharma.
Pack Size(s): 1's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:

Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting shall be provided since submitted reference product has been declared as Discontinued in US FDA without any declaration</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of reply to shortcomings communicated to firm.	
96	**JasmPharma** Plot No 4,SIZ Nowshera Risalpur (**000920**) Tracking ID: (UY5-U6L-BP3U, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Jasotilium suspension 5mg/5ml** Each ml conatain: Domperidone..... 01 mg RRA Status: MHRA of UK Me Too Status: Motilium Suspension by Janssen pHaramaceutical NV (Reg.No 006527 Pack Size(s): 60 ml / bottle -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations
1.5.2	Submitted label claim shall declare the dosage form as “Film coated”, along with submission of relevant fee.
1.5.6	Justification shall be submitted for claiming BP specifications for applied formulation, since no BP monograph is available for applied formulation.
3.2.S.7.3	Long term stability data of drug substance shall be submitted as per Zone IV conditions.
3.2.P.1	• €€€€€€€€€Justification shall be submitted for using Tween 80in applied formulation
3.2.P.5.1	• €€€€€€€€€Justification shall be submitted for adopted specifications of pH. • €€€€€€€€€Justification shall be submitted for applying UV spectrophotometric method for the Assay method.
3.2.P.8.3	• €€€€€€€€€Justification shall be submitted for not performing Preservative efficacy test during drug product stability studies. • €€€€€€€€€Clearance certificate issued by DRAP I&E office shall be submitted for evidence of import of Domperidone.

Decision: Deferred

for submission of reply to shortcomings communicated to firm.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
97	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (V1W-M2B-19VZ, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Montes 4mg Sachet** Each Sachet contains: Montelukast Sodium (equivalent to Montelukast).....4mg (USP Spec's) United States Pharmacopeia RRA Status: Singulair 4mg Sachet, Manufacturer: MERCK & CO., INC. (Me Too Status: Myteka 4mg Sachet, Manufacturer: Hilton Pharma (Private) Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Response
1.6.5	Valid DML/GMP certificate of the drug substance manufacturer shall be submitted.	Submitted
3.2.S.5	Justification shall be submitted for using "Montelukast sodium" working standard while the USP monograph recommends use of Montelukast Dicyclohexylamine	Montelukast sodium working standard is used for routine The working standard of montelukast sodium is alread reference standard of montelukast Dicyclohexylamine.
3.2.S.7	Drug substance stability studies shall be signed and stamped by the drug substance manufacturer.	Submitted
3.2.P.2.2.1	Justification shall be submitted for not performing pharmaceutical equivalence against the Innovator/reference drug product.	As the innovator product (Singulair 4 mg sachet) was market, The pharmaceutical equivalence of test pr reverence produced (Myteka 4 mg sachet, Registration by Hilton Pharma) already approved from DRAP
3.2.P.6	Justification shall be submitted for using "Montelukast sodium" working standard while the USP monograph recommends use of Montelukast Dicyclohexylamine	Montelukast sodium working standard is used for routir and stability studies. The working standard of monte standardized with USP reference standard of montelukast
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted • €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted. • €€€€€€€€€Submitted chromatograms does not reflect performance of system suitability as recommended by USP monograph. Justification shall be submitted in this regard.	Stability of 6 month time point shall be submitted as per completed The drug substance i.e. Montelukast Sodium is pharmaceutical, DRAP R&I cop[y of agreement and oth ADC clearance certificate, GMP, DML are enclosed System suitability is performed using working standard montelukast is not calculated in System suitability due to CIS isomer.Theoretical plates, tailing factor and RSD chromatogram of reference standard.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Registration Board further directed the firm to use reference/working standard as per USP monograph for batch analysis of commercial batches.	
98	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (V8W-A9M-WBLJ, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Defros 250mg Tablets (Uncoated dispersible)** Each un-coated dispersible tablet contains; Deferasirox.....250mg (BP Spec's) British Pharmacopeia RRA Status: EXJADE 250mg dispersible tablets, Manufacturer: Novartis Pharma Stein AG(Registered in Switzerland) Me Too Status: Arefed 250mg Tablets (Dispersible), Manufacturer: M/s Genome Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Response
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying "15 minutes" time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Details of the dissolution media preparation shall be submitted for each buffer used in performance of comparative dissolution profile.	Defros 250mg Tablets are Uncoated Dispersible ta guidelines(available online) for dispersible tablets (Tablet time points for sampling are 10, 20, 30 and 45, The drug substance i.e. Deferasirox has low solubility dissolution of tablets cannot be achieved till 85% i Dissolution of product can only be achieved above 8 medium i.e. (Phosphate Buffer pH 6.8 with 0.5% Tween mentioned in submitted data. Dissolution medium was prepared as per FDA guidelines 4.5 and Phosphate buffer pH6.8 with 0.5% Tween included in revised 3.2.P.2.2.1, submitted for your kind co
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted • €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.	Stability of 6 month time point shall be submitted as per as completed

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
99	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (V8Z-M2L-M3PT, 2024-07-09) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Defros 180mg Tablets** Each film coated tablet contains; Deferasirox.....180mg (BP Spec's) British Pharmacopeia RRA Status: EXJADE 180mg film coated tablets, Manufacturer: Novartis Europharm Limited (Registered in Irland) Me Too Status: Arefed 180mg film coated Tablets, Manufacturer: M/s Genome Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Reply
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved performance of comparative dissolution profile, as recommended by the relevant guidelines.	Defros 180mg Tablets are film coated tablets and dissolu compared with reference product at same time point according to FDA guidelines. The drug substance i.e. Deferasirox has low solubility dissolution of tablets cannot be achieved till 85% i Dissolution of product can only be achieved above 8 medium i.e. (0.5% Tween 20 with Phosphate Buffer pH 6 mentioned in submitted data The revised dissolution profile according to FD onlinehttps://www.accessdata.fda.gov/scripts/cder/dissolu is enclosed for kind consideration
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted	Stability of 6 month time point shall be submitted as per as completed. The drug substance i.e. Deferasirox is borrowed fron DRAP R&I cop[y of agreement and other details docur certificate, GMP, DML are enclosed

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>10
0</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (URU-NL4-8XNB, 2024-07-22)
Fee Paid: 30000.0
Paid Date: 2024-06-27
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Flocinol Cream 0.025%
Each gm Contains; Fluocinolone Acetonide.....0.25mg (USP Spec’s)
United States Pharmacopeia
RRA Status: Fluocinolone Acetonide cream 0.025% USP, Manufacturer: Pharmaceuticals, inc. (Registered inUnited state)
Me Too Status: Synalar cream 0.025%, Manufacturer: Mass Pharma(Pvt). Ltd.
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Sr. No</th><th>Shortcomings</th><th>Reply</th></tr>
<tr><td>1.</td><td>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since submitted reference product is not verifiable from U SFDA website</td><td>Following reference has been verified:
Brand Name: FLUOCINOLONE ACETONIDE 0.025%
ANDA no.: 087104
Company: Taro
USFDA Approved
Drugs@FDA: FDA-Approved Drugs</td></tr>
</table></td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
101	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (V9Y-EGD-3GTZ, 2024-07-26) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Dinxip 1% Cream** Each gm Contains; Silver Sulphadiazine.....10mg (USP Specification) United States Pharmacopeia RRA Status: Flamazine 1% cream, Manufacturer: Smith & nephew Pharmaceuticals (Registered in United state) Me Too Status: Quench Cream 1%, Manufacturer: Ferozsons Laboratories Ltd. Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved Registration letter will be issued upon submission of drug product stability studies data of 6th month time point.	
102	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (W4E-RBA-31B2, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Clovagizol Vaginal Cream (2%w/w)** Each gram cream contains; Clotrimazole.....20mg (USP Spec's) United States Pharmacopeia RRA Status: Canesten Vaginal Cream 2%, Manufacturer: Bayer PLC UK Ltd. (MHRA Approved) Me Too Status: Gynosporin cream 2%, Manufacturer: Nabiqasim Industries (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Reply</th></tr>
<tr><td>3.2.P.2.2.1</td><td>Justification shall be submitted for not performing pharmaceutical equivalence against the Innovator/reference drug product.</td><td>The pharmaceutical equivalence of test product is c produced (Gynosporin Cream 2.0%, Registration No. NabiQasim industries already approved from DRAP. Al products for reference product and test products are comp</td></tr>
<tr><td>3.2.P.8.3</td><td>• €€€€€€€€€Stability studies of 6th month time point shall be submitted.
• €€€€€€€€€Documents confirming procurement of drug substance shall be submitted
• €€€€€€€€€Complete batch manufacturing record of drug product stability batches shall be submitted.</td><td>Submitted

The drug substance i.e. Clotrimazole is borrowed from DRAP R&I copy of agreement and other details docur certificate, GMP, DML are enclosed

Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>10
3</td><td>Polyfine Chempharma
51 Industrial Estate Hayatabad Peshawar, Pakistan (000216)
Tracking ID: (X53-RLR-45JT, 2024-03-18)
Fee Paid: 30000.0
Paid Date: 2024-03-05
Case Category: New Section
(Ammar Ashraf Awan)</td><td>Proposed Name: Optibram 0.3% w/w ointment
Each gram of ointment contains: Tobramycin USP. ……3mg (0.3%w/w)

RRA Status: Tobrex by Novartis Pakistan Ltd.
Me Too Status: Tobrex by Novartis Pakistan Ltd.
Pack Size(s): 1's-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observation
1.6.5	• €€€€€€€€Valid DML/GMP certificate of the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.
2.3.R	• €€€€€€€€Complete batch manufacturing record of stability batches shall be submitted.
3.2.S.4	• €€€€€€€€Drug substance specifications and analytical procedure shall be submitted from the drug substance manufacturer.
3.2.S.4.3	• €€€€€€€€Clarification shall be submitted regarding the composition of placebo solution, applied for the performance of specificity parameter in analytical method verification studies.
3.2.S.7.3	Long term stability studies data of drug substance shall be submitted till clamed shelf life.
3.2.P.5.1	Justification shall be submitted for not including test of Antimicrobial/preservative effectiveness studies in drug product specifications as required by the USP general chapter <51>, since applied formulation contains preservative.
3.2.P.5.3	• €€€€€€€€Sample preparation method applied for the performance of precision and recovery parameter in analytical method verification studies are not as recommended by the USP monograph. • €€€€€€€€Detailed results shall be submitted along with details of blank and placebo solution preparation for the performance of specificity parameter. • €€€€€€€€System suitability parameters performance is not as recommended by the USP monograph.

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Deferred

for submission of reply to shortcomings communicated to firm.</td></tr>
<tr><td>10
4</td><td>Q. Track Pharma
Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (000982)
Tracking ID: (XYZ-6NP-WZRQ, 2024-06-11)
Fee Paid: 30000.0
Paid Date: 2024-05-22
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Q-ZOLE
Each Hard Gelatin Capsule Contains Omeprazole Enteric coated Pellets E.Q to Omeprazole..... 40mg

RRA Status: USFDA/MHRA
Me Too Status: RISEK 40mg
Pack Size(s): Alu Alu Blister 2x7'-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>3.2.P.2.2.1</td><td>Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.</td><td>innovator product not available. hence, it was done on brand leader product.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>10
5</td><td>Solaris Life Sciences Private Limited,
Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (000992)
Tracking ID: (ZGZ-ZX1-94MP, 2024-07-04)
Fee Paid: 30000.0
Paid Date: 2024-06-27
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Defros 360mg Tablets (Film coated)
Each film coated tablet contains; Deferasirox.....360mg (Innovator Specifications)
As per Innovators Specification
RRA Status: EXJADE 360mg film coated tablets, Manufacturer: Novartis Europharm Limited (Registered in Irland)
Me Too Status: Arefed 360mg film coated Tablets, Manufacturer: M/s Genome Pharmaceuticals (Pvt.) Ltd.
Pack Size(s): As per SRO-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section#	Observations	Reply
1.6.5	Valid copy of MDL/GMP certificate of drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	• €€€€€€€€€Justification shall be submitted for not applying “15 minutes” time point sampling for performance of comparative dissolution profile, as recommended by the relevant guidelines. • €€€€€€€€€Justification shall be submitted for not continuing sampling till 85% of drug release is achieved performance of comparative dissolution profile, as recommended by the relevant guidelines.	Defros 360mg Tablets are film coated tablets and dissolu compared with reference product at same time point according to FDA guidelines. The drug substance i.e. Deferasirox has low solubility dissolution of tablets cannot be achieved till 85% i Dissolution of product can only be achieved above 8 medium i.e. (0.5% Tween 20 with Phosphate Buffer pH 6 mentioned in submitted data. The revised dissolution profile according to FD onlinehttps://www.accessdata.fda.gov/scripts/cder/dissolu is enclosed for kind consideration
3.2.P.8.3	• €€€€€€€€€Stability studies of 6th month time point shall be submitted. • €€€€€€€€€Documents confirming procurement of drug substance shall be submitted	Stability of 6 month time point shall be submitted as per as completed. Submitted

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
106	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (ZJ8-N7P-6EDG, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-29 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Cardi-AV 10mg/ 160mg Tabletss** Each Film Coated Tablet Contains; Amlodipine besylate (equivalent to Amlodipine).....10mg Valsartan.....160mg United States Pharmacopeia RRA Status: Exforge® 10mg/160mg film-coated tablets Manufacturer:Novartis Pharmaceuticals UK Ltd.(MHRA Approved) Me Too Status: Exforge 10mg/160mg film-coated tablets Manufacturer:Novartis Pharma(Pakistan)Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
107	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (92J-1PH-W43R, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Dr. Farhad Ullah)**	Proposed Name: **Curazole 40mg Sachet** Each Sachet contains: Omeprazole....40mg & Sodium Bicarbonate...1680mg RRA Status: OMEPRAZOLE AND SODIUM BICARBONATE Sachet is approved in USFDA link is: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=079182 Me Too Status: Risek Insta Sachet 40mg Reg# 058548 Mfg By Mfg By Getz Pharma (Pvt.) Limited (000284) Pack Size(s): 30s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

1.3.5	GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.6	You have applied for USP specifications while applied product is not available in USP, clarify
1.6.5	Valid copy of cGMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required Address of Drug substance manufacturer mentioned in submitted GMP certificate for omeprazole is different than that mentioned in form 5F section 1.6.5, clarify
3.2.S.4	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance omeprazole and sodium bicarbonate by Drug Product manufacturer is required. Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer is required. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance omeprazole and sodium bicarbonate shall be submitted.
3.2.S.7	Stability study data of drug substance omeprazole at real time conditions till claimed shelf life shall be submitted. Stability study data of drug substance sodium Bicarbonate at Zone-IVA conditions till claimed shelf life shall be submitted

3.2.	Results of CDP studies in three physiological medias of applied product against the reference product has not been submitted

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of reply to the above cited shortcomings	
108	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (QEB-1LJ-7DDD, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2023-03-08 Case Category: New Section **(Dr. Farhad Ullah)**	Proposed Name: **Bril 1gm Injection** Each vial contains: Cefazolin as sodium.....1gm RRA Status: Cefazolin sodium injection 1gm approved in USFDA link: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=065345 Me Too Status: Kefzol Injection 1gm Reg# 003756 Mfg By AGP Limited Pack Size(s): 1gm-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	

1.3.5	GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	Address of Drug substance manufacturer mentioned in submitted GMP certificate is different than that mentioned in form 5F section 1.6.5, clarify
3.2.S.4	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. The expiry date mentioned on the COA of drug substance in batch analysis is 03-03-2023 by drug substance manufacturer while manufacturing date of trial batches is 05-2023. Clarification is required if the same drug substance has been used in the manufacturing of trial batches

	Decision: Deferred **for submission of reply to the above cited shortcomings.**

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
109	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (XJN-G4P-YJ7U, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Dr. Farhad Ullah)**	Proposed Name: **Curazole 20mg Sachet** Each Sachet Contains: Omeprazole....20mg & Sodium Bicarbonate.....1680mg RRA Status: OMEPRAZOLE AND SODIUM BICARBONATE Sachet is approved in USFDA link is: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=079182 Me Too Status: Risek Insta Sachet 20mg Reg# 058547 Mfg By Mfg By Getz Pharma (Pvt.) Limited (000284) Pack Size(s): 30s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

1.

1.3.5	GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required • Address of Drug substance manufacturer mentioned in submitted GMP certificate for omeprazole is different than that mentioned in form 5F section 1.6.5, clarify
3.2.S.4	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance omeprazole and sodium bicarbonate by Drug Product manufacturer is required. Copies of the Drug substance analytical procedures used for routine testing of the Drug substance sodium bicarbonate by Drug substance manufacturer is required. Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance omeprazole and sodium bicarbonate shall be submitted.
3.2.S.7	Stability study data of drug substance omeprazole at real time conditions till claimed shelf life shall be submitted Stability study data of drug substance sodium Bicarbonate at Zone-IVA conditions till claimed shelf life shall be submitted
3.2.P.2	Results of CDP studies in three physiological medias of applied product against the reference product has not been submitted
3.2.P.5	Justification shall be submitted for not including the dissolution test for applied product in finished product specifications as per reference product review document

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred **for submission of reply to the above cited shortcomings.**	
110	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore (**000395**) Tracking ID: (18R-J1Y-QA98, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-05-31 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **DV-Leo 25mg Tablet** Each Tablet contains: Levosulpiride…25mg As per Innovators Specification RRA Status: Italy (AIFA Approved) Me Too Status: Sulvorid Tablets (High Q) Pack Size(s): 10's, 20's, 30's, 40-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
111	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (1X2-L3N-YTQH, 2024-06-10) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Moxinn 0.5% Ophthalmic Solution** Each ml contains: Moxifloxacin (as HCl)... 5mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Vigamox by Novartis Pack Size(s): 1x5ml-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: • 1. Submit document confirming import of API	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
112	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (2T8-EUS-RQ7D, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **LOTENUM Ophthalmic suspension** Each ml of ophthalmic suspension contains: Loteprednol etabonate……5mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: LOTEPRED FORTE by Sante Pack Size(s): 5 ml-As per SRO
	Evaluation Remarks: • Submit API import / clearance documents from where loan was obtained.	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
113	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (2XW-LA9-HXY1, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Diopta 0.1% Ophthalmic Solution** Each ml contains: Olopatadine (as HCl).....1mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Patadin by Shaigan Pack Size(s): 1x5ml-Controlled
	Evaluation Remarks: • Submit document confirming import of API •	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
114	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (3RJ-Q5H-QHYN, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **NELRAX 500mg Capsule** Each capsule contains: Cephradine…..500mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Velosef capsule (GSK Pharmaceuticals) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
115	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (3XM-Q1L-75Q9, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Esadiab 100mg Tablet** Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…100mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Sitaglu 100mg Tablets by Hilton Pack Size(s): 14"s-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
116	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (41R-MSB-5EHW, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Roklar 125mg/5ml Suspension** Each 5ml of reconstituted suspension contains: Cefaclor (as monohydrate)……125mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Ceclor 125mg/5ml suspension (AGP) Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
117	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (4NN-WHZ-4R3Y, 2024-06-27) Fee Paid: 30000.0 Paid Date: 2024-06-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VOMIRON INJECTION** Each 4ml contains: Ondansetron (as hydrochloride dihydrate)…..8mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Onset injection by pharmedic Pack Size(s): 4ml-As per SRO
	Evaluation Remarks: Submit API import / clearance documents from the firm which has given loan of API	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
118	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (4US-5TM-P12D, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-05-14 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nycacin 100mg Injection** Each 2ml ampoule contains: Amikacin as Sulphate.....100mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Amkay 100mg/2ml injection by Bosch Pack Size(s): 5s-As per SRO
	Evaluation Remarks: 1. Submit evidence of procurement of API.	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
119	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (5MM-94B-W7ZN, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-06-21 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **NYDOL TABLETS** Each Tablet contains: Tramadol HCl….50mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zultra 50mg tablet Pack Size(s): 2*10 tablets-As per SRO
	Evaluation Remarks: Submit API Import / clearance documents	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
120	**Don Valley** don valley pharmaceuticals (Pvt.) Ltd, 31 kilometer main Ferozepur Road Lahore (**000395**) Tracking ID: (5VZ-ZD2-NHLJ, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-05-31 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **DV-Leo 50mg Tablet** Each tablet contains: Levosulpiride.....50mg As per Innovators Specification RRA Status: Italy (AIFA Approved) Me Too Status: Sulvorid Tablets (High Q) Pack Size(s): 10's, 20's, 30's, 40-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
121	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (614-ZD4-HTGA, 2024-06-25) Fee Paid: 30000.0 Paid Date: 2024-06-10 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nemoclop Injection** Each 2ml Contains: Metoclopramide (as HCl)...10mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Metoclon Injection Indus Pharma Pack Size(s): 2:×25s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Submit API Import / clearance documents	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
122	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (797-5XZ-25AQ, 2024-07-23) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Ciprova 0.3% Ophthalmic Solution** Each ml of ophthalmic solution contains: Ciprofloxacin HCl eq. to Ciprofloxacin.....3mg United States Pharmacopeia RRA Status: Ciloxan Ophthalmic solution (USFDA Approved) Me Too Status: Ciloxan by Novartis Pack Size(s): 1x5ml-Controlled
	Evaluation Remarks: • Submit evidence of procurement of API	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
123	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (8YW-L2U-4X4R, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-06-28 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VIROSIM 5% Cream** Each gm contains: Acyclovir……50mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Acylex Cream by Ferozesons Pack Size(s): 10 g Aluminium Colla-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
124	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (8N6-REX-B718, 2024-07-14) Fee Paid: 30000.0 Paid Date: 2024-07-08 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **CUTISOL 0.05% Cream** Each gram of cream contains: Clobetasol propionate.....0.5mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: CLOBEVATE CREAM by GSK Pack Size(s): 20 g-As per SRO
	Evaluation Remarks: • Submit documents confirming import and clearance of API from where Loan was taken.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
125	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (ASH-L9U-ALAT, 2024-07-11) Fee Paid: 30000.0 Paid Date: 2024-06-14 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **FUSINIL CREAM** Each gm of cream contains: Fusidic Acid…. 20mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: FUSIDERM CREAM by Seatle Pack Size(s): 15 g-As per SRO
	Evaluation Remarks: • 1. Innovator's specifications have been claimed while product monograph is available in BP. Clarification is required in this regard. • 2. Submit API import / clarance document from where loan was obtained.	
	Decision: Approved with BP Specifications. Firm shall submit documents for procurement of API before issuance of Registration Letter.	
126	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (BMB-SJ9-ZYJR, 2024-06-21) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Leedox 125mg/5ml Suspension** Each 5ml of reconstituted suspension contains: Cefadroxil (as monohydrate)……125mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Duricef 125mg/5ml powder for oral suspension (GSK) Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
127	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (BRU-MXE-5P7W, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Leedox 500mg Capsule** Each Capsule contains: Cefadroxil (as monohydrate)……500mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Duricef 500mg Capsule (GSK) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
128	**Cure Laboratories (Pvt.) Ltd** Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi (**000897**) Tracking ID: (BTS-EQV-39SX, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-02-20 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Curlid 600mg Tablet** Each film coated tablet contains: Linezolid.....600mg As per Innovators Specification RRA Status: Zyvox Tablets 600mg (USFDA) Me Too Status: Nezkil 600mg Tablets by Continental Pharma Pack Size(s): 10's-De-Controlled,2x6's -De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
129	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (E31-JLE-NLPZ, 2024-06-07) Fee Paid: 30000.0 Paid Date: 2024-05-02 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Sibghalid 600mg Tablet** Each film coated tablet contains: Lineozolid..... 600mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Linzo Tablet by Maxitech Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: • Submit documents for procurement of API	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
130	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (EMQ-R63-HY2N, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nelrax 250mg Capsule** Each capsule contains: Cephradine …...250mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Velosef capsule (GSK Pharmaceuticals) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
131	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (G7W-4EY-B3UY, 2024-05-31) Fee Paid: 30000.0 Paid Date: 2024-05-24 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Iriretin Ophthalmic Suspension** Each ml of ophthalmic suspension contains: Loteprednol Etabonate……5mg, Tobramycin……3mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: LOTEPRED-T ophthalmic Suspension by Sante Pack Size(s): 5ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: • Submit documents for procurement of API	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
132	**Cure Laboratories (Pvt.) Ltd** Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi (**000897**) Tracking ID: (E72-23Y-V2MG, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-02-20 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Malrid 40/240mg Tablets** Each tablet contains: Artemether.....40mg, Lumefantrine.....240mg The International Pharmacopeia RRA Status: WHO PQ Me Too Status: Artem Plus Tablet by Hilton Pack Size(s): 8's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
133	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (HQA-6NS-1974, 2024-07-23) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Ciprovadex Ear Drops** Each 1ml otic suspension contains: Ciprofloxacin (as HCl)……3mg, Dexamethasone.....1mg United States Pharmacopeia RRA Status: CIPRODEX Otic suspension (USFDA Approved) Me Too Status: CIPOTIC-D Ear Drop by Barret Hodgson Pack Size(s): 5ml-As per SRO
	Evaluation Remarks: Submit documents confirming clearance of API of Innvotek Pharma from where loan was taken	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
134	**Pasteur & Fleming Pharmaceuticals** Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (**000945**) Tracking ID: (JE2-3DG-AAP3, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-04-03 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **LINZOFLEM 100MG/5ML DRY SUSPENSION** Each 5ml of reconstituted suspension contains: Linezolid.....100mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Nezkil 100mg/5ml Dry Suspension by Continental pharma Pack Size(s): 60ml & 120m-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
135	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (JU9-T4Y-7EGN, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Kalark 200mg Capsule** Each capsule contains: Cefixime (as trihydrate)……200mg Manufacturer Specification RRA Status: USFDA Approved Me Too Status: Cef-OD Capsule by CCL Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
136	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (LY8-WMU-JLJ3, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2023-12-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **JECTSOL-MANNITOL 20% Infusion (1000ml)** Each 100ml contains: Mannitol……20g British Pharmacopeia RRA Status: 20% Mannitol Injection, MHRA Me Too Status: Zeesol-M 20% w/v Infusion by Shahzeb Pack Size(s): 1000ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
137	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (LSL-G6A-E6SX, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nelrax 250mg/5ml Suspension** Each 5ml of reconstituted suspension contains: Cephradine…….250mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Velosef Suspension (GSK) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
138	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (NVE-A8M-EU8A, 2024-07-24) Fee Paid: 30000.0 Paid Date: 2024-06-26 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Neurobal Injection** Each ml contains: Mecobalamine ....500mcg Manufacturer Specification RRA Status: PMDA Approved Me Too Status: Methycobal Injection by Hilton Pack Size(s): 1 × 10 -As per SRO
	Evaluation Remarks:	
	Decision: Approved	
139	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (P4H-W4M-DNJ6, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Kalark 200mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)…….200mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cefiget suspension by Getz Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
140	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (P5N-E42-X818, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2023-12-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **JECTSOL-MANNITOL 20% Infusion (500ml)** Each 100ml contains: Mannitol……20g British Pharmacopeia RRA Status: 20% Mannitol Injection, MHRA Me Too Status: Zeesol-M 20% w/v Infusion by Shahzeb Pack Size(s): 500ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
141	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (PRU-JDJ-EEWE, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **JEWRACET PLUS TABLET** Each film coated tablet contains: Paracetamol….325mg, Tramadol HCl…….37.5mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Tramal Plus Tablet by Searle Pack Size(s): 1*10 tablets-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: • Submit API Import / clearance documents	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
142	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (Q2E-YJ2-XULJ, 2024-05-31) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Esadiab 25mg Tablet** Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…25mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Sitaglu 25mg Tablets by Hilton Pack Size(s): 14"s-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
143	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (QMW-6JD-5R1Z, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Esadiab 50mg Tablet** Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…25mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Sitaglu 50mg Tablets Pack Size(s): 14"s-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
144	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (QTR-HTU-83G2, 2024-04-29) Fee Paid: 30000.0 Paid Date: 2024-01-17 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **JECTSOL-R Infusion (1000ml)** Each 100ml contains: Sodium chloride…….0.86g, Calcium Chloride dihydrate…..0.033g, Potassium Chloride……..0.03g United States Pharmacopeia RRA Status: Ringer’s Solution for Infusion USFDA Me Too Status: MACRIN RS I.V INFUSION by Searle Pack Size(s): 1000ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
145	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (R6Y-55Z-DVGH, 2024-06-10) Fee Paid: 30000.0 Paid Date: 2024-05-24 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Ciprova 200mg/100ml Infusion** Each 100ml of infusion contain: Ciprofloxacin (as HCl).....200mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Novidat 200mg/100ml Infusion Pack Size(s): 1 x 1's-As per SRO
	Evaluation Remarks: • 1. The MHRA approved reference product contains Ciprofloxacin base, while you have used Ciprofloxacin HCl. Clarification is required in this regard. • 2. Reference product has used lactic acid as excipient while this excipient is not used in your formulation. Clarification is required in this regard. • Response of the firm: Firm has submitted that that they have revised their formulation as per reference product using ciprofloxacin base and they will use revise formulation for commerial batches.	
	Decision: Approved Firm shall submit requisite fee for revision of label claim as per the reference product.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
146	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (RVJ-8SH-7V6D, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **DIOPTA PL Ophthalmic Solution** Each ml contains: Olopatadine (as HCL)……2mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: OLOTEK-DS Ophthalmic Solution by Innvotek Pack Size(s): 5ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
147	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (RM5-9B7-TTRQ, 2024-05-30) Fee Paid: 30000.0 Paid Date: 2024-01-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **JECTSOL-25% Infusion (1000ml)** Each 100ml contains: Dextrose anhydrous……25g British Pharmacopeia RRA Status: Glucose 25% Intravenous Infusion TGA Australia Approved Me Too Status: Sterifluid- 25 Infusion by FDL Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
148	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (TG4-7PB-78TU, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-14 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nydol Injection** Each 2 ml contains: Tramadol Hydrochloride.....100mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Tonoflex Injection 100mg/2ml ampoule by M/s Sami Pharmaceuticals, Karachi, Reg. No. 053224. Pack Size(s): 2ml x 5's-Free of Cost
	Evaluation Remarks: Submit API Import / clearance documents (Submitted)	
	Decision: Approved	
149	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (UWV-AT6-QLZ7, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Kalark 100mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……100mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cefiget suspension by Getz Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
150	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (UGZ-795-RYSP, 2024-07-12) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tim-D Ophthalmic Solution** Each ml of ophthalmic solution contains: Dorzolamide (as HCl)……20mg, Timolol (as Maleate).....5mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: COSOPT Ophthalmic Solution by OBS Pack Size(s): 5ml-As per SRO
	Evaluation Remarks: • Submit import / clearance document from where the loan was taken.	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
151	**Naeem Pharmaceuticals (SMC-Pvt) Ltd.** Plot No.95-A, Industrial Estate, K.L.P Road, Rahim Yar Khan (**000986**) Tracking ID: (VHU-GXN-EE5J, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **N-FLOX Ophthalmic Solution** Each 1 ml contains: Ofloxacin.....3mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: EXOCIN by Barret Hodgson Pack Size(s): 5 ml-As per SRO
	Evaluation Remarks: Submit API import / clarance documents	
	Decision: Approved Firm shall submit documents for procurement of API before issuance of Registration Letter.	
152	**Cure Laboratories (Pvt.) Ltd** Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi (**000897**) Tracking ID: (VXS-425-AXTA, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-02-20 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Malrid 20/120mg Tablets** Each Tablets Contains: Artemether.....20mg, Lumefantrine.....120mg The International Pharmacopeia RRA Status: WHO PQ Me Too Status: Artem Plus Tablet by Hilton Pack Size(s): 2x8's -As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
153	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (W3Z-HND-17UA, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-01-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Jectsol-20% Infusion (1000ml)** Each 100ml contains: Dextrose anhydrous……20g British Pharmacopeia RRA Status: 20% DEXTROSE INJ Health Canada Approved Me Too Status: Dextrose 20% w/v Infusion by Zafa Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
154	**Pasteur & Fleming Pharmaceuticals** Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan (**000945**) Tracking ID: (WP3-ADW-VD3N, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-04-03 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **LINZOFLEM 600MG TABLET** Each film coated tablet contains: Linezolid……600mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Nezkil 600mg Tablet by Continental pharma Pack Size(s): 2 x 6’s -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
155	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (WYZ-X93-BGMQ, 2024-06-21) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Roklar 250mg Capsule** Each capsule contains: Cefaclor (as monohydrate)……250mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Ceclor 250mg Capsule (AGP) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
156	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (XB6-5A2-8HBW, 2024-06-07) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Kalark 400mg Capsule** Each capsule contains: Cefixime (as trihydrate)……400mg Manufacturer Specification RRA Status: USFDA Approved Me Too Status: Cefiget Capsule by Getz Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
157	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (YEJ-15N-41NB, 2024-06-26) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Roklar 250mg/5ml Suspension** Each 5ml of reconstituted suspension contains: Cefaclor (as monohydrate)……250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ceclor 250mg/5ml suspension (AGP) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
158	**Ashrafsons Pharmaceutical (Pvt) Ltd.** Plot No. 40 Road No. R-2 Industrial Estate Gadoon, Amazai, Swabi (**000947**) Tracking ID: (YP2-8JH-QV1J, 2024-05-30) Fee Paid: 30000.0 Paid Date: 2024-01-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Jectsol-20% Infusion (500ml)** Each 100ml contains: Dextrose anhydrous……20g British Pharmacopeia RRA Status: 20% DEXTROSE INJ Health Canada Approved Me Too Status: Dextrose 20% w/v Infusion by Zafa Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
159	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (YQ7-HXW-SHTB, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-07-11 Case Category: New Section **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Gabikon 150mg Capsule** Each capsule contains: Pregabalin.....150mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Gabica 150mg Capsule by Getz Pack Size(s): 2 * 7 's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
160	**Pharman Pharmaceuticals(Pvt)Ltd** Khewat No.59,khatooni No. 114-120, Tehsil Wazirabad,District Gujranwala (**000958**) Tracking ID: (QTJ-A9P-G5LY, 2024-04-18) Fee Paid: Paid Date: Case Category: New License **(Farzana Raja)**	Proposed Name: **Bisacodyl Tablets** Each enteric coated tablet contains:Bisacodyl …… 5 mg United States Pharmacopeia RRA Status: Bisacodyl 5mg Gastro-resistant Tablets, MHRA approved. Me Too Status: Bylax 5mg Tablets (Faas Pharmaceuticals 088335) Pack Size(s): 100 (10 x 10)-As per SRO,200 (20 x 10)-As per SRO,500 (50 x 10)-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

S.No	Section	Shortcoming	Reply
1.	1.1	Fee details are not incorporated in fee details entries. Add fee details in fee detail entries.	Fee Details: Incorporated.
2.	3.2.S.5	Drug substance specification by drug product manufacturer are USP than how working standard of BP grade can be used. Clarification is required.	The method provided in BP is via titration, we have adopted more stringent USP HPLC method and undertake to carried out testing against USP Official CRS while commercialization.
3.	3.2.P.2.2.4	Justification for overage should be submitted.	1.5% overage is added due to very less batch size and quantity of API. Also to over-come process loss during manual mixing This overage will not be added in commercial scale batches.
4.	3.2.P.6	Drug product specification by drug product manufacturer are USP than how working standard of BP grade can be used. Clarification is required.	We have adopted more stringent USP method, and will ensure to carryout testing against USP CRS while commercialization.
5.	3.2.P.8	Documents for the procurement of API with approval from DRAP.	Loan from Batala Pharma is taken.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
161	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (5ZG-X93-NXN6, 2024-05-02) Fee Paid: 30000.0 Paid Date: 2023-10-16 Case Category: New License **(Hafiz Muhammad Asif Iqbal)**	Proposed Name: **Artham Tablets** Artham Tablets: Each Tablet Contains:- Artemether 40mg/Lumefantrine 240mg(Innovator's Specification) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Arceva 40/240 Tablets manufactured by SAMI Pharmaceuticals Pvt. Ltd (Reg. No. 053226) Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No	Shortcomings
1.	Justification shall be submitted for claiming innovator specifications, since Pharmacopoeial monograph is available for applied formulation in International Pharmacopoiea.
2.	Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation since the submitted limits are in contrary to the provision of Pharmacopoeia general monographs for immediate release formulations.
3.	Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis.
4.	Justification shall be submitted that how the “specificity” of the applied drug product analytical method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.
5.	Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed.
6.	Readable copy of the commercial invoice attested by DRAP I&E office shall be submitted for evidence of import of drug substance.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for the submission of above-mentioned shortcomings.	
162	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (6GT-NJV-NPE2, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-31 Case Category: New License **(Hafiz Muhammad Asif Iqbal)**	Proposed Name: **Vono-S 20mg Tablet** Each Film Coated Tablet Contains: - Vonoprazan Fumarate eq. to Vonoprazan ……...20mg (Innovator's Specification) As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: Vonopran 20 20mg Tablet (Shaigan Pharmaceuticals (Pvt) Ltd) Reg. No. 110801 Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No.	Shortcomings
1.	Name of the firm shall be corrected in e-app portal as per revised title approved by Licensing Divison.
2.	Valid DML/GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority of country of origin shall be submitted.
3.	Submitted CAS number is not of Vonoprazan fumarate. Clarification shall be submitted from the drug substance manufacturer along with evidence of characterization of the drug substance to establish its identification.
4.	Reference shall be submitted for the limits of “Fumaric acid” content declared in drug specifications submitted from M/s ICU Pharmaceuticals since the drug substance manufacturer has not proposed this test. Reference shall be submitted for the limits of “pH test” declared in drug specifications submitted from M/s ICU Pharmaceuticals since the drug substance manufacturer has not proposed this test. Justification shall be submitted for variation in the limits of Assay test between specifications from drug substance manufacturer and drug product manufacturer.
5.	Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation.
6.	Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis. Different limits of dissolution test have been submitted in drug product specification and analytical procedure. Justification shall be submitted in this regard. Submitted analytical procedure for dissolution test does not include details of quantification method of dissolution samples. Submitted drug product analytical method does not include details of test of content uniformity test. Justification shall be submitted that how the “specificity” of the applied drug product analytical method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for the submission of above stated shortcomings.	
163	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (85P-TEJ-ELB2, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-06-14 Case Category: New License **(Hafiz Muhammad Asif Iqbal)**	Proposed Name: **Mepzole 40mg Capsule** Each Capsule contains: Omeprazole (as enteric coated pellets)…….40mg (USP Specification) United States Pharmacopeia RRA Status: Approved by US FDA Me Too Status: Omecap Capsule (Next Pharma) Reg. No. 084494 Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No	Shortcomings
1.	Name of the firm shall be corrected in e-app portal as per revised title approved by Licensing Divison.
2.	Justification shall be submitted for variation in sampling time points applied for dissolution profile of reference product and applied product in dissolution medium of pH 6.8.
3.	• Submitted drug product analytical method does not include details of test of content uniformity test.
4.	• Complete raw data sheet for the performance of dissolution test shall be submitted including details of sample and standard solution preparation. • Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed. • Submitted chromatograms declare the run time of about 6 minutes, while the analytical method specifies the gradient programme of about 25 minutes. Justification shall be submitted in this regard.
5.	Evidence of approval of change of Qualified person from Licensing Division shall be submitted since various documents submitted in the applications bears different names and signatures for Quality control manager.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for the submission of above stated shortcomings.	
164	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (DB6-DUW-S4W3, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-06-14 Case Category: New License **(Hafiz Muhammad Asif Iqbal)**	Proposed Name: **Artham Tablets (Artemether 80mg/Lumefantrine 480mg)** Each Tablet Contains:Artemether……80mgLumefantrine……...480mg(Innovator's Specification) As per Innovators Specification RRA Status: WHO prequalified productUSFDA Approved Me Too Status: Arceva 80/480 Tablets manufactured by SAMI Pharmaceuticals Pvt. Ltd (Reg. No. 058381) Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	

Sr. No.	Shortcomings
1.	Justification shall be submitted for claiming innovator specifications, since Pharmacopoeial monograph is available for applied formulation in International Pharmacopoiea.
2.	Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation since the submitted limits are in contrary to the provision of Pharmacopoeia general monographs for immediate release formulations.
3.	Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis.
4.	Justification shall be submitted that how the “specificity” of the applied drug product analytical method has been inferred without the performance of “Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component”.
5.	Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed. Readable copy of the commercial invoice attested by DRAP I&E office shall be submitted for evidence of import of drug substance.
6.	Evidence of approval of change of Qualified person form Licensing division shall be submitted

Decision: Deferred

for the submission of the above-mentioned shortcomings.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
165	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (N16-LGS-GNAU, 2024-06-27) Fee Paid: 30000.0 Paid Date: 2024-05-31 Case Category: New License **(Hafiz Muhammad Asif Iqbal)**	Proposed Name: **Vono-S 10mg Tablet** Each Film Coated Tablet Contains:- Vonoprazan Fumarate eq. to Vonoprazan ……...10mg (Innovator's Specification) As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: Vonopran 10 10mg Tablet (Shaigan Pharmaceuticals (Pvt) Ltd) Reg. No. 110800 Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.Name of the firm shall be corrected in e-app portal as per revised title approved by Licensing Divison. 2.Valid DML/GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority of country of origin shall be submitted. 3.Submitted CAS number is not of Vonoprazan fumarate. Clarification shall be submitted from the drug substance manufacturer along with evidence of characterization of the drug substance to establish its identification. 4.(i) Reference shall be submitted for the limits of "Fumaric acid" content declared in drug specifications submitted from M/s ICU Pharmaceuticals since the drug substance manufacturer has not proposed this test. (ii) Reference shall be submitted for the limits of "pH test" declared in drug specifications submitted from M/s ICU Pharmaceuticals since the drug substance manufacturer has not proposed this test. (iii) Justification shall be submitted for variation in the limits of Assay test between specifications from drug substance manufacturer and drug product manufacturer. 5.Results of CDP in three dissolution mediums shall be justified along with literacy reference for the solubility profile of applied formulation. 6. (i) Justification shall be submitted for the dissolution limits and parameters adopted for finished drug product analysis. (ii) Different limits of dissolution test have been submitted in drug product specification and analytical procedure. Justification shall be submitted in this regard. (iii) Submitted analytical procedure for dissolution test does not include details of quantification method of dissolution samples. (iv) Submitted drug product analytical method does not include details of test of content uniformity test. (v) Justification shall be submitted that how the "specificity" of the applied drug product analytical method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". 7. (i) Documents confirming import of drug substance i.e., commercial invoice/clearance certificate issued by DRAP I&E Office shall be submitted as evidence if import. (ii) Reconciliation record for the imported quantity of drug substance shall be submitted. (iii) Complete raw data sheet for the performance of dissolution test shall be submitted including details of sample and standard solution preparation. (iv) Submitted chromatograms does not declare the wavelength of UV detector upon which analysis has been performed. (v) Submitted chromatograms declare the run time of about 4 minutes, while the analytical method specifies the gradient programme of about 57 minutes. Justification shall be submitted in this regard. 8. Evidence of approval of change of Qualified person form Licensing division shall be submitted since various documents submitted in the applications bears different signatures for Quality control manager.	
	Decision: Deferred for the submission of above stated shortcomings.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
166	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (9XB-8TV-74B4, 2024-05-20) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Iqra Aftab)**	Proposed Name: **Moody Syrup** Each 1ml syrup contains: Risperidone……1mg RRA Status: USFDA Approved. Me Too Status: Risp Oral Suspension (Manufacturer by Addamjee Pharmaceutical Pvt. Ltd.) Pack Size(s): 30ml-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Syrup/Suspension (General) (Revised New).	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 3.2.S.4.1 Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.” 3.2.S.4.3 Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted”. 3.2.P.5.2 The standard and sample preparation in USP(200mcg/ml) is different than preparation(0.1mg/ml) provided in section 3.2.P.5.2.Clarification is required. 3.2.P.7 Clarification for container closure system is required whether HPDE or PET bottle due to variation in data provided in Module . 3.2.P.8.3 a) The container closure system for applied formulation is semipermeable, but the test of water loss has not been performed. Justify. b) The Chromatograms of sample solution contains three major peaks .Identify the peak at RT 1 and 2. c) Submit commercial invoice for import of API.	
	Decision: Deferred .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
167	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (G83-PG1-75D5, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Iqra Aftab)**	Proposed Name: **Swish Oral Drops (Suspension)** Each 1ml contains Nystatin 100,000 IU. United States Pharmacopeia RRA Status: Nilstat Oral Drops approved in TGA link: https://www.tga.gov.au/resources/lab-test-reports/nilstat-oral-drops-nystatin-100000-iuml-suspension-bottle-aspen-pharma-pty-ltd-0 Me Too Status: Nilstat Drops Reg # 001554, Manufactured by ICI Pakistan Ltd. Pack Size(s): 50ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: (2.3.R.1.1)Submit executed production documents. (3.2.S.4.1)Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." (3.2.S.4.3)Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". (3.2.S.4.4)Submit discussion and justification for any incomplete analyses of the drug substance / API by Drug Product manufacturer. (3.2.P.2)Submit compatibility studies of the Drug Substance(s) with excipients if the formulation is not similar to innovator / reference product. (3.2.P.7)Clarification for container closure system is required whether HPDE or PET bottle due to variation in data provided in section 3.2.P.7 and 3.2.P.8.3 . (3.2.P.8.3) Ø Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	

Ø Submit commercial invoice for import of API.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred .	
168	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (WGH-R5S-3JWY, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Iqra Aftab)**	Proposed Name: **Curaon Syrup** Each 5ml contains:Ondansetron (as) HCL Dihydrate….4mg RRA Status: MHRA Approved. Me Too Status: Dysit syrup 4mg/5ml (Manufactured by Wimits Reg:) Pack Size(s): 50ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 3.2.S.4.1 Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." 3.2.S.4.3 Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". 3.2.P.2.1 Submit compatibility studies of the Drug Substance(s) with excipients if the qualitative composition of the formulation is not similar to innovator / reference product. 3.2.P.2.2 The innovator product contains "5 mg of ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron" whereas, the applied product contains 4.36mg of ondansetron hydrochloride. Justification and clarification is required. 3.2.P.5.1 The total microbial count of mold and yeast is not as per USP. USP:NMT 50 cfu/g. Applicant:NMT 10cfu/g 3.2.P.5.2 The formula to calculate qty. of ondansetron in mg is missing.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred .	
169	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (ZDZ-RY4-PXMH, 2024-05-13) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Iqra Aftab)**	Proposed Name: **Zinc-OD Syrup** Each 5ml syrup contains: Zinc sulphate monohydrate equivalent to Elemental zinc…….20mg United States Pharmacopeia RRA Status: Applied formulation has been verified from International Pharmacopoeia of WHO (Available strengths: Me Too Status: OSIRIS 20mg/5ml Syrup Reg# 066902 by Sami Pharmacueticals Pack Size(s): 60ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.5.9 Evidence of approval / registration / marketing status of the applied formulation in the same composition, same strength (20mg/5ml) salt form and dosage form in one of the reference regulatory authorities specified by Registration Board. The name of the reference authority shall be mentioned as adopted by Board currently. 2.3.R.1.1 Submit executed production documents. 3.2.S.4.1 Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.” 3.2.S.4.3 Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted”. 3.2.S.4.4	

Submit discussion and justification for any incomplete analyses of the drug substance / API by Drug Product manufacturer.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred .	
170	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road (**000296**) Tracking ID: (2LP-5X9-V98T, 2024-04-19) Fee Paid: 30000.0 Paid Date: 2024-03-07 Case Category: New Section **(Maham Misbah)**	Proposed Name: **Hydrosone 1%** Each ml Contains Hydrocortisone…….. 10mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Lacticare 1% Lotion Pack Size(s): 30ml, 60ml,120ml 240-De-Controlled
	Evaluation Remarks: New section Section name: Lotion (general) (clarification is required from applicant) Shortcomings: As the applied product is a steroidal preparation, evidence of separate dispensing facility verified by DRAP shall be submitted along with GMP certificate of the relevant section. **3.2.P.8** Justify the number and size of stability batches i.e. two batches of 300 units each. **3.2.P.8** Long term stability studies of the Drug product shall be submitted as per Zone-IVa conditions for 6 month time point.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred Applicant shall submit response to above cited shortcomings.	
17 1	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (**000955**) Tracking ID: (G5B-NU7-25M9, 2024-07-05) Fee Paid: 30000.0 Paid Date: 2024-06-07 Case Category: New License **(Maham Misbah)**	Proposed Name: **Itropine 100mg Capsules** Each Capsule contains: Itraconazole as immediate release pellets..... 100mg United States Pharmacopeia RRA Status: Sporanox 100mg capsules. MHRA Approved Me Too Status: Rolac 100mg Capsules by Sami Pack Size(s): 1x4s-As per SRO
	Evaluation Remarks: New license Section: Capsule (General) Source of pellets: Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved .	
172	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road (**000296**) Tracking ID: (QYH-W8W-6U1A, 2024-03-22) Fee Paid: 30000.0 Paid Date: 2024-01-03 Case Category: New Section **(Maham Misbah)**	Proposed Name: **Betazole** Each grams Contains:Betamethasone(Dipropionate)……0.05%W/WClotrimazole .....…1% W/W RRA Status: USFDA Me Too Status: Lotricort Cream Mass Pharma Pack Size(s): 15g 30g-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: New section **Observations/Deficiencies/ Short-comings** Complete stability studies data of Betamethasone API shall be submitted for the assigned shelf life. Label claim is different from that of reference product in USFDA. Change label claim accordingly along with submission of requisite fee. Pharmaceutical equivalence is conducted against Lotricort cream. Submit manufacturer name and Batch no. of the reference product. Valid GMP certificates of drug substance manufacturers shall be submitted. In which section will this applied product be manufactured. Submit section approval letter of the relevant section, issued by Licensing Division of DRAP.	
	Decision: Deferred Applicant shall submit response to above cited shortcomings	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
173	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (**000955**) Tracking ID: (TVE-26W-313G, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-01-09 Case Category: New License **(Maham Misbah)**	Proposed Name: **Dexzol 60mg capsule** Each Capsule contains: Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole…….60mg As per Innovators Specification RRA Status: Dexilant 60mg Capsule Approved by USFDA Me Too Status: Razodex 60mg Capsule by Getz Pharma Pakistan Pack Size(s): 3x10s-As per SRO
	Evaluation Remarks: New License Section : Capsule (General) Source of pellets: Vision Pharmaceuticals (pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan Observations/Deficiencies/ Short-comings: Six months time point real time and accelerated stability studies sheets and associated data of drug product shall be submitted.	
	Decision: Deferred Applicant shall submit response to above cited shortcomings	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
174	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (**000955**) Tracking ID: (UL3-SD1-QUUE, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-01-09 Case Category: New License **(Maham Misbah)**	Proposed Name: **Dexzol 30mg capsule** Each Capsule contains: Enteric coated pellets of Dexlansoprazole Equivalent to Dexlansoprazole…….30mg As per Innovators Specification RRA Status: Dexilant 30mg Capsule Approved by USFDA Me Too Status: Razodex 30mg Capsule by Getz Pharma Pakistan Pack Size(s): 3x10s-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks: New License Section: Capsule (General) Source of pellets: Vision Pharmaceuticals (pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan Observations/Deficiencies/ Short-comings: Six months time point real time and accelerated stability studies sheets and associated data of drug product shall be submitted.	
	Decision: Deferred Applicant shall submit response to above cited shortcomings	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
175	**Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad (**000955**) Tracking ID: (Y3W-APT-48EX, 2024-05-14) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Maham Misbah)**	Proposed Name: **Mebin 200mg SR Capsule** Each Capsule contains: Mebeverin hydrochloride as Sustained release pellets equivalent to Mebeverin hydrochloride …….200mg (BP Specifications) British Pharmacopeia RRA Status: Colofac 200mg Modified Release Capsule Mylan, MHRA Approved Me Too Status: Mebever 200mg MR Capsule, GETZ PHARMA PAKISTAN Pack Size(s): 1x10s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: New license Section: Capsule (General) Source of pellets: Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan Shortcomings: 1.5.6: Specifications given are BP whereas product monograph is not available in BP. Clarify the product specifications and submit applicable pre-registration fee in case of change of specifications. 3.2.S.7: Real time stability studies results and associated data of three batches of drug substance for complete assigned shelf life i.e. 36 months shall be submitted.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred Applicant shall submit response to above cited shortcomings	
176	**AstraZeneca Pharmaceuticals Pakistan Private Limited** C-50, Block-2, Clifton, Karachi Pakistan (**290**) Tracking ID: (PEP-ETM-1ASQ, 2024-07-12) Fee Paid: 300000.0 Paid Date: 2024-05-20 Case Category: New Molecule/Formulation **(Muneeb Ahmed Cheema)**	Proposed Name: **CALQUENCE® Tablets, 100mg (acalabrutinib)** Each film coated tablet contains:100 mg of acalabrutinib (equivalent to 129 mg of acalabrutinib maleate) As per Innovators Specification RRA Status: Product is approved in USFDA, EU, Health Canada and Australia Me Too Status: Calquence is an Originator Brand (Research Brand) Pack Size(s): 10 Film-Coated Table-De-Controlled,60 Film-Coated Table-De-Controlled
	Marketing Authorization Holder (Abroad): AstraZeneca UK Limited , Charter Way, Macclesfield, Cheshire East SK10 2NA UNITED KINGDOM, United **Manufacturer(s):** -AstraZeneca AB, Sweden-AstraZeneca AB, Gartunavagen, Sodertalje 152 57 SWEDEN-Sweden	
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): CoPP No. XQQU-MD54 dated 11.12.2023 issued by USFDA	
	Evaluation Remarks: Innovator Drug Product	
	Decision: Approved subject to compliance of Import Policy for Finished Drugs	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
177	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (11D-S33-9XT7, 2024-07-01) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX 15% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….150mg British Pharmacopeia RRA Status: N/A Me Too Status: AMOCILLIN 15% INJECTION (100ml) (113596) ETERNA PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
178	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (1LR-86M-3L6L, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 2 % Liquid Injection** Each mL Contains Ivermectin BP 20 mg As per Innovators Specification RRA Status: Ivercare 2 % Injection USA Me Too Status: Selmec (071087) Selmore. Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
179	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (1NS-EVD-MD39, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLORNIX-30 INJECTION (100 ml)** Each ml Contains: Florfenicol 300 mg As per Innovators Specification RRA Status: NA Me Too Status: Florofen INJECTION (Reg # 043160) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
180	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (1R1-XLE-P74E, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLUX-50 INJECTION (50 ml)** Each ml Contains: Flunixin Meglumine 50 mg United States Pharmacopeia RRA Status: NA Me Too Status: FM-50 INJECTION (Reg # 111550) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: **Target species:** Cattle, horse **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
181	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (1XR-ZGU-VZ1H, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH PROSTREP 400 INJECTION** Each ml contains: Procaine Penicillin G (USP)…..……..…..…200,000IU Dihydrostreptomycin Sulphate (USP)……..…200mg As per Innovators Specification RRA Status: N/A Me Too Status: PENOXIL INJECTION (099447) MYLAB PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
182	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (237-RZH-EJSV, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 20% Injection** Each ml contains: : Amoxicillin as Trihydrate…..…….20mg Colistine Sulphate…… 0.5MIU As per Innovators Specification RRA Status: N/A Me Too Status: COLISTIN MOX-20/0.5 INJECTION (113601) ETERNA PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
183	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (288-RE9-BHM2, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New License **(Najia Saleem)**	Proposed Name: **MULTI-NIX INJECTION (50 ml)** Each ml Contains: Vitamin A 100000 IU Vitamin D3 40000 IU Vitamin E 40 mg As per Innovators Specification RRA Status: NA Me Too Status: ADEKA INJECTION (Reg # 075792) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
184	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (3M5-7A6-Q75B, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH GENMOX 190 INJECTION** Each ml contains: Amoxicillin Trihydrate…..……..…150mg Gentamycin Sulphate EQ to Gentamycin..…40mg As per Innovators Specification RRA Status: N/A Me Too Status: AMOXYGENT INJECTION (097945) SELMORE PHARMA Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
185	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (3PW-JDZ-2QY4, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH PROSTREP 450 INJECTION** Each ml contains: Procaine Penicillin (USP)…..……..…..…200mg Dihydrostreptomycin Sulphate (USP)……..…250mg As per Innovators Specification RRA Status: N/A Me Too Status: ELPRE-STREP INJECTION (025374) ELKO ORGANIZATION Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
186	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (3V1-L3J-53XA, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEOXY-10 INJECTION (100 ml)** Each ml Contains: Meloxicam 10 mg British Pharmacopeia RRA Status: NA Me Too Status: Meloxter-10 INJECTION (Reg # 109919) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats	
	Decision: Approved	
187	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (3VQ-SHL-MB61, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 1 % Liquid Injection** Each mL Contains Ivermectin BP 10 mg As per Innovators Specification RRA Status: Ivomec Injection UK Me Too Status: Ivobak Injection (053908) Attabak Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
188	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (3M4-8YU-QVT9, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **OXY 20% INJECTION (100 ml)** Each ml Contains: Oxytetracycline HCl 200 mg United States Pharmacopeia RRA Status: NA Me Too Status: Oxster- 20% INJECTION (Reg #111399) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: **Target species:** calves, goats, sheep	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
189	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (499-PVJ-JRYV, 2024-05-23) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **one Mec super Liquid injection** Each mL contains Ivermectin BP 10 mg Clorsulon USP 100 mg United States Pharmacopeia RRA Status: Ivomec Super. UK Me Too Status: Actimec Super (033251) selmore 2. Elvomec Super (025788) Elko Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
190	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (55P-4S2-XY1H, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 1 % Liquid Injection** Each mL Contains Ivermectin BP 10 mg As per Innovators Specification RRA Status: Ivomec Injection. UK Me Too Status: Primec 10 injection (072696) Prix Pack Size(s): 250 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
191	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (5NL-JGP-EAMZ, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 2 % Liquid Injection** Each mL Contains Ivermectin BP 20 mg As per Innovators Specification RRA Status: Ivercare 2 % Injection USA Me Too Status: Selmec (071087) Selmore. Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
192	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (5Q1-ELR-WYZW, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH PROSTREP 400 INJECTION** Each ml contains: Procaine Penicillin G (USP)…..……..……200,000IU Dihydrostreptomycin Sulphate (USP)……..…200mg As per Innovators Specification RRA Status: N/A Me Too Status: PENOXIL INJECTION (099446) MYLAB PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
193	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (5U7-QZ8-515G, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **One D 3 Liquid injection** Each mL contains Vitamin A BP 80,000 IU Vitamin D3 USP 40,000 IU Vitamin E USP 20 mg As per Innovators Specification RRA Status: Vitamin AD3E, Netherland Me Too Status: Vital 3 (049635)n selmore 2. VAD 3 (059179) ICI Pack Size(s): 100 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
194	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (614-8JS-M4QS, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onefos Liquid Injection** Each mL Contains Toldimfos Sodium MS 200 mg Cyanocobalmin BP 0.05 mg As per Innovators Specification RRA Status: N/A Me Too Status: Tonovit (033253) Selmore Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
195	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (61G-GEP-LH2H, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 20% Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 200 mg As per Innovators Specification RRA Status: Genta inj 20 %. Me Too Status: Gentabar 20 (087122) Baariq Pack Size(s): 50 mL-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
196	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (61S-GDA-W756, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MOX 15% INJECTION** Each ml contains: (As Per Innovator Spec.) Amoxicillin Trihydrate eq to Amoxicillin base..…….150mg As per Innovators Specification RRA Status: N/A Me Too Status: ALMOXIN 15% LA INJECTION (052371) CHERISHED PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The firm has already applied for the same formulation vide tracking Id 11D-S33-9XT7	
	Decision: Rejected Same formulation vide tracking Id 11D-S33-9XT7 has been considered and approved in instant meeting.	
197	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (63X-9XG-UXTA, 2024-05-23) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Fluxi Injection** Each mL contains Flunixin as Meglumine USP 50 mg United States Pharmacopeia RRA Status: Pyroflam 50 mg. UK Me Too Status: 1, Flumeg (085471) Elko 2. Loxin (035098) selmore Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
198	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (7LP-E68-WM6L, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **PROBEN 40 Dry Powder Inj.** Each dry powder vial contains: Procaine Penicillin …..……..…..…3,000,000 IU Benzyl Penicillin ……..1000,000 IU RRA Status: N/A Me Too Status: B-Penicillin Injection (112313) ETERNA Pharma Pack Size(s): 1 x 1's-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, goats, sheep	
	Decision: Approved	
199	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (6P3-37N-RSLB, 2024-07-01) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX15% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….…150mg British Pharmacopeia RRA Status: N/A Me Too Status: AMOCILLIN 15% INJECTION (10ml) (113593) ETERNA PHARMACEUTICALS Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
200	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (7MD-S1R-ER5Y, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEOXY-20 INJECTION (50 ml** Each ml Contains: Meloxicam 20 mg British Pharmacopeia RRA Status: NA Me Too Status: Meloxter-20 INJECTION (Reg # 109920) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: dogs, cats	
	Decision: Approved	
201	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (7NP-22U-PXMW, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH CLAVMOX 150 INJECTION** Each ml contains: Amoxicillin (as Trihydrate)……100mg Cloxacillin (As Sodium)…….…….50mg As per Innovators Specification RRA Status: N/A Me Too Status: CLOMIX INJECTION (049680) ALINA COMBINE PHARMA Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
202	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (7S9-ERZ-RD5X, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-16 Case Category: New License **(Najia Saleem)**	Proposed Name: **PMP-100 INJECTION** Each ml Contains: Phenoxy 2-Methyl 2-propionic acid 100 mg As per Innovators Specification RRA Status: NA Me Too Status: Nelster Injection (Reg # 111401) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
203	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (7V7-RVP-NNBD, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH GENMOX INJECTION** Each ml contains: Amoxicillin Trihydrate…..…….….150mg Gentamicin (Sulphate) ……...…40,000IU As per Innovators Specification RRA Status: N/A Me Too Status: GENTAMOX INJECTION (094467) HIPRA PAKISTAN PVT LTD Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
204	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (7VH-TD7-HYGT, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 20% Liquid Injection** Each mL contains Gentamicin as sulphate BP 200 mg As per Innovators Specification RRA Status: Genta-Inj 20 % Me Too Status: Gentabar-20 (087120) Baariq Pharma Pack Size(s): 100 mL-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
205	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (7WL-SN7-54G8, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 10 % liquid Injection** Each mL contains Enrofloxacin USP 100 mg As per Innovators Specification RRA Status: Baytril UK Me Too Status: Enromall (109802) Mallard. Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
206	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (882-D2P-2MQ5, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 3.15 % Liquid Injection** Each mL contains Ivermectin BP 31.5 mg British Pharmacopeia RRA Status: Bovimec, Canada Me Too Status: 1, Elvomec 3.15% (063728) Star Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
207	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (8DY-ZTP-7TTZ, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 3.15 % Liquid Injection** Each mL Contains Ivermectin BP 31.5 mg As per Innovators Specification RRA Status: Bovimec, 3.15%, injection Agrovet , Canada Me Too Status: Elvomec Star 3.15% Injection (063728) Elko Pack Size(s): 10 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
208	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (8ZE-WSD-HPWD, 2024-07-01) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX 15% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….150mg British Pharmacopeia RRA Status: N/A Me Too Status: AMOCILLIN 15% INJECTION (50ml) (113595) ETERNA PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
209	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (915-HNP-E8P3, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MOX 15% INJECTION** Each ml contains: (As Per Innovator Spec.) Amoxicillin Trihydrate eq to Amoxicillin base..…….150mg As per Innovators Specification RRA Status: N/A Me Too Status: ALMOXIN 15% LA INJECTION (052371) CHERISHED PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: The firm has already applied for the same formulation vide tracking Id 87E-WSD-HPWD	
	Decision: Rejected Same formulation vide tracking Id 87E-WSD-HPWD has been considered and approved in instant meeting.	
210	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (9QZ-YGA-T2MU, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onefos Liquid Injection** Each mL Contains Toldimfos Sodium MS 200 mg Cyanocobalmin BP 0.05 mg As per Innovators Specification RRA Status: N/A Me Too Status: Tonovit (033253) Selmore Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
211	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (9U8-NJP-UPZ9, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX 20% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….…200mg British Pharmacopeia RRA Status: N/A Me Too Status: NOVAMOX 20% LA INJECTION (043145) SELMORE PHARMACEUTICALS Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
212	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (9M8-XGJ-HYUL, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Fluxi Liquid Injection** Each mL Contains Flunixin as Meglumine USP 50 mg United States Pharmacopeia RRA Status: Pyroflam 50 mg. UK Me Too Status: 1.Flumeg (085471) Elko 2. Loxin Injection (035098) Selmore Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
213	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (9Y5-AVU-22A6, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLUX-50 INJECTION (10 ml)** Each ml Contains: Flunixin Meglumine 50 mg United States Pharmacopeia RRA Status: NA Me Too Status: FM-50 INJECTION (Reg # 111549) Pack Size(s): 10ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Cattle, horse Shortcomings: The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
214	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (AT1-A1G-AVJ7, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Cozole Liquid Injection** Each mL contains Trimethoprim 80 mg Sulphadiazine 400 mg British Pharmacopeia RRA Status: Norodine UK Me Too Status: Triberssen (091891) Hilton, Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
215	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (AN3-1VB-LVRD, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH BENPEN 450 INJECTION** Each ml contains: Benzathine Penicillin G …..……..…..…100,000 IU Procaine Penicillin G ……..150,000 IU Dihydrostreptomycin Sulphate ……..…200mg As per Innovators Specification RRA Status: N/A Me Too Status: B.G PROBENZ INJECTION (072699) BIOGEN PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
216	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (B2E-TVX-B8WN, 2024-05-23) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **T.Genta Injection** Each mL contains Gentamicin as Sulphate BP 50 mg Tylosin as Tartrate USP 100 mg As per Innovators Specification RRA Status: Gen.Tylo. Jordan Me Too Status: 1, Tygent (049636) Selmore. 2. Synogent (079856) Mallard. Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
217	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (B5D-EMB-HGYG, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **T. Genta Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 50 mg Tylosin as Tartrate USP 100 mg As per Innovators Specification RRA Status: Gen.Tylo. Jordan Me Too Status: 1, Tygent (049636) Selmore. 2. Synogent (079856) Mallard. Pack Size(s): 100 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
218	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (BJD-ERX-1GJ3, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **VANIC MOX INJECTION** Each ml contains: Amoxicillin (As Amoxicillin Trihydrate)…..……140mg Clavulanic Acid as Potasium Clavulante…….35mg As per Innovators Specification RRA Status: N/A Me Too Status: NUGMENTAN INJECTION (072675) NAWAN LABORATORIES Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
219	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (D5V-U2Z-H3Z9, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 2 % Liquid Injection** Each mL contains Ivermectin BP 20 mg British Pharmacopeia RRA Status: IverCare USA Me Too Status: Selmec (071087) Selmore. 2. Ivermall 2% (079854) Mallard Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
220	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (BWG-RQ4-6N8A, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 10% Injection** Each ml contains: : Amoxicillin as Trihydrate…..…….100mg Colistine Sulphate……250,000IU As per Innovators Specification RRA Status: N/A Me Too Status: COLIMOXIN INJECTION (034576) SELMORE PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
221	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (DJN-QW3-3VXE, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **VERME 2% INJECTION (100 ml)** Each ml Contains: Ivermectin 20 mg United States Pharmacopeia RRA Status: NA Me Too Status: Vectin- 2% INJECTION (Reg #109907) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: cattle	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
222	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (DYR-PLY-PZ5Z, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **REPTOBEN 2.5g Dry Powder Inj.** Each dry powder vial contains: Benzyl Penicillin ……..500,000 IU Penicillin G Procaine……..…..…15, 00,000 IU Streptomycin Sulphate…….2.5g RRA Status: N/A Me Too Status: Strellin 20/2.5 Injection (113467) ETERNA Pharma Pack Size(s): 1 x 1's-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, goats, sheep	
	Decision: Approved	
223	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (EQ8-D3L-RQYA, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **VANIC MOX INJECTION** Each ml contains: Amoxicillin (As Amoxicillin Trihydrate)…..……140mg Clavulanic Acid as Potassium Clavulanate…….35mg As per Innovators Specification RRA Status: N/A Me Too Status: NUGMENTAN INJECTION (072675) NAWAN LABORATORIES Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
224	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (GH3-41A-65BH, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 10% Injection** Each ml contains: : Amoxicillin as Trihydrate…..…….100mg Colistine Sulphate……250,000IU As per Innovators Specification RRA Status: N/A Me Too Status: COLIMOXIN INJECTION (034576) SELMORE PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
225	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (E7N-NTG-AGWV, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 1 % Liquid Injection** Each mL Contains Ivermectin BP 10 mg As per Innovators Specification RRA Status: Ivomec Injection UK Me Too Status: Everest injection (102011) Vetz Pharma Pack Size(s): 500 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
226	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (EHH-VHT-L4V4, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH PROSTREP 360 INJECTION** Each ml contains: Procaine Penicillin G (USP)…..……..…..…200mg Dihydrostreptomycin Sulphate (USP)……..…160mg As per Innovators Specification RRA Status: N/A Me Too Status: STREPTOCAIN INJECTION (106742) GRAND PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
227	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (GVE-UBM-2ZB6, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH PROSTREP 450 INJECTION** Each ml contains: Procaine Penicillin (USP)…..……..…..…200MG Dihydrostreptomycin Sulphate (USP)……..…250mg As per Innovators Specification RRA Status: N/A Me Too Status: ELPRE-STREP INJECTION (025374) ELKO ORGANIZATION Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
228	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (H3H-QHY-RLE1, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MYSTREP 400 INJECTION** Each ml contains: Procaine Penicillin G (BP)…..……..…..…200,000IU Streptomycin Sulphate (BP)……...….200mg As per Innovators Specification RRA Status: N/A Me Too Status: STREP-STREP INJECTION (057047) LEADS PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
229	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (GRM-43H-17D9, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 1 % Liquid Injection** Each mL Contains Ivermectin BP 10 mg As per Innovators Specification RRA Status: Ivomec Injection UK Me Too Status: Ivobak Injection (053908) Attabak Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
230	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (H3W-DV3-V3G5, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLUX-50 INJECTION (100 ml)** Each ml Contains: Flunixin Meglumine 50 mg United States Pharmacopeia RRA Status: NA Me Too Status: Flumag INJECTION (Reg # 046539) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: **Target species:** Cattle, horse **Shortcomings:** The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
231	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (HAB-MMH-ZS8A, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-16 Case Category: New License **(Najia Saleem)**	Proposed Name: **MULTINIX-P INJECTION** Each 100 ml contains: Calcium Gluconate 20.83 % Calcium D-Saccharate 1.0 % Magnesium Hypophosphite 5.33 % Magnesium Chloride 2.0 % Boric Acid 4.33 % Dextrose 20.0 % As per Innovators Specification RRA Status: NA Me Too Status: Calcicare Injection (Reg # 025323) Pack Size(s): 300ml-De-Controlled
	Evaluation Remarks: confirmation of relevant filling facility.	
	Decision: Deferred The firm shall submit evidence of relevant filling facility.	
232	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (J78-T39-P8NV, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **BENTRO Dry Powder Inj.** Each dry powder vial contains: Benzyl Penicillin ……..500,000 IU Streptomycin Sulphate…….5 GM RRA Status: N/A Me Too Status: G-Benz Injection (106731) Grand Pharma Pack Size(s): 1 x 1’s-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, goats, sheep	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
233	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (J7N-T9L-9VAW, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Cozole Liquid Injection** Each ml contains Trimethoprim BP 80 mg Sulphadiazine BP 400 mg British Pharmacopeia RRA Status: Norodine UK Me Too Status: Triberssen (091891) Hilton, 2. Tribectral (029613) Selmore Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
234	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (JD9-PV9-71DQ, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 20 % liquid Injection** Each mL Contains Enrofloxacin USP 200 mg As per Innovators Specification RRA Status: Enroflox 20 America Me Too Status: Enroflox-20 (048153) SJ&G Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
235	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (JME-A79-QY9V, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-16 Case Category: New License **(Najia Saleem)**	Proposed Name: **TG-NIX INJECTION** Each ml Contains: Tylosin Tartrate 100 mg Gentamycin Sulphate 50 mg As per Innovators Specification RRA Status: NA Me Too Status: Genin Injection (Reg # 075793) Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
236	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (JNY-XGD-78EE, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MOX 20% INJECTION** Each ml contains: (As Per Innovator Spec.) Amoxicillin Trihydrate eq to 200mg Amoxicillin As per Innovators Specification RRA Status: N/A Me Too Status: ZAMOX 20% LA INJECTION (048154) ZAKFAS PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: The firm has already applied for the same formulation vide tracking Id W2V-985-1Q97	
	Decision: Rejected Same formulation vide tracking Id W2V-985-1Q97 has been considered and approved in instant meeting.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
237	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (L6A-1YD-NT8H, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 10% Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 200 mg As per Innovators Specification RRA Status: Genta inj 20 %. Me Too Status: Gentabar 20 (087122) Baariq Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
238	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (LU3-RD1-MGDQ, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH GENMOX 190 INJECTION** Each ml contains: Amoxicillin Trihydrate…..…….….150mg Gentamicin Sulphate EQ to Gentamicin..…40mg As per Innovators Specification RRA Status: N/A Me Too Status: AMOXYGENT INJECTION (097945) SELMORE PHARMA Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
239	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (LXM-1NE-TDYH, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-16 Case Category: New License **(Najia Saleem)**	Proposed Name: **SD-NIX INJECTION** Each 100ml Contains: Sulphadimidine 33.30 gm British Pharmacopeia RRA Status: NA Me Too Status: Entradine 33.3% Injection (Reg # 043584) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with official monograph as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with official monograph as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
240	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (LY9-BSM-E2S1, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 10 % liquid Injection** Each mL Contains Enrofloxacin USP 100 mg As per Innovators Specification RRA Status: Baytril injection. United Kingdom. Me Too Status: Enromall (109802) Mallard. Pack Size(s): 50 mL-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
241	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (M69-YRB-L2XT, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 10% Liquid Injection** Each mL contains Gentamicin as sulphate BP 100 mg As per Innovators Specification RRA Status: Genta 100. Netherland Me Too Status: Gentasel 10 (034594) selmore Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
242	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (M74-391-PYB7, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH CLAVMOX 250 INJECTION** Each ml contains: Amoxicillin (as Trihydrate)……125mg Cloxacillin (As Sodium)…….…….125mg As per Innovators Specification RRA Status: N/A Me Too Status: MOX INJECTION (094471) INSHAL PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
243	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (MMU-E43-6V1Z, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-16 Case Category: New License **(Najia Saleem)**	Proposed Name: **MULTI-NIX INJECTION** Each ml Contains: Vitamin A 100000 IU Vitamin D3 40000 IU Vitamin E 40 mg As per Innovators Specification RRA Status: NA Me Too Status: ADEKA INJECTION (075792) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
244	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (MVL-ZRE-LE6N, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **VERME 2% INJECTION (50 ml)** Each ml Contains: Ivermectin 20 mg United States Pharmacopeia RRA Status: NA Me Too Status: Vectin- 2% INJECTION (Reg # 109906) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: cattle	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
245	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (N8Q-E7A-UA9R, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MOX 15% INJECTION** Each ml contains: (As Per Innovator Spec.) Amoxicillin Trihydrate eq to Amoxicillin base..…….150mg As per Innovators Specification RRA Status: N/A Me Too Status: ALMOXIN 15% LA INJECTION (052371) CHERISHED PHARMACEUTICALS Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: The firm has already applied for the same formulation vide tracking Id 6P3-37N-RSLB	
	Decision: Rejected Same formulation vide tracking Id 6P3-37N-RSLB has been considered and approved in instant meeting	
246	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (N4M-VZY-GAZ4, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Oxymine Liquid Injection** Each ml contains Oxytetracycline HCL BP 300 mg Flunixin Meglumine BP 20 mg As per Innovators Specification RRA Status: Hexasol . Ireland Me Too Status: I-Foam (062076) IPL Pack Size(s): 50 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
247	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (P51-HX8-QJ54, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 20 % liquid Injection** Each mL Contains Enrofloxacin USP 200 mg As per Innovators Specification RRA Status: Enroflox 20 America Me Too Status: Enroflox-20 (048153) SJ&G Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
248	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (PMU-2X9-6W8Z, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Cozole Liquid Injection** Each mL contains Trimethoprim 80 mgSulphadiazine 400 mg British Pharmacopeia RRA Status: Norodine UK Me Too Status: Triberssen (091891) Hilton, Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
249	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (NN7-DA1-J5S1, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **REPTOBEN 5g Dry Powder Inj.** Each dry powder vial contains: Benzyl Penicillin ……..500,000 IU Penicillin G Procaine……..…..…15, 00,000 IU Streptomycin Sulphate……. 5g RRA Status: N/A Me Too Status: Biopen 5 GM Injection (081718) SELMORE PHARMA Pack Size(s): 1 x 1's-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, goats, sheep	
	Decision: Approved	
250	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (PT3-5PH-JDV7, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 12% Injection** Each ml contains: Amoxicillin as Trihydrate…..……. 120mg Colistine Sulphate…… 300,000IU As per Innovators Specification RRA Status: N/A Me Too Status: COLA-MOXIN 12% INJECTION (093809) INSHAL PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
251	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (PVJ-166-SVAX, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec 1% Liquid Injection** Each mL contains Ivermectin BP 10 mg British Pharmacopeia RRA Status: Ivomek, UK Me Too Status: 1. Actimec (034595) Selmore. 2.Elvomec (022189) Elko Pack Size(s): 10 mL-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
252	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (PX3-MS9-DWP6, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Fluxi Liquid Injection** Each mL Contains Flunixin as Meglumine USP 50 mg United States Pharmacopeia RRA Status: Pyroflam 50 mg. UK Me Too Status: 1.Flumeg (085471) Elko Pack Size(s): 100 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
253	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (PZP-SZB-4PGH, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Liquid Injection** Each mL Contains Vitamin A BP 80,000. IU Vitamin D3 USP 40,000. IU Vitamin E USP 20 mg As per Innovators Specification RRA Status: Vitamin AD3E, Netherland Me Too Status: VAD 3 Injection (059179) ICI Pakistan Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
254	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (Q6H-TXV-E342, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLORNIX-30 INJECTION (50 ml)** Each ml Contains: Florfenicol 300 mg As per Innovators Specification RRA Status: NA Me Too Status: Florofen INJECTION (Reg # 043160) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
255	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (R3E-NTR-SRPN, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **OXY 20% INJECTION (50 ml)** Each ml Contains: Oxytetracycline HCl 200 mg United States Pharmacopeia RRA Status: NA Me Too Status: Oxster- 20% INJECTION (Reg # 111398) Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: **Target species:** calves, goats, sheep	
	Decision: Approved	
256	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (R95-BV3-XZ72, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MYSTREP 450 INJECTION** Each ml contains: Procaine Penicillin (BP)…..……..…..…200mg Streptomycin Sulphate (BP)……...….250mg As per Innovators Specification RRA Status: N/A Me Too Status: I-P-STREP INJECTION (080524) INTERNATIONAL PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
257	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (R9W-GA8-WLNP, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEOXY-10 INJECTION (50 ml)** Each ml Contains: Meloxicam 10 mg British Pharmacopeia RRA Status: NA Me Too Status: Meloxter-10 INJECTION (Reg # 109918) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: dogs, cats	
	Decision: Approved	
258	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (RBU-7W2-WWLJ, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **T. Genta Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 50 mg Tylosin as Tartrate USP 100 mg As per Innovators Specification RRA Status: Gen.Tylo. Jordan Me Too Status: 1, Tygent (049636) Selmore. 2. Synogent (079856) Mallard. Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
259	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (S25-SJP-YZBP, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARC PEN-40 LAC Dry Powder Inj.** Each dry powder vial contains: Penicillin G Procaine……..……4, 000,000 IU RRA Status: N/A Me Too Status: PP Cillin 4-M Injection (112338) ETERNA Pharmaceuticals Pack Size(s): 1 x 1's-De-Controlled
	Evaluation Remarks: Dry Powder Injectable (Penicillin) Vet section confirmed vide letter No. F. 5-6/2021-Lic dated 31-01-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
260	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (S2Z-P9H-X3WV, 2024-05-26) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 10 % liquid Injection** Each mL Contains Enrofloxacin USP 100 mg As per Innovators Specification RRA Status: Baytril injection. United Kingdom. Me Too Status: Encure-10 Injection (020803) Nawan Pharmaceuticals Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
261	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (RL4-SB7-ESZX, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **VERME 1% INJECTION (50 ml)** Each ml Contains: Ivermectin 10 mg United States Pharmacopeia RRA Status: NA Me Too Status: Vectin - 1% INJECTION (Reg # 109903) Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: cattle	
	Decision: Approved	
262	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (TAD-BBW-ZXYL, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEOXY-20 INJECTION (100 ml)** Each ml Contains: Meloxicam 20 mg British Pharmacopeia RRA Status: NA Me Too Status: Meloxter-20 INJECTION (Reg # 109921) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
263	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (SQL-16T-PZLR, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Najia Saleem)**	Proposed Name: **STREPEN Dry Powder Inj.** Each dry powder vial contains: Penicillin G Procaine……..……3, 000,000 IU Penicillin G Sodium ……..1,000,000 IU Dihydrostreptomycin Sulphate…….5 GM As per Innovators Specification RRA Status: N/A Me Too Status: DG Strept Injection (113469) ETERNA Pharma Pack Size(s): 1 x 1's-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, goats, sheep	
	Decision: Approved	
264	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (THS-TMH-DNAJ, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH CLAVMOX 150 INJECTION** Each ml contains: Amoxicillin (as Trihydrate)……100mg Cloxacillin (As Sodium)…….…….50mg As per Innovators Specification RRA Status: N/A Me Too Status: CLOMIX INJECTION (049680) ALINA COMBINE PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
265	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (UNS-Y2W-MXHP, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onefos Liquid Injection** Each mL contains Toldimfos Sodium MS 200 mg cyanocobalmin (Vit B12) BP 0.05 mg As per Innovators Specification RRA Status: N/A Me Too Status: Tonovit (033253) Selmore Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
266	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (UTN-TVD-WXEJ, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **VERME 1% INJECTION (100 ml)** Each ml Contains: Ivermectin 10 mg United States Pharmacopeia RRA Status: NA Me Too Status: Vectin - 1% INJECTION (reg # 109904) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle	
	Decision: Approved	
267	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (TJ7-ZQ2-SUHG, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MOX 20% INJECTION** Each ml contains: (As Per Innovator Spec.) Amoxicillin Trihydrate eq to 200mg Amoxicillin As per Innovators Specification RRA Status: N/A Me Too Status: ZAMOX 20% LA INJECTION (048154) ZAKFAS PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: The firm has already applied for the same formulation vide tracking Id Z36-L79-HXSL	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Rejected Same formulation vide tracking Id Z36-L79-HXSL has been considered and approved in instant meeting.	
268	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (V7L-N14-PAHV, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 10% Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 100 mg As per Innovators Specification RRA Status: Genta 100. Netherland Me Too Status: Gentamall (079853) Mallard Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
269	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (VDA-9LP-8BBB, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Oxymine Liquid Injection** Each mL contains Oxytetracycline HCL BP 300 mg Flunixin Meglumine BP 20 mg As per Innovators Specification RRA Status: Hexasol . Ireland Me Too Status: I-Foam (062076) IPL Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
270	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (W2V-985-1Q97, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX 20% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….200mg British Pharmacopeia RRA Status: N/A Me Too Status: AMOCILLIN 20% LA INJECTION (100ml) (113598) ETERNA PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
271	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (WAS-JAY-LZV9, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec Super Liquid Injection** Each mL Contains Ivermectin BP 10 mg Clorsulon USP 100 mg As per Innovators Specification RRA Status: Ivomec Super. UK Me Too Status: Actimec Super (033251) selmore Pack Size(s): 10 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
272	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (X3V-BGR-5ED6, 2024-07-03) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH CLAVMOX 250 INJECTION** Each ml contains: Amoxicillin (as Trihydrate)……125mg Cloxacillin (As Sodium)…….…….125mg As per Innovators Specification RRA Status: N/A Me Too Status: MOX INJECTION (094472) INSHAL PHARMACEUTICALS Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
273	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XEV-9XJ-5U1V, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 12% Injection** Each ml contains: Amoxicillin as Trihydrate…..……. 120mg Colistine Sulphate…… 300,000IU As per Innovators Specification RRA Status: N/A Me Too Status: COLA-MOXIN 12% INJECTION (093808) INSHAL PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
274	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XWA-PGL-9ATU, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MYSTREP 360 INJECTION** Each ml contains: Procaine Penicillin (BP)…..……..…..…200mg Streptomycin Sulphate (BP)……...….160mg As per Innovators Specification RRA Status: N/A Me Too Status: I-PRO-STREP INJECTION (080525) INTERNATIONAL PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
275	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (XZ6-99H-A3XG, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **TG-NIX INJECTION (50 ml)** Each ml Contains: Tylosin Tartrate 100 mg Gentamycin Sulphate 50 mg As per Innovators Specification RRA Status: NA Me Too Status: Genin INJECTION (Reg # 075793) Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	
	Decision: Approved The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter	
276	**Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat (**000990**) Tracking ID: (Y59-623-GZ52, 2024-04-17) Fee Paid: 30000.0 Paid Date: 2024-04-17 Case Category: New License **(Najia Saleem)**	Proposed Name: **OXY 5% INJECTION (100 ml)** Each ml Contains: Oxytetracycline HCl 50 mg United States Pharmacopeia RRA Status: NA Me Too Status: Oxster- 5% INJECTION (Reg # 111397) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: **Target species:** calves, goats, sheep	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
277	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (YRV-5QM-JXL8, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onero 20 % Liquid Injection** Each ml contains Enrofloxacin USP 200 mg As per Innovators Specification RRA Status: Enroflox 20 America Me Too Status: Enroflox-20 (048153) SJ&G Pack Size(s): 100 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
278	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (YW8-B7W-T2JE, 2024-07-02) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH MTIN 20% Injection** Each ml contains: Amoxicillin as Trihydrate…..…….….20mg Colistine Sulphate…… 0.5MIU As per Innovators Specification RRA Status: N/A Me Too Status: COLISTIN MOX-20/0.5 INJECTION (113602) ETERNA PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
279	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (Z36-L79-HXSL, 2024-07-01) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH LA MOX 20% INJ.** Each ML contains: Amoxicillin as Trihydrate…..…….….200mg British Pharmacopeia RRA Status: N/A Me Too Status: AMOCILLIN 20% LA INJECTION (50ml) (113597) ETERNA PHARMACEUTICALS Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
280	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (Z3N-LZN-6JXU, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARCH BENPEN 450 INJECTION** Each ml contains: Benzathine Penicillin G …..……..…..…100,000 IU Procaine Penicillin G ……..150,000 IU Dihydrostreptomycin Sulphate ……..…200mg As per Innovators Specification RRA Status: N/A Me Too Status: B.G PROBENZ INJECTION (072699) BIOGEN PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Approved	
281	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (ZNP-AGQ-BLP1, 2024-05-27) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **G One 10% Liquid Injection** Each mL Contains Gentamicin as Sulphate BP 100 mg As per Innovators Specification RRA Status: Genta 100. Netherland Me Too Status: Gentalin 10 (017944) Star labortaries Pack Size(s): 100 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
282	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (ZWP-T7Z-RLG9, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **One Mec Super Liquid Injection** Each mL Contains Ivermectin BP 10 mg Clorsulon USP 100 mg As per Innovators Specification RRA Status: Ivomec Super. UK Me Too Status: Actimec Super (033251) selmore 2. Elvomec Super (025788) Elko Pack Size(s): 50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
283	**Getz Pharma (Pvt.) Ltd. - (Unit I)** Plot No. 1, Sector 25, Korangi Industrial Area (**000933**) Tracking ID: (1DM-EZX-SDBV, 2024-05-09) Fee Paid: 30000.0 Paid Date: 2023-12-22 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Cefoproxil DS** Each film-coated tablet contains: Cefpodoxime proxetil USP equivalent to Cefpodoxime ……200mg United States Pharmacopeia RRA Status: Cefpodoxime Proxetil Tablets 200mg by M/s Sandoz Limited, United Kingdom (MHRA Approved) Me Too Status: Cefpower Tablets 200mg by M/s Platinum Pharmaceuticals (Pvt.) Ltd. Pack Size(s): 10-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
284	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (1DS-Q7H-G1PQ, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Gabaqad Capsule 75 mg** Each capsule contains pregabalin 75mg British Pharmacopeia RRA Status: EMC, FDA Me Too Status: Gabica Capsule by Getz Pharma Pack Size(s): 2x7's=14's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
285	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (1DV-5WE-5ZN4, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Capsule Gabaqad 150mg** Each capsule contains pregabalin 150mg British Pharmacopeia RRA Status: MHRA approved formulation Me Too Status: Gabica Capsule by Getz Pharma Pack Size(s): 2x7's=14's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
286	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (1HB-5BR-E6GL, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **MESOFER 500MG/10ML INJECTION** Each 10ml Vial Contains: -Iron Carboxy maltose Injectable ……500mg (Innovator's Specification) As per Innovators Specification RRA Status: MHRA Approved formulation Me Too Status: Feservoir (Martin Dow) Reg. No. 108355 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
287	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (1JS-96L-BJ2M, 2024-07-29) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Methyll 500mg Injection** Each Vial Contains (Sterile powder for reconstitution):Methylprednisolone as Sodium Succinate (USP)…….500mg(Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solu Medrol Injection by Pfizer Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
288	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (1HX-39J-1ULM, 2024-06-10) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Ezimep 40mg Capsule** Each Capsule contains: Esomeprazole as enteric coated pellets (USP) …..... 40mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Sold Capsule by Regal Pharmaceuticals Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: **Source of pellets:** Winbrains Research Laboratories (DML # 000919 - Semi-Basic Manufacturing) Plot NO. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Source of pellets: Winbrains Research Laboratories (DML # 000919 - Semi-Basic Manufacturing) Plot NO. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.	
289	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (1TX-4B2-PMRR, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-24 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Permgen 5% Lotion** Each ml contains: Permethrin…….50 mg (5% w/v) RRA Status: Permethrin 5% w/v lotion MHRA approved Me Too Status: Permirive Lotion 60ml by Maxitech Pack Size(s): 1's-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>290</td><td>Welcome Pakistan Trading Pharma (Pvt) Ltd
Chakri Interchange, Gangawala (000987)
Tracking ID: (1RT-MZX-D242, 2024-06-11)
Fee Paid: 30000.0
Paid Date: 2024-05-29
Case Category: New License
(Salateen Waseem Philip)</td><td>Proposed Name: ICON 100MG CAPSULE
Each Capsule contains: Itraconazole as IR Pellets 22%.....…..... 100mg (Product Complies USP Specifications)
United States Pharmacopeia
RRA Status: UK MHRA
Me Too Status: ICONYX CAPSULE BY WNSFEILD PHARMA
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:<table><tr><td>1.6.5</td><td>Submit valid / fresh GMP certificate of API manufacturer issued by DRAP which should enlisted itraconazole IR pellet

Reply of the firm:

Approved in 276th meeting of CLB</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved

Source of pellets:

Winbrains Research Laboratories</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
291	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (226-MTX-HGL3, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-06-07 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Smectamed Sachet 3g** Each sachet contains;Dioctahedral smectite……..…..3.00g (Innovator's Specifications) As per Innovators Specification RRA Status: Smecta Powder in Sachet ANSM M/s IPSEN Industrie. France Approved Me Too Status: Smecta sachet (Atco Lab.) Reg. No. 010905 Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
292	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore (**000655**) Tracking ID: (2E5-TR2-HS8Z, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Tiroban 12.5mg Injection** Each vial contains Tirofiban (as HCl) .... 12.5mg/50mL (Innovator Specification) RRA Status: Aggrastat Injection Me Too Status: Aggrastat Injection (Atco Laboratories) Pack Size(s): 1's (50mL)-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
293	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (2H4-SJ3-65H7, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-10 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Iron-Fer** Each 5ml Ampoule Contains: Elemental Iron as Iron Sucrose 100mg British Pharmacopeia RRA Status: TGA Approved Me Too Status: Venofer Injection by Searle Pakistan Limited Pack Size(s): 5ml x 5's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
294	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (29R-LU6-RBA2, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Emezole 40mg capsule** Each Capsule contains: Esomeprazole Coated pellets of Magnesium trihydrate equivalent to Esomeprazole …...40mg (USP Specification) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Nexum Capsule 40mg (Getz Pharma) Reg. No. 033891 Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of pellets Vision Pharmaceuticals (Private) Limited (DML # 000806 - semi basic manufacturer) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets Vision Pharmaceuticals (Private) Limited (DML # 000806 - semi basic manufacturer) Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
295	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (2T9-EPR-W8Y1, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wari-cef 125mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cephradine……125mg British Pharmacopeia RRA Status: Velosef® (cephradine) for Oral Suspension USP, 125 mg/5mL by Me Too Status: Velosef 125mg/5ml Dry powder suspension by GSK Pharma Pack Size(s): 90ml-As per SRO
	Evaluation Remarks: The RRA of product is not available.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
296	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (2JE-VTA-JXJZ, 2024-06-06) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **E-CEP 20MG CAPSULE** Each capsule contains;Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole…….20mg(USP Specifications) RRA Status: USFDA Approved Me Too Status: Nexum 20mg Capsule (Getz Pharma) Reg. 033890 Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved Source of pellets: Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
297	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (2TE-8AT-4QYV, 2024-04-30) Fee Paid: 30000.0 Paid Date: 2024-04-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lecebact sterile powder for injection** Each vial contains:Cefoperazone as Sodium....500mgSulbactam as Sodium.....500mg As per Innovators Specification RRA Status: Cefoperazone + Sulbactam 1g injection, Approved by PMDA of Japan Me Too Status: Nichlobact 1g Injection by Nicholas Pharmaceuticals Pack Size(s): 1's-As per SRO
	Evaluation Remarks: Firm needs to submit fee for change of specifications.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
298	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (33E-JT8-6Y6E, 2024-05-14) Fee Paid: 30000.0 Paid Date: 2023-08-01 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Biocin 500mg/2ml Injection** Each 2ml Vial Contain: Amikacin (as Sulphate)...500mg British Pharmacopeia RRA Status: AMIKACIN 500mg/2ml Injection Me Too Status: Grasil 500mg Injection SAMI Pharmaceuticals Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
299	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (2XG-R3H-YME5, 2024-06-25) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Brainy Syrup 500mg/5ml** Each 5ml contains...citicoline as sodium 500mg As per Innovators Specification RRA Status: Somazine 100 mg/ml oral solution - Cima Spain Me Too Status: Citolin Syrup reg# 029540 by Global Pharmaceutical (Pvt.) Ltd. Pack Size(s): 60ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Submit reply of following observations for further processing of your case. Section: 1.3.4: Submit GMP certificate issued by DRAP for manufacturing facility of Syrup Genera Section which should be valid till date. Section 3.2.P.7: Clarify that primary container mentioned as HDPE white colored bottle while in the table of Product general details the the nature of primary container has been mentioned as A light brown color clear viscous liquid filled in amber color pet bottle sealed with cap and packed in specially designed tray holder with insertion of leaflet in unit carton.	
	Decision: Deferred The case has been deferred till submission of shortcomings in the application of the firm. .	
300	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (365-3XV-3ZZ4, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-07 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Medizek 40mg Capsule** Each capsule Contains: Omeprazole (as enteric coated pellets 22.5%)…….40mg (USP Specifications) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Risek 40mg Capsule (Getz Pharma) Reg. No. 022109 Pack Size(s): As Per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: **Source of pellets** **Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan**	
	Decision: Approved **Source of pellets** **Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan**	
301	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (444-VDM-8MH4, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-07 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Medizek 20mg Capsule** Each capsule Contains: Omeprazole (as enteric coated pellets 8.5%)…….20MG (USP Specifications) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Risek 20mg Capsule (Getz Pharma) Reg. No. 019364 Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks: Source of pellets: Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets: Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
302	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (4QS-LUR-LGSZ, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-05-02 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Nurofen Solution for Infusion 400 mg/100ml** Each 100ml of solution contains: Ibuprofen …… 400 mg As per Innovators Specification RRA Status: Ibuoprofen B. Braun Infusion of M/s B. Braun Melsungen AG (HPRA Approved) Me Too Status: Ubrof 400 mg/100ml Infusion of M/s SAMI Pharmaceuticals Pack Size(s): 100ml, As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
303	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (49N-HNL-TSS5, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Dexsofast 30mg Capsule** Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent to Dexlansoprazole .....30mg (Innovators Specification) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex 30mg Capsule Getz Pharma Reg. 086976 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Source of pellets: VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Source of pellets: VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
304	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (4AY-8RX-EVUP, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-04-02 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Parical 2mcg soft gel capsules** Each soft gelatin capsule contains: Paricalcitol ……..2mcg (USP Spec) United States Pharmacopeia RRA Status: Zemplar (Paricalcitol soft gelatin) 2 mcg Capsule FDA Approved Me Too Status: N/A Pack Size(s): 30's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
305	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (4BW-TDZ-VVBM, 2024-05-15) Fee Paid: Paid Date: Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Dexnoor 30mg** Each Capsule contains: Dexlansoprazole (as Dual Delayed-Release Pellets) ……. 30mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex 30 mg capsule By Getz Pharma Pack Size(s): 30's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of pellets : M/S Vision Pharmaceuticals (Pvt.) Ltd.	
	Decision: Approved Source of pellets : M/S Vision Pharmaceuticals (Pvt.) Ltd.	
306	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (4EG-18N-W52L, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Lansodex 60mg Capsule** Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent to Dexlansoprazole…….60mg (Innovators Specification) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex 60mg Capsule Getz Pharma Reg. 000793 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: **Source of pellets:** Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets: Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
307	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (4RD-TRG-JNU2, 2024-07-26) Fee Paid: 30000.0 Paid Date: 2024-07-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Teflor 600mg Sterile powder for Injection** Each vial Contains (Sterile powder for reconstitution) :Ceftaroline Fosamil Monoacetate Monohydrate with L-arginine eq. to Ceftaroline Fosamil……..600mg As per Innovators Specification RRA Status: Teflaro (ceftaroline Fosamil) for Injection 600mg/vial of M/s Allergan USA, Inc.Madison, NJ 07940 (USFDA Approved) Me Too Status: Zinforo Powder for Concentrate for Solution for Injection of M/s Pfizer Pack Size(s): 1x1's,1x10's, 1x20's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
308	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (4HL-LB2-Q8HH, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-27 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Zolan 10mg Tablets (Orodispersible)** Each Orodispersible Tablet Contains; Olanzapine (as citrate) .....10mg (USP Spec's) United States Pharmacopeia RRA Status: Zyprexa 10mg Orodispersible Tablets, Manufacturer: Eli Lilly and Company. (Registered in United State) Me Too Status: Psyclan 10mg Orodispersible Tablets, Manufacturer: Pharm Evo Private Limited. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Submit reply of following observations at the earliest for further processing of your case. Section 3.2.P.8: Submit stability data for the last interval 06 month and resubmit stability data sheets with comparison of results of 0,3 & 6 month. (date due for 06th month stability 17-09-2024)	
	Decision: Approved Firm shall submit the stability data of drug product for the last interval of 06th month before issuance of registration letter.	
309	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (4NW-7TE-4LPQ, 2024-04-30) Fee Paid: 30000.0 Paid Date: 2024-02-19 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Komizole 20mg** Each Capsule contains: Omeprazole (as Enteric Coated Pellets) = 20 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Risek 20 mg By Getz Pharma Pack Size(s): 10's-As per SRO,14's-As per SRO
	Evaluation Remarks: **Source of pellets:** M/S Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved **Source of pellets:** M/S Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad	
310	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (4YD-98G-E26Z, 2024-06-07) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Moxilone** Each 250ml Vial Contains: Moxifloxacin as Hydrochloride 400mg As per Innovators Specification RRA Status: Health Canada Me Too Status: Available i.e. Moxiget Infusion 400mg/250ml by Getz Pharma, Karachi-Pakistan Pack Size(s): 250mlx1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section	Observations	Reply of the firm
1.3.5	• Please clarify the status of your ampoule / vial section SVP or LVP?	Our manufacturing facility for sterile liquid for ampoule / vial section is for Small Volume Parenteral (SVP) but, vial filling & stoppering machine in our manufacturing facility has a fill capacity of 2ml to 250ml in single dosing capability. (40 vials / minutes).
	• Please submit inspection report of your firm conducted for grant of sterile section for ampoules & vials.	Submitted
3.2.P.3	• Please submit documented evidence that vial filling machine used is capable to fill 250 ml sterile solution in glass vials.	We are submitting the brochure of vial filling & stoppering machine in our manufacturing facility which requires a 2 H.P. electric supply and has a fill capacity of 2ml to 250ml in single dosing capability. (40 vials / minutes)
	• Please submit the filtration plan for manufacturing process of LVP (250ml) solution of moxifloxacin,	The validation protocol for LVP Moxifloxacin infusion has been submitted.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred The Board decided to defer the case and directed the Pharmaceutical Evaluation Cell to submit a report for making a final decision for those manufacturers who have filling machine with capacity to fill infusion and vials up to 300 ml and doesn't require any special precaution as required in case of LVPs formulation such as lipids formulation / TPNs / macromolecules etc.	
311	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (53B-LAN-7E7M, 2024-07-17) Fee Paid: 30000.0 Paid Date: 2024-07-11 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Micip 500mg Tablet** Each Film Coated Tablet Contains: -Ciprofloxacin HCl eq. to Ciprofloxacin……...500mg(USP Specification) RRA Status: Ciprofloxacin 500 mg Film-coated Tablets M/s Aurobindo Pharma Ltd MHRA approved Me Too Status: Cip Val Tablet 500mg (GlaxoSmithKline Pakistan Limited F/268, SITE Karachi) Reg. No. 050688 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
312	**Titlis Pharma (Private) Limited** 528-A Sundar Industrial Estate, Raiwind Road Lahore (**000799**) Tracking ID: (4X3-DEB-73XP, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2022-03-28 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Emlint** Each Film Coated Tablet Contains: Linagliptin…..…….5mg Empagliflozin…….10mg As per Innovators Specification RRA Status: USFDA APPROVED (Glyxambi 5/10mg Tablet) Me Too Status: Diampa-LT by GETZ Pharma Pack Size(s): 14s-As per SRO
	Evaluation Remarks: Section 3.2.P.8: Give your point of view that why analysis has been carried out on a HPLC whose baseline was not stable and number of unknown peaks were eluting very close to the peak of interest that limit of resolution has been not followed. How would you justify the unstable baseline giving validated results? Reply of the firm: The extra peaks close to the peak of interest are of pure solvent (Menthol and Perchloric acid) used in the mobile phase for analysis; as per already submitted analytical method. The blank run chromatogram of analytical method validation study in which the specificity is clarifying the solvent peaks is also attached for your kind perusal.	
	Decision: Deferred The registration Board deferred the case. Firm shall again perform assay and submit chromatograms with value of resolution between the peak of interest and other peaks in the chromatogram.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
313	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (56Q-38L-WPBT, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Gabaqad Capsule 300 mg** Each capsule contains pregabalin 300mg British Pharmacopeia RRA Status: MHRA approved formulation Me Too Status: Gabica By Getz Pharmaa Pack Size(s): 2x7's=14's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
314	**Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan (**000725**) Tracking ID: (5L6-D45-Q9X1, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2023-01-11 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Combrain 400/12mcg DPI Capsule** Each Rotacap Rota Capsule contains: Budesonide (USP)…….400Mcg Formoterol Fumarate (USP) …….12Mcg (Product Complies Innovators Specs) As per Innovators Specification RRA Status: UK MHRA Approved Me Too Status: Venticort Rotacaps 400mg + 12mcg Highnoon Labs (Reg#089365) Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
315	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (5L7-TS2-89S9, 2024-02-12) Fee Paid: 30000.0 Paid Date: 2023-12-15 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Teflor 400mg sterile powder for Injection** Each Vial contains (sterile owder for reconstitution) :Ceftaroline Fosamil as Ceftaroline Fosamil Monoacetate Monohydrate with L-Arginine……..400mg As per Innovators Specification RRA Status: Teflaro (ceftaroline Fosamil) for Injection 400mg/vial M/S Allergan USA, Inc.Madison, NJ 07940(USFDA Me Too Status: N.A Pack Size(s): 1x1's,1x10's As per -As per SRO
	Evaluation Remarks:	
	Decision: Approved	
316	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (5MP-M7Z-HQPB, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Emezole 20mg capsule** Each Capsule contains: Esomeprazole Coated pellets of Magnesium trihydrate equivalent to Esomeprazole …...20mg (USP Specification) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Nexum Capsule 20mg (Getz Pharma) Reg. No. 033890 Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of pellets: VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets: VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
317	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (5W1-RLJ-QJLB, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Bizlucan Capsule 150mg** Each Capsule Contain:- Fluconazole…. 150mg (B.P Specifications) British Pharmacopeia RRA Status: Azocan 150mg Capsule (MHRA Approved) Me Too Status: Zolanix Capsule 150mg (GlaxoSmithKline Pakistan Ltd.) Reg No. 084720 Pack Size(s): 1’s, 2’s, 5’s, 7’s, -As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
318	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (5W2-LG8-75VH, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Getcip 250mg Tablet** Each film coated tablet contains: - Ciprofloxacin Hydrochloride Eq. to Ciprofloxacin……250mg (USP Specifications) United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: CIPVAL 250mg Tablet (GSK) Reg. No. 050687 Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
319	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore (**000577**) Tracking ID: (653-JQZ-74EX, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Fomen dry oral suspension 40mg/5ml** Each 5ml reconstituted Suspension contains Famotidine 40mg United States Pharmacopeia RRA Status: USFDA approved formulation Me Too Status: Zepsin By Cirin Pack Size(s): 60 ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
320	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (66M-45J-YSQP, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Tablet Miadine 5 mg** Each Film Coated Tablet Contains: Desloratadine 5mg United States Pharmacopeia RRA Status: US-FDA Approved Me Too Status: Available i.e. Larinex 5mg Tablet by Getz Pharma, Karachi Pack Size(s): 1x10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
321	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (6DG-3Z9-HP95, 2024-06-25) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Capri 3mg Capsule** Each Capsule Contains: Cariprazine as Cariprazine Hydrochloride (USP)…….....3mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Caripra Capsule by Genix Pharma Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
322	**Biorex Pharmaceuticals** Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad (**000528**) Tracking ID: (652-ZBE-DAMZ, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-26 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Moxibay 400mg /250 ml Infusion** Each 250ml Vials Contains: Moxifloxacin as Hydrochloride 400mg As per Innovators Specification RRA Status: Health Canada Me Too Status: Moxiget Infusion by Getz Pharma, Karachi Pack Size(s): 250mlx1's-As per SRO
	Evaluation Remarks: The firm has only section for SVP Vials for sterile solution.	
	Decision: Deferred The Board decided to defer the case and directed the Pharmaceutical Evaluation Cell to submit a report for making a final decision for those manufacturers who have filling machine with capacity to fill infusion and vials up to 300 ml and doesn't require any special precaution as required in case of LVPs formulation such as lipids formulation / TPNs / macromolecules etc.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
323	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (6N2-88S-GMZ5, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Gaba Biz Capsule 50mg** Each Capsule Contain:-Pregabalin 50mg(BP Specifications) RRA Status: MHRA approved Pregabalin Noumed 50 Mg Capsules Me Too Status: PREGY Capsule 50mg REG No. 076670 (SAMI Pharmaceuticals) Pack Size(s): 1's, 5's, 7's, 10's,-As per SRO
	Evaluation Remarks: The applicant applied with Innovator specification, However in reply of query, firm has submitted the Chromatograms as per HPLC method of BP specification on 20-07-2024. The results are found within limits of BP specification. Firm needs to submit the fee for change in specification.	
	Decision: Approved The registration letter shall be issued after submission of requisite fee for change in specifications.	
324	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (77W-HDA-DA4M, 2024-04-24) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **OmBiz Capsule 20mg** Each Capsule contains:- Delayed Release Pellets of Omeprazole Equivalent to Omeprazole……20mg (USP Specification) United States Pharmacopeia RRA Status: MHRA approved Losec® Capsule 20mg (Neon Healthcare Limited) Me Too Status: OMEGA Capsule 20mg Reg No. 018024 (Ferozsons Laboratories Limited) Pack Size(s): 1's, 5's, 7's, 10's,-As per SRO
	Evaluation Remarks: # Source of Pellets: **Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan**	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved **Source of Pellets:** **Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan**	
325	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (6SH-A54-EMVZ, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2023-08-01 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Biocin 1gm/4ml Injection** Each 4ml vial contains:Amikacin (as Sulphate).....1000mg British Pharmacopeia RRA Status: AMIKACIN 1g/4ml Injection Me Too Status: Bikil Injection 1g/ 4 ml by Siza Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
326	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (6VR-N7V-BWBY, 2024-07-13) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Hepato Sachet 5gm** Each Sachet Contains: L-ornithine-L-aspartate....3gm As per Innovators Specification RRA Status: Hepa Merz Sachet is approved in Austria link is: https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx Me Too Status: Hepa Merz Sachet by Brooks Pharma Reg#012143 Pack Size(s): 5s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section	Observations	Reply of the firm
1.3.4	Submit GMP certificate of you firm issued by DRAP which should be valid till date."	GMP certificate of Curatech Pharma (Pvt) Ltd and newly approved Section Approval letter for Sachet section is attached herewith.
3.2.S.7	Explain that why the values of temperature and humidity are not mentioned on stability summary sheets of API".	Revised stability data of L-ornithine L-aspartate with temperature and humidity conditions mentioned is attached herewith.

Decision: Approved

The firm shall submit valid GMP certificate issued by DRAP for the manufacturing facility of drug product before issuance of registration letter.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
327	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (99Z-8HN-Z86W, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Capri 6mg Capsule** Each Capsule Contains: Cariprazine as Cariprazine Hydrochloride (USP)…….....6mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Caripra Capsule by Genix Pharma Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
328	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (A14-N6N-BYNT, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Dense** Each 5ml contains: Iron polysaccharide complex eq to elemental iron.....100mg As per Innovators Specification RRA Status: Ferrica syrup Me Too Status: Ironone syrup Pack Size(s): 1's (120ml) -De-Controlled,1's (30ml) -De-Controlled,1's (60ml) -De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
329	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (A5E-Q5V-DADH, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wari-cef 250mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains:Cephradine……250mg British Pharmacopeia RRA Status: USFDA approval year 1974. But currently discontinued on official website of USFDA. Me Too Status: Velosef 250mg/5ml Dry powder suspension by GSK Pharma Pack Size(s): 90ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
330	**M/s Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore (**000576**) Tracking ID: (97S-U2U-QVMW, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-04 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Matine Tablet 25mg** Each film coated tablet Contains: Agomelatine…….. 25mg As per Innovators Specification RRA Status: Valdoxan by Servier Laboratories Me Too Status: Agoviz by Pharmevo Pack Size(s): 10’s, 14’s, 28’s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section	Observations	Reply of the firm
3.2.S.7	The stability data of API has been submitted at zone IV while the storage condition mentioned on material safety data sheet of agomelatine is 2-8° degree Celsius. Justify with reference of storage.	As per available DMF of drug substance the stability condition of real time is 30 to 65 ° degree Celsius and drug substance is stable at this temperature and MSDS is not authentic and requirement of CTD but the stability study is mandatory document.
3.2.P.3	The innovator brand has chosen dry granulation method while your formulation has been prepared by wet granulation. Please justify.	The innovator contains Maize starch that contains 5 to 10% moisture content and in formulation sticking and powder flowing issues that leads to weight variation problem observed so we chosen the wet granulation technique, in commercial batches we will make sure to manufacture the product with dry granulation.

Decision: Approved

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
331	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (AAJ-BWB-JNRA, 2024-07-29) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **HY?KOR 100MG Sterile powder for INJECTION** Each Vial Contains (Sterile powder for reconstitution) :Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP)……..100mg(Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: CORTISONE 100MG INJECTION by VISION PHARMACEUTICALS Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
332	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (AWX-VWA-8BGM, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-22 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lawazed 250mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cefadroxil as Monohydrate……250mg United States Pharmacopeia RRA Status: Cefadroxil powder, for suspension by Ranbaxy Pharmaceuticals Inc. Jacksonville, FL 32257 USA Me Too Status: Bio oxil 250mg/5ml Dry powder suspesnion by Bio-Labs Pharmaceuticals Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
333	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (B53-6AZ-7S1J, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-06-05 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wono Tablet 10mg** Each Film Coated Tablet Contain:- Vonoprazan as fumarate 10mg (Innovator's Specifications) As per Innovators Specification RRA Status: (PMDA Japan Approved) Me Too Status: VPN-10 Tablet 10mg Reg. No. 110203 by Helix Pharma Karachi Pack Size(s): 1's, 5's, 10's,20's,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
334	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (B62-R5X-VXXH, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-04-02 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Parical 1mcg Soft gelatin Capsule** Each Soft gelatin contains:- Paricalcitol……..1mcg (USP Specs) United States Pharmacopeia RRA Status: FDA Approved. Zemplar (Paricalcitol soft gelatin) 1 mcg Capsule Me Too Status: N/A Pack Size(s): 30's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
335	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (AYN-HY7-DDDT, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Albet-H Cream** Each gram cream contains; Fusidic acid ……20mg Hydrocortisone Acetate…..10mg (Innovator Specifications) As per Innovators Specification RRA Status: Fucidin-H Cream, Manufacturer: Leo laboratories limited UK (MHRA-UK Approved) Me Too Status: Fudic-H cream, Manufacturer: Shaigan Pharmaceuticals (Pvt.) Limited Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section</th><th>Observations</th><th>Reply of the firm</th></tr>
<tr><td>3.2.P.2</td><td>submit pharmaceutical equivalence in tabulated form for a comparison between the tests and results of your drug product against comparator product.</td><td>Submitted</td></tr>
<tr><td>3.2.P.8</td><td>Submit stability data of complete 06 months for consideration of your case. (06 month stability data due on 11-09-2024)</td><td>Submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved Firm shall submit 06th month stability study data of drug product before issuance of registration letter.</td></tr>
<tr><td>336</td><td>VENUS PHARMA
23-KM MULTAN ROAD, LAHORE (000300)
Tracking ID: (BBY-DZN-YM3P, 2024-07-29)
Fee Paid: 30000.0
Paid Date: 2024-07-12
Case Category: New Section
(Salateen Waseem Philip)</td><td>Proposed Name: Oxytocin Injection 5 IU
Each ml contains: Oxytocin .....5 IU USP Specs
United States Pharmacopeia
RRA Status: MHRA
Me Too Status: Syntomax Injection 5 IU by Indus Pharma (PVT) LTD.
Pack Size(s): 100amp X 1ml-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
337	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (BJ8-EG5-MR4E, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wari-cef 500mg Capsule** Each capsule contains: Cephradine……500mg British Pharmacopeia RRA Status: CEFRADINE 500mg Capsule by Kent Pharma UK Limited Me Too Status: Velosef 500mg Capsule by M/s GSK Ltd Pack Size(s): 12's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
338	**Cure Laboratories (Pvt.) Ltd** Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi (**000897**) Tracking ID: (BU2-YLG-M7TB, 2024-06-27) Fee Paid: 30000.0 Paid Date: 2024-02-20 Case Category: Routine **(Salateen Waseem Philip)**	Proposed Name: **Monti** One chewable tablet contains montelukast sodium, which is equivalent to 5 mg montelukast United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Montika 5 mg Chewable Tablet Pack Size(s): 14 Tablets-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
339	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (BXU-M9Q-9RAW, 2024-05-02) Fee Paid: 30000.0 Paid Date: 2024-04-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **GEN-D3 200,000 IU SOFT GEL CAPSULE** Each soft gelatin capsule contains: Cholecalciferol ……..200,000 IU United States Pharmacopeia RRA Status: ANSM France Me Too Status: Sunny-D soft gel Capsule of Scotmann Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Submit reply of the following observations at the earliest for further processing of your case. · Section 3.2.P.3 : 1- How will you confirm the inert atmosphere for handling and storage of API? 2- Give evidence that your manufacturing facility is capable of preserving API in hermetically sealed containers under nitrogen? · Section 1.5..8 1- Submit website link of France's regulatory authority website for the confirmation of the same formulation in same strength and dosage form as RRA recommended by DRAP. · Section 3.2.P.8 1- Submit DRAP clearance for procurement of API. 2- Submit GMP certificate of API manufacturer issued by regulatory authority of country of origin which should be valid till date.	
	Decision: Deferred for above mentioned shortcomings .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
340	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (D7R-J9J-TLUB, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-04-08 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Acepol 120 mg/5ml** Each 5ml contains: Paracetamol …… 120mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Calpol Suspension by GSK Pack Size(s): 100 ml-As per SRO,120 ml-As per SRO,400 ml-As per SRO,450 ml-As per SRO,60ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
341	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (DHS-5LW-93PD, 2024-07-23) Fee Paid: 30000.0 Paid Date: 2024-07-08 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Cefadox 125mg/5ml oral Powder for suspension** Each 5 mL of reconstituted suspension contains cefadroxil monohydrate equivalent to 125 mg of cefadroxil United States Pharmacopeia RRA Status: European Medicine Agency (EMA) Me Too Status: Neusef Suspension 125mg/5ml Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
342	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (BVZ-TVX-78ZD, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **K-Lok Sachet 15gm** Each single use 15 gm sachet contains calcium polystyrene sulfonate (Powder for reconstitution) As per Innovators Specification RRA Status: MHRA approved formulation in single dose sachet Me Too Status: K-styrene by Genome Pack Size(s): 20 sachets-As per SRO
	Evaluation Remarks:	
	Decision: Approved Firm shall submit summary sheet of stability data of API manufacturer before issuance of registration letter.	
343	**Dynatis Pakistan Pvt. Ltd.** Plot 710, Sundar Industrial Estate, Lahore (**000891**) Tracking ID: (BZ7-M5T-727R, 2024-05-22) Fee Paid: 10000.0 Paid Date: 2024-04-02 Case Category: Any Other **(Salateen Waseem Philip)**	Proposed Name: **Levocil** Each film-coated tablet contains: Levofloxacin hemihydrate eq. to Levofloxacin……. ….500mg. United States Pharmacopeia RRA Status: Levofloxacin Tablet 500mg Me Too Status: Leflox Tablet 500mg Pack Size(s): 5’s, 7’s, 10’s, 14’s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Evaluated on priority as per 157 meeting of Authority dated 20-01-2023 for GMP of applicant from PIC/s member NRAs. Its 2nd molecule for year 2024. PIC/s certificate also attached with this application from UKraine. For this application, Fee Challan of PKR 30000/- (Slip # 471173700948) has been submitted by firm.	
	Decision: Approved	
344	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (EJ8-XAB-TG1Y, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-06-10 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Itracon 100mg Capsule** Each Capsule contains:Itraconazole (as IR Pellets) = 100 mg RRA Status: Health Canada Me Too Status: Sporanox 100mg capsule by Aspin Pharma Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.	
345	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (GAE-432-4955, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-06-05 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wono Tablet 20mg** Each Film Coated Tablet Contain:- Vonoprazan as fumarate 20mg (Innovator's Specifications) As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: VPN-20 Tablet Reg No. 110204 by Helix Pharma Karachi Pack Size(s): 1's, 5's, 10's,20's,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
346	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (GL2-X4P-2NJV, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Rinogen 500mg Capsule** Each Capsule contains: Cephalexin (as monohydrate).....500mg (USP Specification). United States Pharmacopeia RRA Status: Cephalexin capsule (MHRA Approved) Me Too Status: Keflex 500mg capsule(Reg No:098687) by AGP LIMITED Pack Size(s): As per SRO.-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
347	**Al Barakat Pharmaceutical Industries** Plot # B/66-A, S.I.T.E, Nooriabad (**000973**) Tracking ID: (DSR-EJ4-P8GQ, 2024-06-26) Fee Paid: 30000.0 Paid Date: 2024-04-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Betazon-N Eye Ointment** Each 1gm contains: Betamethasone Sodium Phosphate USP……1mg (0.1%w/w) Neomycin Sulphate USP……5mg (0.5%w/w) Manufacturer Specification RRA Status: Brand Name: Betanesol - N Eye Ointment 0.1%/0.50% Market Authorization: Glaxo SmithKline UK Reference Regulatory Authority: Glaxo SmithKline UK Me Too Status: Brand Name: Betnesol – N Eye Ointment Strength: 1mg/gm ,5mg/gm Dosage Form: Ophthalmic Ointment Pack Size: 5.00gm Regn No.000251 Manufacturer: Glaxo SmithKline Pakistan Limited. 35-Docyard Road, Pack Size(s): 1x5gm-As per SRO
	Evaluation Remarks: Submit reply of following observations so that your application will be further processed for evaluation . 1- Submit reference product approval in RRA countries (MHRA UK, USFDA, TGA AUSTRALIA etc.) with Betamethasone sodium phosphate & neomycin in the same strength.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred **Proceeding of the case:** **The Board was apprised that the formulation of firm contains Betamethasone Sodium Phosphate USP as a salt instead of Betamethasone Valreate. the firm was advised to submit approval of product with Betamethasone Sodium Phosphate USP in the RRA countries but firm has not provided any reference in RRA with such formulation.** **The firm has provided the approval of product in Pakistan manufactured by GSK with brand name Betnesol – N Eye Ointment with same formulation containing Betamethasone Sodium Phosphate.** **USP.** **The Board decided to defer the case for submission of approval of drug product in RRA countries with betamethasone sodium phosphate as salt . The Board also decided to issue a letter to GSK to ask clarification for the active ingredient in Betnesol N eye ointment containing Betamethasone sodium phosphate instead of betamethasone valreate.**	
348	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (G35-43M-JXQ5, 2024-05-13) Fee Paid: 30000.0 Paid Date: 2024-02-19 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **IBUNOOR DS SUSPENSION** Each 5ml contains: Ibuprofen..... 200mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Brufen DS suspension by Abbot Laboratories Pack Size(s): 90ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
349	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (DXV-R4Z-PU6V, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Ezimep 20mg Capsule** Each Capsule contains: Esomeprazole as enteric coated pellets (USP) …..... 20mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Sold Capsule by Regal Pharmaceuticals Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: **Source of pellets:** Winbrains Research Laboratories (DML # 000919 - Semi-Basic Manufacturing) Plot NO. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Source of pellets: Winbrains Research Laboratories (DML # 000919 - Semi-Basic Manufacturing) Plot NO. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.	
350	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (GXE-B35-9WQ8, 2024-05-20) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Levocet 2.5mg/5ml** Each 5ml oral solution contains Levocetirizine 2HCl .....2.5mg As per Innovators Specification RRA Status: Xyzal , USFDA approved formulation Me Too Status: Neo Sedil Syrup by Sami Pharma Pack Size(s): 1 x 90ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
351	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (GZS-T97-E69B, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2024-07-11 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Levosaq 500mg Tablet** Each Film Coated Tablet Contains: - Levofloxacin Hemihydrate eq. to Levofloxacin ……...500mg (USP Specification) United States Pharmacopeia RRA Status: Levofloxacin (500mg) Film-coated Tablets M/s Accord Healthcare Limited, MHRA Approved Me Too Status: Leflox 500mg Tablet (Getz Pharma (Pvt.) Ltd Karachi) Reg. No. 026163 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
352	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (GT5-JLP-6J4J, 2024-05-15) Fee Paid: 30000.0 Paid Date: 2024-04-08 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Azinoor 250mg** Each Capsule contains: Azithromycin (as dihydrate) = 250 mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Azomax 250mg By AGP Pack Size(s): 10's-As per SRO,12's-As per SRO,6's-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
353	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (H5V-VUT-DNR5, 2024-07-29) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Methyll 1g Injection** Each Vial Contains (Sterile powder for reconstitution) :Methylprednisolone as Sodium Succinate (USP)…….1000mg(Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solu Medrol Injection by Pfizer Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
354	**Pharman Pharmaceuticals(Pvt)Ltd** Khewat No.59,khatooni No. 114-120, Tehsil Wazirabad,District Gujranwala (**000958**) Tracking ID: (HSJ-LEU-YD41, 2024-05-02) Fee Paid: 30000.0 Paid Date: 2024-01-22 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Tramadol Plus** Each film coated tablet contains Tramadol HCl 37.5 mg and Paracetamol 375 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Tonoflex-P by Sami Pharmaceuticals Pack Size(s): 10's-As per SRO,20's-As per SRO,30's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
355	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE (**000300**) Tracking ID: (HWP-QTE-PEP6, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Fero-Well 500mg/10ml Injection** Each ml contains:Iron as Ferric carboxymaltose ……. 50mg (500mg/10ml) As per Innovators Specification RRA Status: AM REGENT approved by USFDA Me Too Status: Ferinject by Vifor Pharma Pack Size(s): 1 vial x 10ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
356	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (HXV-Q7Q-AEBH, 2024-07-26) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **IROGEN 50MG/ML INJECTION** Each 10ml vial contains:Ferric carboxymaltose equivalent to elemental iron ……..500mg(Innovator Spec) As per Innovators Specification RRA Status: Ferinject Dispersion for Injection/Infusion is Approved in MHRA Me Too Status: Frotox 50mg/ml Injection Pack Size(s): 5's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
357	**Air Pharmaceuticals(Pvt.)Ltd** Plot No's 74, 75-A, Small Industrial Estate, Kasur (**000977**) Tracking ID: (HLH-E5E-24ES, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Scanty** Each 5ml contains: Hyoscine butyl bromide ……5mg Manufacturer Specification RRA Status: Gastrosoothe Oral liquid 1mg/ml BY AFT Pharmaceuticals Me Too Status: Spasler-P by AGP Pharma Pack Size(s): 1's (120ml)-De-Controlled,1's (30ml)-De-Controlled,1's (60ml)-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Submit the reference product approval in anyone of following regulatory authorities .USFDA / MHRA UK/ TGA AUSTRALIA / Health Canada, EMAE etc. Submit formulation development with particle size distribution of API, mixing process instrument compatibility with nature of formulation.	
	Decision: Deferred The case has been deferred till submission of evidence of approval of same formulation with same strength in reference regulatory authorities declared in 275 meeting of registration Board.	
358	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (J28-E2S-UPRL, 2024-07-23) Fee Paid: 30000.0 Paid Date: 2024-07-08 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Cefadox 250mg/5ml oral suspension** Each (reconstituted) 5ml contains: Cefadroxil as Monohydrate.....250mg Finished Product specification:USP United States Pharmacopeia RRA Status: European Medicine Agency (EMA) Me Too Status: Neusef DS Suspension 250mg/5ml Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
359	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (J68-LAA-GGNP, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Lansodex 30mg Capsule** Lansodex 30mg Capsule Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent to Dexlansoprazole 30mg (Innovators Specification) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex 30mg Capsule Getz Pharma Reg. 086976 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Source of pellets VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
360	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (J8P-ZRV-VZNP, 2024-04-26) Fee Paid: 30000.0 Paid Date: 2024-04-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lecebact 2g Injection** Each vial contains:Cefoperazone as Sodium.....1000mgSulbactam as Sodium....1000mg As per Innovators Specification RRA Status: PERTAWAY Injection by Betterway Pharmaceutical Group INN. Carson City, NV 89710 USA Me Too Status: Cefbac Injection 2g by Seraph pharmaceuticals Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Subject to submission of fee for change in specification.	
	Decision: Approved	
361	**shrooq pharmaceuticals pvt ltd** 21km feorzpur road lahore (**000577**) Tracking ID: (JL4-2E2-5A84, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-20 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Inzox Powder for oral Suspension 100mg/5ml** Each 5ml reconstituted suspension contains Linezolid 100mg As per Innovators Specification RRA Status: USFDA approved formulation Me Too Status: A product of Barret Hodgson Pakistan pvt limited Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
362	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (JM3-MXW-ED5T, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-11 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Levosaq 250mg Tablet** Each Film Coated Tablet Contains:- Levofloxacin Hemihydrate eq. to Levofloxacin ……..250mg (USP Specification) United States Pharmacopeia RRA Status: Levofloxacin (250mg & 500mg) Film-coated Tablets M/s Accord Healthcare Limited, MHRA Approved Me Too Status: Leflox 250mg Tablet (Getz Pharma (Pvt.) Ltd Karachi) Reg. No. 026164 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
363	**Cure Laboratories (Pvt.) Ltd** Plot No. 11 &12, Street No. NS-2, National Industrial Zone, Rawat , Rawalpindi (**000897**) Tracking ID: (JN8-NTZ-THLS, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-02-20 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Vonsid** Each Film coated tablet contains: Vonoprazan Fumarate eq. to Vonoprazan.....10mg As per Innovators Specification RRA Status: Takecab 10mg Tablets (PMDA JAPAN APPROVED) Me Too Status: Vonozan 10mg Tablets Pack Size(s): 2x10's-De-Controlled,2X7'S-De-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
364	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (JNA-4EU-A58Q, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Nalbusaq** Each 1ml of Nalbusaq Injection Contains: Nalbuphine Hydrochloride 10mg Manufacturer Specification RRA Status: Health Canada Me Too Status: Available i.e. Nalfy Injection by Global Pharmaceuticals Pvt. Ltd. Islamabad-Pakistan Pack Size(s): 1mlx10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
365	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (JS6-UEP-HS7D, 2024-07-18) Fee Paid: Paid Date: Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Capsule Doxin 100mg** Each capsule contains:Doxycycline Hyclate equivalent to Doxycycline =100 mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Vibramycine Capsule by Pfizer Pack Size(s): 10's-As per SRO,100's-As per SRO,120's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
366	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (JU8-AXU-AJD9, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **HY?KOR 250MG sterile powder for injection** Each Vial Contains (Sterile powder for reconstitution) :Hydrocortisone Sodium Succinate (USP) equivalent to Hydrocortisone ……..250mg (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: CORTISONE 250MG INJECTION by VISION PHARMACEUTICALS Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
367	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (L3V-PDM-1HBJ, 2024-07-26) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Waripime 500mg Injection** Each vial contains: Cefepime as Hydrochloride (with L-arginine)……500mg United States Pharmacopeia RRA Status: Maxipime 500mg Powder for Solution for Injectionor Infusion by Hospira, Inc. Lake Forest, IL 60045 USA Me Too Status: Pimestar Injection 500mg by M/s Aulton Pharmaceuticals Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
368	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad (**000927**) Tracking ID: (L4B-BYH-8G7N, 2024-07-29) Fee Paid: 30000.0 Paid Date: 2024-07-25 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **SEDOFEN 200/30MG TABLET** Each film coated tablet contains: Ibuprofen……200mgPseudoephedrine Hydrochloride… 30mg United States Pharmacopeia RRA Status: EMA Approved Me Too Status: Arinac Tablet by M/s Abbott Laboratories, Pakistan Pack Size(s): 10,12,20,24-As per SRO
	Evaluation Remarks: Stability data of drug product has been submitted for 0 & 3 month interval however 06 month interval is due on 22-08-2024.	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Decision: Approved

The registration letter shall be issued after submission of stability data of drug product for the last interval (06th month due on 22-08-2024)</td></tr>
<tr><td>369</td><td>World Biz Pharmaceuticals Company, Multan
340, Phase-II, Industrial Estate, Multan (000942)
Tracking ID: (L8H-R1M-7HEH, 2024-06-11)
Fee Paid: 30000.0
Paid Date: 2024-03-27
Case Category: New Section
(Salateen Waseem Philip)</td><td>Proposed Name: EsoBiz Capsule 20mg
Each Capsule contains:- Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole……20mg (USP Specification)
United States Pharmacopeia
RRA Status: MHRA approved Esomeprazole Capsule 20mg by Cipla EU Ltd
Me Too Status: Esso-20 Capsule 20mg REG No. 032960 (SHAIGAN Pharmaceuticals)
Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section</th><th>Observations</th><th>Reply of the firm</th></tr>
<tr><td rowspan="2">3.2.P.8</td><td>In the chromatograms submitted, two different components are eluting very close together (peak of interest vs unknown peak). clarify that why the analysis being carried out when parameters were out of control?</td><td>The peak appearing close to peak of interest is of blank/diluent peak.</td></tr>
<tr><td>Submit evidence that Chromatograms are in electronically stored records and must have an audit trail ensuring traceability.</td><td>Copy of Audit trail submitted</td></tr>
</table></td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred The Registration Board decided to defer the case. Firm shall again perform assay and submit data of chromatograms to ensure the resolution between peaks.	
370	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (L8Z-LT1-6UNR, 2024-05-15) Fee Paid: 30000.0 Paid Date: 2024-03-01 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **GENOCIN 1G INJECTION** Each vial contains:(Sterile Powder for reconstitution) Vancomycin as HCl …. 1000mg (50mg/ml after dilution in 20ml WFI) USP Specification United States Pharmacopeia RRA Status: Vancomycin 1gm powder for concentrate for solution for infusion vials (MHRA approved) Me Too Status: VINJEC 1g Injection by BOSCH PHARMACEUTICALS (PVT) LTD. Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
371	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (LES-HBE-3X3E, 2024-04-30) Fee Paid: 30000.0 Paid Date: 2024-04-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lecebact 500mg Injection** Each vial contains:Cefoperazone as Sodium....250mgSulbactam as Sodium....250mg As per Innovators Specification RRA Status: Cefoperazone + Sulbactam 500mg injection, Approved by PMDA of Japan Me Too Status: Nichlobact 500mg Injection by Nicholas Pharma Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Subject to submission of fee for change of specifications.	
	Decision: Approved The registration letter shall be issued after submission of requisite fee for change of specification.	
372	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (**000504**) Tracking ID: (LN6-TUE-ELZB, 2024-05-20) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Glyum 50mcg DPI Capsule** Each capsule contains:63 micrograms of glycopyrronium bromide equivalent to…… 50 micrograms of glycopyrronium.Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 55 micrograms of glycopyrronium bromide equivalent to 44 micrograms of glycopyrronium. As per Innovators Specification RRA Status: EMA Approved Seebri Breezhaler Me Too Status: Seebri by Novartis (Import) Pack Size(s): 5's 7's 10's 14's 20-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section 3.2.S.7: In the material safety data sheet of Glycopyrronium bromide, the storage conditions of API specify to Keep refrigerated & to store under an inert atmosphere. clarify the stability studies conducted at Zone IV and also provide arrangement along with documented evidence that manufacturing facility of your firm possess equipment & instrument in warehouses and dispensing area for confirmation of inert atmosphere for container of API.

Reply of the firm: In accordance with the current edition of United States Pharmacopeia (USP–NF 2024) the storage condition for Glycopyrronium is at room temperature (evidence attached for your reference). Additionally, stability data of Glycopyrronium bromide performed by the API manufacturer indicates that the API is stable under 30°C (data is enclosed with this letter for your perusal).

Section 3.2.P.5: Submit evidence of Halogen Moisture analyzer in your Laboratory to perform test for measuring moisture content.

Reply of the firm: We have performed moisture content test by using Karl fisher equipment that is used to determine moisture content in FP or API. It is our in-house test to verify the control of drug product or substance from moisture level.

Section 3.2.P.7: Provide details of inhaler device used for your drug product (Source of inhaler, its construction material and other details including COA to confirm the deliver dose flow rate)

Reply of the firm: One BDD07 DPI device is packed in a PE bag, and 500 units are packed in one carton. Storage condition: Sealed and stored in a dry place. Expire date: 36 months.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
373	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (MAR-5VS-9AR9, 2024-05-14) Fee Paid: 30000.0 Paid Date: 2024-04-18 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Aqua-wari** Each ampoule contains: Water for Injection……5ml United States Pharmacopeia RRA Status: Sterile water for injection USP by M/s Baxter Healthcare Corporation Deerfield, IL 60015 USA Me Too Status: WFI (5ml/ampoule) by M/s Global Pharmaceuticals Pack Size(s): 5ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
374	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (MJ6-GV1-W8B4, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **TRACKCIN** Each Film coated tablet contains: Ciprofloxacin HCl equivalent to Ciprofloxacin .....250mg United States Pharmacopeia RRA Status: USFDA/MHRA approved formulation Me Too Status: CIPROQUINE Pack Size(s): 10s'-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
375	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (**000504**) Tracking ID: (MGT-Y5M-G5EX, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-09 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Diair 50+110mcg DPI Capsule** Each capsule contains: 143 micrograms of indacaterol maleate equivalent to 110 micrograms of indacaterol and 63 micrograms of glycopyrronium bromide equivalent to 50 micrograms of glycopyrronium Each delivered dose contains: (the dose that leaves the mouthpiece of the inhaler) 110 micrograms of indacaterol maleate equivalent to 85 micrograms of indacaterol and 54 micrograms of glycopyrronium bromide equivalent to 43 micrograms of glycopyrronium As per Innovators Specification RRA Status: EMA Approved Ultibro Breezhaler Me Too Status: Ultivair by Highnoon Laboratories Ltd. Pack Size(s): 1's 5's 7’s 10’s 14’-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section 1.5.8: Submit evidence of local registration in Pakistan with pictorial presentation of pack with registration number.

Reply of the firm: Ultivair RotaCap 50/110, Reg # 113986

Section 3.2.S.7: In the material safety data sheet of Glycopyrronium bromide & **indacaterol maleate**, the storage conditions of API specifies to Keep refrigerated & to store under an inert atmosphere. clarify the stability studies conducted at Zone IV and also provide arrangement along with documented evidence that manufacturing facility of your firm possess equipment & instrument in warehouses and dispensing area for confirmation of inert atmosphere for container of API.

Reply of the firm: In accordance with the Patient Labeling Review of Utibron Neohaler (Indacaterol + Glycopyrrolate) issued by Food and Drug Administration-FDA which states that both the API's store in a dry place at 77°F (25°C); excursions permitted to 59°F to 86°F (15°C to 30°C). Moreover, the stability data of Glycopyrronium bromide & Indacaterol maleate performed by the API manufacturer also stated that the materials are stable under 30°C. Evidences are enclosed with this letter for your perusal.

Section 3.2.P.5: Submit evidence of Halogen Moisture analyzer in your Laboratory to perform test for measuring moisture content.

Reply of the firm: We have performed moisture content test by using Karl fisher equipment that is used to determine moisture content in finished product or API. It is our in-house test to verify the control of drug product or substance from moisture level.

Section 3.2.P.7: Provide details of inhaler device used for your drug product (Source of inhaler, its construction material and other details including

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
376	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (ND3-J27-B42Y, 2024-07-23) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Waripime 1g Injection** Each vial contains (Sterile powder for reconstitution): Cefepime as Hydrochloride (with L-arginine)……1g RRA Status: Maxipime 1g Powder for Solution for Injectionor Infusion by Hospira, Inc. Lake Forest, IL 60045 USA Me Too Status: Pimestar Injection 1g by M/s Aulton Pharmaceuticals Pack Size(s): 1's-As per SRO
	Evaluation Remarks: The stability data of 0 & 3 month interval has been submitted. The 6 month stability date will be September 2024. firm stated that they will provide the 6 months stability data as it will completed & request to approve registration.	
	Decision: Approved The registration letter shall be issued after submission of stability data of the drug product for the last interval (due on 09-2024)	
377	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (ND8-W7B-EAA1, 2024-04-30) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **OmBiz Capsule 40mg** Each Capsule contains:- Delayed Release Pellets of Omeprazole Equivalent to Omeprazole……40mg (USP Specification) United States Pharmacopeia RRA Status: MHRA approved Losec® Capsule 40mg (Neon Healthcare Limited) Me Too Status: OMEGA Capsule 40mg Reg No. 050818 (Ferozsons Laboratories Limited) Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of pellets Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
378	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (N3A-781-NSTP, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **EsoBiz Capsule 40mg** Each Capsule contains:- Delayed Release Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole……40mg (USP Specification) United States Pharmacopeia RRA Status: Esomeprazole Capsule 40mg by Cipla EU Ltd (MHRA Approved) Me Too Status: Esso-40 Capsule 40mg Reg No. 032961 (Shaigan Pharmaceutical Private Limited) Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO

<table>
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<tr><th>Section</th><th>Observations</th><th>Reply of the firm</th></tr>
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<tr><td>Submit evidence that Chromatograms are in electronically stored records and must have an audit trail ensuring traceability.</td><td>Audit trail submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Deferred

The registration Board deferred the case. Firm shall again perform assay and submit chromatograms with value of resolution between the peak of interest and other peaks in the chromatogram.</td></tr>
<tr><td>37
9</td><td>M/s Medella Pharmaceuticals (Pvt) Ltd
569/570 Sundar Industrial Estate Raiwind Road Lahore (000749)
Tracking ID: (PB6-5A6-BNZQ, 2024-06-20)
Fee Paid: 30000.0
Paid Date: 2024-05-16
Case Category: New Section
(Salateen Waseem Philip)</td><td>Proposed Name: PLADOL 37.5MG/325MG TABLET
Each film coated tablet contains; Tramadol HCl…37.5mg, Paracetamol……325mg (USP Specifications)
United States Pharmacopeia
RRA Status: Zaldiar Tablet (M/s Aspen Pharmacare Australia) TGA Approved
Me Too Status: Tonoflex-P (Sami Pharma) Reg. No. 067163
Pack Size(s): As Per SRO-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
380	**Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. (**000571**) Tracking ID: (PNS-MAJ-W8AX, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2023-07-04 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Cefixime** USP United States Pharmacopeia RRA Status: Boscef sachets Me Too Status: Qxim Sachets Pack Size(s): 10,s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Section	Observations	Reply of the firm
1.5.2	How much quantity of powder per sachet containing cefixime 100 mg?	1.5 gm
	Total quantity of powder per pack?	1.5 gm
	How much water in ml required for constitution of suspension?	20 ml
1.5.8	Submit the approval of same formulation with same strength and packing in the countries declared as stringent regulatory bodies by DRAP.	Boscef manufacturer in Portugal
3.2.S.4	Clarify the nature of cefixime API used (micronized or compacted)	Micronized
	Mention quantity of salt as well as base	Salt (Cefixime Trihydrate) 100mg, Base (Dextrose anhydrous) 1322.5mg

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred The Registration Board defer the case for following clarifications:- 1- Submission of approval of drug product (100 mg/20ml) approval in the reference regulatory authorities declared in 275 registration meeting. 2- clarify the concentration of final solution after reconstitution either 100mg/5ml or 100mg / 20ml?	
38 1	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (NR8-6UP-9RSZ, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Curamont Sachet 4mg** Each Sachet contains: Montelukast (as Sodium).....4mg British Pharmacopeia RRA Status: Montelukast Sachet is approved in USFDA link is attached as: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090955 Me Too Status: Montika Sachet by Sami Pharmaceuticals (Pvt.) Ltd. Reg# 050744 Pack Size(s): 14s-As per SRO
	Evaluation Remarks:	
	Decision: Approved The registration letter shall be issued after submission of GMP certificate of the firm which should be valid till date.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
382	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (PUN-9M2-83AY, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Acepol DS 250 mg/5ml** Each 5ml contains: Paracetamol …… 250mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Calpol Six Plus Suspension by GSK Pack Size(s): 120ml-As per SRO,400ml-As per SRO,450ml-As per SRO,60ml-As per SRO,90ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
383	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad (**000927**) Tracking ID: (PVJ-SHE-W2QG, 2024-07-12) Fee Paid: 30000.0 Paid Date: 2024-06-21 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Dermicin-H-CREAM** Each gram of cream contains: Fusidic acid……20mg (2%w/w) Hydrocortisone acetate…10mg (1%w/w) As per Innovators Specification RRA Status: HPRA/EMA/USFDA Me Too Status: Fucidin-H Cream by LEO Laboratories Ltd Pack Size(s): 15g-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
384	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (PER-214-7RJB, 2024-07-26) Fee Paid: 30000.0 Paid Date: 2024-05-23 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Acetadol-M Tablet** Each Film Coated Tablet Contains: Paracetamol……325mg Tramadol Hydrochloride….37.5mg (USP Specification) United States Pharmacopeia RRA Status: Tramadol hydrochloride and Paracetamol 37.5 mg/325 mg Film-coated Tablets (tramadol hydrochloride and Paracetamol) - PL 30684/0222 MHRA Approved. Me Too Status: Tonoflex-P Tablet (Sami Pharmaceuticals (Pvt.) Ltd. Karachi) Reg. No. 067163 Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
385	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (PPM-WRZ-Z7DS, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Gaba Biz Capsule 100mg** Each Capsule Contain:-Pregabalin 100mg(BP Specifications) RRA Status: Pregabalin Noumed 100 mg Capsules (Approved in MHRA) Me Too Status: PREGY Capsule 100mg (Reg No. 076672) SAMI Pharmaceuticals Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The applicant applied with Innovator specification, However in reply of query, firm has submitted the Chromatograms as per HPLC method of BP specification on 20-07-2024. The results are found within limits of BP specification. Firm needs to submit the fee for change in specification.	
	Decision: Approved The registration letter shall be issued upon submission of fee for change of specifications.	
386	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (Q5P-R72-179P, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Ferifer Syrup** Each 5ml contains Iron (III) Hydroxide Polymaltose complex Eq. to elemental iron…….50mg As per Innovators Specification RRA Status: Maltofer Syrup (Approved in TGA) TGA Link : https://www.tga.gov.au/resources/artg/230643 Me Too Status: Maltofer Syrup Reg. No. 100184 , Manufacturer by Searle Pakistan Limited Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved The registration letter shall be issued after submission of GMP certificate of the firm which should be valid till date.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
387	**ICU Pharmaceuticals** Khewat No. 13/13, Khatooni 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura, (**000956**) Tracking ID: (Q6W-PMZ-ALGT, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-06-10 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Azinil 250mg Capsule** Each Capsule contains:Azithromycin (as dihydrate) = 250 mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Azomax 250mg Capsule by AGP Pharma Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
388	**Getz Pharma (Pvt.) Ltd. - (Unit I)** Plot No. 1, Sector 25, Korangi Industrial Area (**000933**) Tracking ID: (QQW-8VD-G9AQ, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2023-12-22 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Cefoproxil** Each film-coated tablet contains: Cefpodoxime proxetil USP equivalent to Cefpodoxime ……100mg United States Pharmacopeia RRA Status: Cefpodoxime Proxetil Tablets 100mg by M/s Sandoz Limited, United Kingdom (MHRA Approved) Me Too Status: Cefpower Tablets 100mg by M/s Platinum Pharmaceuticals (Pvt.) Ltd. Pack Size(s): 10's-As per SRO,12's-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
389	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (QUV-6UT-G826, 2024-07-08) Fee Paid: 30000.0 Paid Date: 2024-06-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Sevelgen 2.4g Sachet** Each Sachet contains :Sevelamer Carbonate…….. 2.4g (Innovator Specification) RRA Status: Renvela 2.4 g powder for oral suspension (MHRA approved) Me Too Status: Renvela 2.4 g powder for oral suspension Pack Size(s): 90's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
390	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (R2J-NQX-622J, 2024-07-22) Fee Paid: 30000.0 Paid Date: 2024-05-02 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Metogyl 500mg/100ml IV Infusion** Each ml of Solution for Infusion contains: Metronidazole…… 5 mg. British Pharmacopeia RRA Status: Flagyl ® 5 mg/ ml of M/s Pfizer (USFDA Approved) Me Too Status: Flagyl Injection of M/s Sanofi Aventis Pakistan Limited Pack Size(s): 100ml, As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Stability study submitted for 0 & 3 month while 6 month study is due on 09-2024.	
	Decision: Approved The registration letter shall be issued after submission of stability data of drug product for the last interval due on 09-2024.	
391	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (R5N-7S4-MN8Q, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-04-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Parical 4 mcg soft gelatin capsule** Each soft gelatin capsule contains: Paricalcitol 4 mcg (USP Specs) United States Pharmacopeia RRA Status: FDA Approved. Zemplar (Paricalcitol soft gelatin) 4 mcg Capsule Me Too Status: N/A Pack Size(s): 30's-As per SRO
	Evaluation Remarks: Differential fee of 45000/- submitted by firm vide challan # 28118369530	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
392	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (R4E-ALV-LHUB, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **OZEPRA 20MG CAPSULE** Each Capsule contains: OMEPRAZOLE as enteric coated pellets (USP) …..... 20mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: UK MHRA Me Too Status: Jumep CAPSULE BY JUPITER PHARMA Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Source of pellets : Winbrains Research Laboratories	
	Decision: Approved Source of pellets : Winbrains Research Laboratories	
393	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (RPE-DVJ-2R3V, 2024-07-25) Fee Paid: 30000.0 Paid Date: 2024-06-04 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Fosfomycin sachets** Each sachet contains fosfomycin trometamol equivalent to fosfomycn= 3 gram As per Innovators Specification RRA Status: USFDA approved formulation Me Too Status: Focin sachets by Tabros Pack Size(s): 1-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
394	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (S66-T2Q-UE7V, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Methyll 40mg Injection** Each Vial Contains (Sterile Powder for Reconstitution) :Methylprednisolone as Sodium Succinate (USP)…….40mg(Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solu Medrol Injection by Pfizer Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
395	**Kohinoor Industries** 158-159-160-161-B, Small Industries Estate, Sahiwal (**000197**) Tracking ID: (SZ5-98S-ZJVR, 2024-05-13) Fee Paid: 30000.0 Paid Date: 2024-02-19 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Ibunoor 100mg/5ml** Each 5 ml suspension contains: Ibuprofen ..... 100 mg British Pharmacopeia RRA Status: MHRA Approved Me Too Status: Brufen Suspension by Abbot laboratories Pack Size(s): 120ml-As per SRO,90ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
396	**Dynatis Pakistan Pvt. Ltd.** Plot 710, Sundar Industrial Estate, Lahore (**000891**) Tracking ID: (S3X-TXA-E327, 2024-05-20) Fee Paid: 30000.0 Paid Date: 2024-03-06 Case Category: Any Other **(Salateen Waseem Philip)**	Proposed Name: **Tablet Levocil 250 mg** Each film-coated tablet contains:Levofloxacin hemihydrate equivalent toLevofloxacin…….. 250mg. United States Pharmacopeia RRA Status: Levofloxacin Tablet 250mg Me Too Status: Leflox Tablet 250mg Pack Size(s): 5’s, 7’s, 10’s, 14’s-As per SRO
	Evaluation Remarks: Evaluated on priority as per 157 meeting of Authority dated 20-01-2023 for GMP of applicant from PIC/s member NRAs. Its 2nd molecule for year 2024. PIC/s certificate also attached with this application from UKraine. The correct fee challan No. for this application is 058944421418 found in Module I of this application. On the dashboard , the firm has mentioned wrong challan no.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
397	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (SBH-B6L-BBQ7, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Lansogen 30 mg Capsule** Each capsulecontains; Dexlansoprazole dual delayed released (DDR) pellets 22.5% Equivalent to Dexlansoprazole .....30 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: DDR-30 mg capsules Pack Size(s): 3x10's-As per SRO
	Evaluation Remarks: Source of pellets: M/s Vision Pharmaceuticals. (DML # 000806 - (Semi-basic manufacturing) Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad	
	Decision: Approved Source of pellets: M/s Vision Pharmaceuticals. (DML # 000806 - (Semi-basic manufacturing) Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad	
398	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (SA6-WD5-HQ5P, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **D-LansUp 60mg Capsule** Each capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent to Dexlansoprazole… 60mg (Innovator's Specification) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Razodex 60mg (Getz Pharma) Reg. No. 086977 Pack Size(s): As Per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: • In section 1.3.5: submit letter of grant of additional section for capsule (General) section **Reply of the firm:** Letter of grant of additional section for capsule (General) section is attached • In section 3.2.P.8: justify that Dissolution testing performed on UV spectroscopy while innovator specification specifies HPLC testing for dissolution testing. **Reply of the firm:** We have followed the API manufacturer testing method for dissolution testing of the applied product, once the product gets registered, we will develop and adopt HPLC testing method for Dissolution testing of the applied product.	
	Decision: Approved The registration letter shall be issued to the firm upon submission of chromatographic data of dissolution test for at last one point of interval of stability data	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
399	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (TGH-LES-H7HE, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-10 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Aqua-Maf** Each 5ml Ampoule Contains: Water for Injection 5ml United States Pharmacopeia RRA Status: US-FDA Approved Me Too Status: Sterile Water for Injection 5ml by Islam Pharmaceuticals Pakistan Pack Size(s): 5mlx100's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
400	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE (**000300**) Tracking ID: (TJS-Y5T-7MJQ, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-04-04 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Vee-Curium Injection** Each 5ml contains: Atracurium Besylate ……. 50mg United States Pharmacopeia RRA Status: HOSPIRA USA- US-FDA Approved Me Too Status: Relocurium by BAJWA Pharmaceutical Pack Size(s): 5 Amp x 5mL-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
401	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (U94-3RX-BR58, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2024-05-29 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Wari-cef 250mg Capsule** Each capsule contains: Cephradine……250mg British Pharmacopeia RRA Status: CEFRADINE 250mg Capsule by Kent Pharma UK Limited Me Too Status: Velosef 250mg Capsule by M/s GSK Ltd Pack Size(s): 12's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
402	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (SWE-SRU-E65A, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Dexsofast 60mg Capsule** Each Capsule contains: Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w Equivalent to Dexlansoprazole…….60mg (Innovators Specification) As per Innovators Specification RRA Status: Dexilant 60 mg CAPSULES by USFDA Approved Me Too Status: Razodex 60mg Capsule Reg. No. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of pellets :VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets :VISION PHARMACEUTICALS Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
403	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (UTG-MY6-TBS4, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Odrel 75mg Tablets (Film coated Tablet)** Each film coated tablet contains: Clopidogrel (as Clopidogrel bisulfate)… ……75mg (USP Specifications) United States Pharmacopeia RRA Status: Clopidogrel 75mg tablets, Manufacturer: Aurobindo Pharma USA, Inc. (USFDA Approved) Me Too Status: Clopidogrel 75mg tablets, Manufacturer: Aurobindo Pharma USA, Inc. Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: at section 3.2.P.8: submit complete stability data of 06 month for consideration of your case. (Due date 19-09-2024 for 06th month interval)	
	Decision: Approved The registration letter shall be issued after submission of stability data of drug product for the last interval (06th month due on 19-09-2024)	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
404	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (V37-D77-RB18, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2023-12-20 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Amoxi 0.6gm Injection** Each vial contains: Amoxicillin Sodium eq. to Amoxicillin……500mg Potassium clavulanate eq. to Clavulanic acid….100mg As per Innovators Specification RRA Status: Co-amoxiclav 500 mg/100 mg powder for solution for injection/infusion of M/s Instituto Biochimico Italiano G. Lorenzini S.p.A. Via Fossignano, 2 04011 Aprilia (LT) Italy, (HPRA Approved) Me Too Status: Calamox 0.6gm Injection of M/s Bosch Pharmaceuticals Pack Size(s): 1 x 1's, As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
405	**M/s Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore (**000576**) Tracking ID: (V8E-1PS-AY9W, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-06-05 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **T GLIP 20MG TABLET** Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate equivalent to Teneligliptin……...20mg (Innovator's Specification) As per Innovators Specification RRA Status: PMDA Japan - Tenelia 20mg Tablet by Mitsubishi Tanabe Pharma Corporation Me Too Status: Tenliptin Tab 20mg By Dynatis Pakistan (Pvt) Ltd Pack Size(s): 10's , 15's, 20's, 3-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
406	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (V9S-VA2-PH7Q, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2023-12-20 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Amoxi 1.2gm Injection** Each vial contains:Amoxicillin Sodium eq. to Amoxicillin……1000mgPotassium clavulanate eq. to Clavulanic acid….200mg As per Innovators Specification RRA Status: Co-amoxiclav 1000mg/200 mg powder for solution for injection/infusion of M/s Instituto Biochimico Italiano G. Lorenzini S.p.A. Via Fossignano, 2 04011 Aprilia (LT) Italy, (HPRA Approved) Me Too Status: Calamox 1.2gm Injection of M/s Bosch Pharmaceuticals Pack Size(s): 1 x 1's, As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
407	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (VGX-7LL-JXW7, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-06-03 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lawadox 100mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cefpodoxime as Proxetil ……100mg United States Pharmacopeia RRA Status: Vantin 100mg/5ml Powder for Susupension by Pharmacia & Upjohn Company (Division of Pfizer Inc, NY, 10017) Me Too Status: Cefprox (100mg/5ml) 100ml Suspension by M/s Continental Pharmaceuticals Limited Pack Size(s): 50ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
408	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (VVY-HMX-N512, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-07-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **K-Saq** Each 1ml Ampoule Contains: Phytonadione 10mg United States Pharmacopeia RRA Status: US-FDA Approved Me Too Status: K-Lot 10mg/1ml Injection By GT Pharma, Lahore-Pakistan Pack Size(s): 1mlx1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
409	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (VYB-VSP-1REB, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lawazed 125mg/5ml Dry Suspension** Each 5ml of reconstituted suspension contains: Cefadroxil as Monohydrate……125mg United States Pharmacopeia RRA Status: Cefadroxil powder, for suspension by Ranbaxy Pharmaceuticals Inc. Jacksonville, FL 32257 USA Me Too Status: Bio oxil 125mg/5ml Dry powder suspesnion by Bio-Labs Pharmaceuticals Pack Size(s): 60ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
410	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (WD9-R5X-8VBR, 2024-06-24) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **D-LansUp 30mg Capsule** Each capsule contains:Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w equivalent toDexlansoprazole… 30mg(Innovator's Specification) RRA Status: USFDA Approved (M/s Takeda Pharmaceuticals U.S.A., Inc.) Me Too Status: Razodex 30mg Pack Size(s): As Per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: In section 3.2.P.8, justify that Dissolution testing performed on UV spectroscopy while innovator specification specifies HPLC testing for dissolution testing. **Reply of the firm:** We have followed the API manufacturer testing method for dissolution testing of the applied product, once the product gets registered, we will develop and adopt HPLC testing method for Dissolution testing of the applied product.	
	Decision: Approved The registration letter shall be issued to the firm upon submission of chromatographic data of dissolution test for at last one point of interval of stability data	
411	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (WXX-8J2-L1LD, 2024-07-18) Fee Paid: 30000.0 Paid Date: 2024-07-05 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **K-Saq** Each 1ml Ampoule Contains: Phytonadione 2mg United States Pharmacopeia RRA Status: Health Canada Me Too Status: Available i.e. K-Lot 2mg/1ml Injection by GT Pharma, Lahore-Pakistan Pack Size(s): 1mlx1's-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
412	**M/s Medella Pharmaceuticals (Pvt) Ltd** 569/570 Sundar Industrial Estate Raiwind Road Lahore (**000749**) Tracking ID: (WTH-Q1Z-R4S7, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **E-CEP 40MG CAPSULE** Each capsule contains;Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole…...40mg(USP Specifications) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Nexum 40mg Capsule (Getz Pharma) Reg. 033891 Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks: Source of pellets : Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
	Decision: Approved Source of pellets : Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan	
413	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (WY7-N7X-13VN, 2024-06-28) Fee Paid: 30000.0 Paid Date: 2024-06-12 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Gabaqad 100 mg Capsule** Each capsule contains pregabalin 100mg British Pharmacopeia RRA Status: MHRA approved formulation Me Too Status: Gabica by Getz Pharma Pack Size(s): 2x7's=14's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
414	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan (**000980**) Tracking ID: (WYE-96P-T1TV, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-03-13 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **G-OMOZOL 40mg Capsule** Each hard gelatin capsule contains : enteric coated pellets equivalent to omeprazole 40 mg United States Pharmacopeia RRA Status: ASTRAZENECA Me Too Status: Prilosec 40mg Capsule Pack Size(s): 14's-As per SRO
	Evaluation Remarks: Source of pellets: Manufacturer: VISION PHARMACEUTICALS (PVT) LTD Address: Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.	
	Decision: Approved Source of pellets: Manufacturer: VISION PHARMACEUTICALS (PVT) LTD Address: Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
415	**Gelcaps (Pakistan) Limited** B 43 Hub Industrial Estate Baluchistan (**000980**) Tracking ID: (WYZ-1XA-3VL5, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2024-03-13 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **G-DICLO 50 mg Capsule** Each hard gelatin capsule contains : 32% Enteric Coated Pellets equivalent to Diclofenac sodium 50 mg As per Innovators Specification RRA Status: EEA Astellas Pharma GmbH Me Too Status: Deflamat 50mg Capsule Pack Size(s): 10 x 10s-As per SRO
	Evaluation Remarks: Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.	
	Decision: Approved Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.	
416	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE (**000300**) Tracking ID: (X52-NSV-NYSM, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-24 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Fero-Well 750mg/15ml Injection** Each ml contains:Iron as Ferric carboxymaltose ……. 50mg As per Innovators Specification RRA Status: AM REGENT approved by USFDA Me Too Status: Ferinject by Vifor Pharma Pack Size(s): 1 vialx 15ml-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
417	**Misaq Pharmaceuticals Pvt Ltd.** Plot no.7-B,Woven Garments Zone, Value addition City, Khurrianwala-Sahianwala Road (FIEDMC), Faisalabad. (**000985**) Tracking ID: (XB2-YTY-3JBJ, 2024-06-20) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **SOL-D-Injection 5mg/ml** Each ml ampoule contains: - Vitamin D3……..5mg As per Innovators Specification RRA Status: VITAMIN D3 GOOD 200,000 IU/1 ml, IM injection solution in ampoule ANSM (France) Approved Me Too Status: Indrop-D Injection by M/s Neutro Pharma (Reg#023170) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
418	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (XHZ-EX8-Z5S7, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Norgesic Tablets (450mg +35mg)** Each tablet contains: Paracetamol.....450mg, Orphenadrine citrate……35mg (Innovator Specs.) As per Innovators Specification RRA Status: Norgesic 35mg/450mg tablets, Manufacturer: Innova Limited (Registered in UK) Me Too Status: Nuberol 450mg/35mg tablets, Manufacturer: M/s Searle Pharmaceuticals (Pvt.) Ltd. Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved firm shall submit stability data for the interval of 06th month (due on September 2024) before issuance of registration letter.	
419	**Biogen Life Scieces** 8-KM, Chak Beli Road, Rawat, (**000911**) Tracking ID: (XT8-4E4-82VU, 2024-07-09) Fee Paid: 30000.0 Paid Date: 2024-04-08 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Pentazole 40mg Injection IV** Each vial contains (Sterile powder for reconstitution): Pantoprazole as (sodium sesquihydrate)…….. 40mg (Innovator Specification) RRA Status: Protonix 40mg Injection (I.V) approved By US FDA Me Too Status: Panpak by Rasco pharma Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
420	**MAFINS PHARMA** A-5 S.I.T.E. SUPERHIGHWAY INDUSTRIAL AREA KARACHI (**000820**) Tracking ID: (Y48-WXY-7LYQ, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-10 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Mytomol** Each 100ml Vial Contains: Paracetamol 1000mg As per Innovators Specification RRA Status: US-FDA Approved Me Too Status: Provas Infusion By Sami Pharmaceuticals-Karachi Pack Size(s): 100mlx1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
421	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (YQM-AGE-XPS1, 2024-08-01) Fee Paid: 30000.0 Paid Date: 2024-07-09 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **Kezel 400mg Tablet** Kezel 400mg Tablet Each Film Coated Tablet Contains: - Linezolid……400mg (USP Specification). United States Pharmacopeia RRA Status: ZYVOX® (linezolid) 400mg tablets, USFDA approved Me Too Status: Ecasil 400mg Tablet by Sami pharmaceuticals Industrial Area,Karachi. Pack Size(s): As per SRO.-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
422	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (YVZ-LG8-37ZV, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-05-16 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Methyll 125mg Injection** Each Vial Contains (Sterile powder for reconstitution):Methylprednisolone as Sodium Succinate (USP)…….125mg(Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Solu Medrol Injection by Pfizer Pack Size(s): As Per SRO-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
423	**Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. (**000982**) Tracking ID: (YVU-JMT-NWJL, 2024-07-30) Fee Paid: 30000.0 Paid Date: 2024-06-10 Case Category: New License **(Salateen Waseem Philip)**	Proposed Name: **QPRAZOLE 20 mg capsule** Each Hard Gelatin Capsule containsEsomeprazole Magnesium enteric coated pellets E.q to Esomeprazole .....20mg United States Pharmacopeia RRA Status: USFDA/MHRA Me Too Status: AXESOM Pack Size(s): Alu Alu Blister 2x7s-As per SRO
	Evaluation Remarks: Source of pellets: VISION PHARMACEUTICALS PVT) LTD. Address: Plot No 22-23, Industrial Triangle Kahuta Road, Islamabad	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Source of pellets: VISION PHARMACEUTICALS PVT) LTD. Address: Plot No 22-23, Industrial Triangle Kahuta Road, Islamabad	
424	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (ZAY-BS2-XE91, 2024-07-10) Fee Paid: 30000.0 Paid Date: 2024-06-04 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Texet Tablet 75/650mg** Each Film Coated Tablet Contain:- Paracetamol…..650mg Tramadol HCl…75mg (USP Specifications) United States Pharmacopeia RRA Status: Tramadol hydrochloride and Paracetamol 75 mg/650 mg Film-coated Tablets (tramadol hydrochloride and Paracetamol)- PL35533/0043 (MHRA Approved). Me Too Status: Tonoflex-P Forte Tablet Reg. No. 094798 by SAMI Pharma Karachi Pack Size(s): 1x5's, 1x10's, 2x7's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
425	**Lawari international** Valley Road Gulkada saidu sharif Swat (**000658**) Tracking ID: (ZSE-5WN-B27T, 2024-07-31) Fee Paid: 30000.0 Paid Date: 2024-07-15 Case Category: New Section **(Salateen Waseem Philip)**	Proposed Name: **Lawazed 500mg Capsule** Each capsule contains: Cefadroxil as Monohydrate ……500mg United States Pharmacopeia RRA Status: Cefadroxil 500mg Capsules by Sandoz Limited. UK Me Too Status: Duricef 500mg Capsule by M/s GSK Pakistan Pack Size(s): 12's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
426	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (3ZT-NLU-GLJS, 2024-05-30) Fee Paid: 30000.0 Paid Date: 2024-05-21 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Ceftam 2g** Each vial contains Cefoperazone (as Sodium) 1000mg and Sulbactam (as Sodium) 1000mg As per Innovators Specification RRA Status: PMDA Me Too Status: Sapizone Injection 2gm Pack Size(s): 1,s -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

S. No.	Section	Observation	Reply submitted by the firm
1.	1.5.6	This section has mentioned JP specifications. Fee of 7500/- shall be submitted for revision of specifications to innovator specifications.	Firm has submitted fee challan of RS. 7500/- for revision of specifications to innovator specifications vide fee challan slip No. 2558794720 dated 29-07-2024.
2.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.2.2	Details of the product against which PE studies are performed shall be submitted.	Firm has submitted that PE studies are performed against Sufzon 1gm, B. No. 23m174, Global pharma.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
427	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (6Q2-X5J-44DZ, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-07-05 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Q-Pride 25mg** Each tablet contains: Levosulpiride 25mg As per Innovators Specification RRA Status: AIFA approved Me Too Status: Solro 25mg Tablet Pack Size(s): 2x10's=20's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
428	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (BL1-4NQ-VT58, 2024-06-07) Fee Paid: 30000.0 Paid Date: 2024-05-21 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Ceftam 1g** Each vail contains Cefoperazone sodium eq. to Cefoperazone 500mg and Sulbactam sodium eq. to Sulbactam 500mg As per Innovators Specification RRA Status: PMDA approved. Me Too Status: Avesulzone Injection 1gm Pack Size(s): 1,s -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

S. No.	Section	Observation	Reply submitted by the firm
1.	1.5.6	This section has mentioned JP specifications. Fee of 7500/- shall be submitted for revision of specifications to innovator specifications.	Firm has submitted fee challan of RS. 7500/- for revision of specifications to innovator specifications vide fee challan slip No. 9609751730 dated 29-07-2024.
2.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.2.2	Details of the product against which PE studies are performed shall be submitted.	Firm has submitted that PE studies are performed against Sufzon 1gm, B. No. 23G158, Global pharma.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
429	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (EQT-57Z-87X3, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Lee-Q 500mg** Each film coated tablet contains levofloxacin hemihydrate eq. to levofloxacin 500mg United States Pharmacopeia RRA Status: MHRA approved. Me Too Status: Levoxin 500mg by Searle Pakistan Pack Size(s): 1 x 10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved Registration letter will be issued after submission of 7500/- for pre registration variation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 &13-07-2021.	
430	**FYNK Pharmaceuticals** 19-KM, G.T. Road, Kala Shah Kaku, Tehsil Ferozwala District Sheikhupura. (**000494**) Tracking ID: (GMV-J1M-1M61, 2024-07-16) Fee Paid: 30000.0 Paid Date: 2023-06-05 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Ampiwell Dry suspension 250mg/5ml** Each 5ml contains: Ampicillin Trihydrate eq. Ampicillin …….250mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ampicillin Suspension 250mg by M/s Amros Pharma Pack Size(s): 60ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No.	Section	Observation	Response by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	2.3	Table for literature references with correct information shall be submitted.	
3.	3.2.P.2.2	Justification for not performing the pharmaceutical equivalence test against the innovator product.	
4.	3.2.P.8	• Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA etc. shall be submitted. • Raw data sheets for calculation of ampicillin content at each time point shall be submitted. • Documents for procurement of API shall be submitted.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred For the submission of reply to the above cited shortcomings.	
431	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (**000941**) Tracking ID: (HE9-ZVZ-3MGE, 2024-06-11) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Azowera 250mg Tablets** Each film coated tablet contains: Azithromycin dihydrate equ. to Azithromycin ..... 250mg Product Specs: BP British Pharmacopeia RRA Status: Zithromax 250mg Tablets Manufacturer: Pfizer Pharmaceuticals Route PR-2, Km 58.2 in Barceloneta, Puerto Rico www.accessdata.fda.gov Me Too Status: Product: Azmin Tablets Manufacturer: Honig Pharmaceuticals Adyala road Rawalpindi Pack Size(s): as per SRO's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.2	Water content in analytical procedure is different from specification	Firm has submitted that followed BP specification and in BP 2022 water content mentioned is 1.8 to 6.5%.
2.	3.2.S.4.4	• COA of the drug substance with same batch number shall be submitted. • COA by the drug product manufacturer has mentioned assay limit of 98% to 102% while specifications have mentioned 96% to 102%. clarify.	Submitted. Firm has submitted that it was due to typographical error and the actual limit is 96% to 102% as mentioned in BP. They also submitted corrected COA.
3.	3.2.P.2.2	CDP data at pH 1.2 shall be submitted.	Firm has submitted that at pH 1.2 both comparator and test product does not show any peak and the scans are already submitted for consideration.
4.	3.2.P.8	Copy of Loan letter shall be submitted.	Submitted.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
432	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (L3P-BTQ-X7ST, 2024-07-19) Fee Paid: 30000.0 Paid Date: 2024-07-05 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Q-Pride 50mg** Each tablet contains: Levosulpiride 50mg As per Innovators Specification RRA Status: AIFA approved Me Too Status: Solro 50 mg tablet Pack Size(s): 2x10's=20's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
433	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (**000941**) Tracking ID: (LEP-D8E-X9S5, 2024-06-13) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Azowera 250mg Capsules** Each Capsule contains: Azithromycin dihydrate equ. to Azithromycin ..... 250mg Product Specs: BP British Pharmacopeia RRA Status: Zithromax 250mg Capsules Manufacturer: Pfizer Pharmaceuticals Route PR-2, Km 58.2 in Barceloneta, Puerto Rico www.accessdata.fda.gov Me Too Status: Product: Zetro Capsules Manufacturer: Getz Pharma Karachi Pack Size(s): as per SRO's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.2	Water content in analytical procedure is different from specification	Firm has submitted that followed BP specification and in BP 2022 water content mentioned is 1.8 to 6.5%.
2.	3.2.S.4.4	• COA of the drug substance with same batch number shall be submitted. • COA by the drug product manufacturer has mentioned assay limit of 98% to 102% while specifications have mentioned 96% to 102%. clarify.	Submitted. Firm has submitted that it was due to typographical error and the actual limit is 96% to 102% as mentioned in BP. They also submitted corrected COA.
3.	3.2.P.2.2	CDP data at pH 1.2 shall be submitted.	Firm has submitted that at pH 1.2 both comparator and test product does not show any peak and the scans are already submitted for consideration.
4.	3.2.P.8	Copy of Loan letter shall be submitted.	**Submitted.**

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
434	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT (**000941**) Tracking ID: (MGE-DQV-AG18, 2024-06-10) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Azowera 500mg Tablets** Each film coated tablet contains: Azithromycin dihydrate equ to Azithromycin ..... 500mg Product Specs: BP British Pharmacopeia RRA Status: Zithromax 500mg Tablets Manufacturer: Pfizer Pharmaceuticals Route PR-2, Km 58.2 in Barceloneta, Puerto Rico www.accessdata.fda.gov Me Too Status: Product: Azmin 500mg Tablets Manufacturer: Honig Pharmaceuticals Adyala road Rawalpindi Pack Size(s): as per SRO's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.2	Water content in analytical procedure is different from specification	Firm has submitted that followed BP specification and in BP 2022 water content mentioned is 1.8 to 6.5%.
2.	3.2.S.4.4	• COA of the drug substance with same batch number shall be submitted. • COA by the drug product manufacturer has mentioned assay limit of 98% to 102% while specifications have mentioned 96% to 102%. clarify.	Submitted. Firm has submitted that it was due to typographical error and the actual limit is 96% to 102% as mentioned in BP. They also submitted corrected COA.
3.	3.2.P.8	Copy of Loan letter shall be submitted.	Submitted.

Decision: Approved

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
435	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (S81-M8W-M3Q3, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Lee-Q 500mg/100mL Infusion** Each mL of solution for Infusion contains Levofloxacin hemihydrate eq. to Levofloxacin 5mg British Pharmacopeia RRA Status: FDA, MHRA Me Too Status: Leflox 500mg/100mL Infusion Pack Size(s): 1's-As per SRO
	Evaluation Remarks:	
	Decision: Approved Registration letter will be issued after submission of 7500/- fee for typo errors as per decision of Registration Board.	
436	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (REA-3P1-R7HV, 2024-05-13) Fee Paid: 30000.0 Paid Date: 2024-04-03 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Auclin 500mg/100ml** Each 100ml Vial contains Metronidazole 500mg United States Pharmacopeia RRA Status: EMC, FDA HPRA Me Too Status: Flagyl Infusion Pack Size(s): 1 x 100ml-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
437	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (UXG-UHM-NX4M, 2024-07-04) Fee Paid: 30000.0 Paid Date: 2024-06-28 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Naprogesic 275mg Tablet** Each Film coated tablet contains: 275mg Naproxen Sodium United States Pharmacopeia RRA Status: TGA, approved Me Too Status: Mayoflex 275mg tablet Pack Size(s): 2 x 10’s -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

S. No.	Section	Observation	Reply submitted by the firm
1.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.2.2	CDP results at pH 1.2 shall be submitted.	Submitted.
5.	3.2.P.8	Stability data sheets have mentioned 30-minute time for dissolution while USP monograph has mentioned 45 minutes. Clarification shall be submitted.	Firm has submitted updated stability data sheets with a dissolution time of 45 minutes.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
438	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (V9L-76Z-UT88, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-05-10 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Lee-Q 250mg** Each film coated tablet contains: levofloxacin hemihydrate eq. to Levofloxacin 250mg United States Pharmacopeia RRA Status: MHRA approved. Me Too Status: Levoxin 250mg by Searle Pack Size(s): 1 x 10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved Registration letter will be issued after submission of 7500/- fee for pre-registration variation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
439	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (WSY-XBX-54JR, 2024-03-01) Fee Paid: 30000.0 Paid Date: 2024-01-25 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Novidol Forte** Each tablet contains Paracetamol 650mg and Orphenadrine Citrate 50mg As per Innovators Specification RRA Status: Could not be confirmed. Me Too Status: Nuberol forte tablets by Searle Pharma Pack Size(s): 3 x 10's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

S. No.	Section	Observation	Reply submitted by the firm
1.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities shall be submitted for further processing of your application.	Firm has submitted a link of TGA, but it is for 450mg and 35mg strength. RRA could not be verified.
2.	2.3	Copies of executed BMR shall be submitted.	Submitted.
3.	3.2.S.4.1	Specifications of both the drug substances from drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures of both the drug substances from drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.2.2	CDP studies shall be submitted.	Submitted.
6.	3.2.P.5.2	Analytical procedure for dissolution test shall be submitted.	Submitted.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred The Board deferred the case for submission of valid RRA reference of applied product OR submission of following as per decision of 179th meeting of the Authority; • i. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA. ii. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP. iii. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database. iv.Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.	
440	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT (**000944**) Tracking ID: (XJP-BX6-VX68, 2024-03-11) Fee Paid: 30000.0 Paid Date: 2024-01-25 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Novidol** Each tablet contains: paracetamol 450mg and Orphenadrine citrate 35mg As per Innovators Specification RRA Status: Norgesic tablet, TGA approved. Me Too Status: Nuberol tablets by Searle Pakistan Pack Size(s): 10 x 10's-As per SRO
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Registration letter will be issued after submission of 30,000/- fee for correction of label claim as per reference product as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
441	**M/s Safina Pharmaceutical (Pvt) Ltd** 17 km. Sheikhupura Road, Lahore (**000654**) Tracking ID: (2BQ-HNY-QWL9, 2024-01-16) Fee Paid: 30000.0 Paid Date: 2023-05-15 Case Category: New License **(Tahir Waqas)**	Proposed Name: **ESOSAF 40mg Capsule** Each capsule contains: Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 40mg United States Pharmacopeia RRA Status: NEXIUM 40mg Capsules (USFDA Approved) Me Too Status: NEXUM 40mg Capsules of M/s Getz Pharma (Pvt.) Limited Pack Size(s): 14's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

The case was deferred in 336th meeting of Registration Board for submission of reply to the following shortcomings, for which the response has been submitted as follows:

Sr. No.	Observations / Shortcomings	Response of the Firm
i.	Label claim needs to be corrected as per Innovator / Reference Product.	Firm have submitted revised label claim. Fee for revision of label claim has not been submitted.
ii.	2.3.P.3.1 Please provide GMP Certificate of FPP Manufacturer (not older than 03 Years).	Submitted
iii.	3.2.P.2.2.1 (c) Comparative Dissolution Study Results have not been submitted, rather only protocol has been enclosed in this section. Please clarify.	Submitted
iv.	As mentioned in 3.2. P. 5.6 Justification of Specifications as well as claimed USP Monograph recommends Dissolution Analysis to be performed on Acid Stage as well as Buffer Stage, whereas 3.2. P.5.4 Batch Analysis and 3.2.P.8 Stability Study Data Results show that Dissolution Test have been performed on single stage. Please justify.	Firm have submitted that they have used USP Test 1 for Dissolution, wherein the dissolution is performed at both acid and Buffer stage, but calculation is done at buffer stage only.
v.	The submitted Audit Trails Reports are for Esomeprazole 20mg Capsules. Please justify.	The firm have again submitted Audit Trails Reports for Esomeprazole 20mg Capsules.

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Registration Board further decided that the Registration Letter will be issued after submission of requisite fee for revision of label claim.	
442	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (**000914**) Tracking ID: (3NV-V4X-ZEVU, 2024-01-09) Fee Paid: 30000.0 Paid Date: 2023-11-15 Case Category: New Section **(Tahir Waqas)**	Proposed Name: **LINEZOVAR 600mg/300ml INFUSION** Each 300ml vial contains: Linezolid ... 600mg As per Innovators Specification RRA Status: ZYVOX 600MG/300ML (2MG/ML) USFDA Approved. Me Too Status: Barizold Infusion 600mg/300ml of Barrett Hodgson Pakistan (Pvt) Ltd. Pack Size(s): 1'S (300ML)-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
443	**Medevo (Pvt.) Limited** 94-Sundar Industrial Estate (**000962**) Tracking ID: (3U2-MD8-ZBUX, 2024-01-08) Fee Paid: 30000.0 Paid Date: 2023-10-24 Case Category: New License **(Tahir Waqas)**	Proposed Name: **SURGIFLOX 0.3% Ophthalmic Ointment** Each gram contains: Ofloxacin ... 3mg As per Innovators Specification RRA Status: Ofloxacin eye ointment 0.3% Me Too Status: Exocin SOP Ophthalmic Ointment of Barrett Hodgson Pakistan (Pvt) Ltd. Pack Size(s): 3.5 g-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The following observations / deficiencies have been communicated to the applicant: 01) Form 5-F and Undertakings have not been signed & stamped by applicant. 02) Please provide valid GMP of API Manufacturer. The enclosed GMP was valid until 05-01-2021. 03) 3.2.S.4 Analytical Method of Drug Substance by Drug Product Manufacturer and Verification of Analytical Method of Drug Substance by Drug Product Manufacturer have not been submitted in this section. 04) 3.2.S.7.3 Stability Data of Drug Substance have not been submitted in this section. 05) Please provide AD(I&E) DRAP Clearance for Import of relevant Batch of API (Ofloxacin).	
	Decision: Deferred Registration Board deferred the case for submission of reply to the above cited shortcomings.	
444	**Pearl Pharmaceuticals** 204, Street No. 1, I-10/3 Industrial Area, Islamabad (**000479**) Tracking ID: (DL1-UX3-8EZY, 2023-12-13) Fee Paid: 30000.0 Paid Date: 2023-11-13 Case Category: New Section **(Tahir Waqas)**	Proposed Name: **Sucrofer 100mg/5ml Injection** Each 5ml contains: Iron sucrose complex (as elemental Iron) ... 100mg British Pharmacopeia RRA Status: VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule, (TGA Australia Approved). Me Too Status: BISLERI-S 100mg/5ml Injection of M/s SAMI Pharmaceuticals (Pvt.) Limited Pack Size(s): 5x5ml ampoules-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1) The enclosed GMP Certificate of API Manufacturer was valid till 18-05-2023. Please provide valid GMP Certificate. (Submitted) 2) 3.2.P.2.3 In Pharmaceutical Equivalence Study it has been mentioned that study was conducted with SUCROFER 10mg/5ml Injection. Please clarify. (Typographic mistake) 3) Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence. (Submitted) 4) 3.2.P.5.1 Please mention USP glass Type of ampoule used for filling. (USP glass Type-1 ampoule) 5) 3.2.P.5.1 BP in its Monograph recommends tests for 'content of Iron, Fe' as well as 'content of Sucrose' both. However, the same has not been conducted by you. Please justify. (We are claiming in our product Iron (Iron sucrose complex as Elemental iron) that's why we have tested only Iron in our product. However, Sucrose had been tested by the API manufacturer. After getting registration of this product, we will perform this test in our product as well.) 6) 3.2.P.5.1 Furthermore, the tests for 'Osmolality' as well as 'Molecular Weight Determination' as mentioned in enclosed BP Monograph, have also not been conducted in this section. Please justify. (Osmolality Test was performed Revised COA attached. Molecular weight Determination of API had been performed by API manufacturer. Sucrose testing and Molecular Weight Determination testing method is same so we will perform these tests in our product after getting registration.) 7) 3.2.P.8 Please provide Stability Study Data along with attested respective documents like Raw data sheets, COA, summary data sheets etc., for 6th Month Testing Interval of all 03 Trials. (Submitted)	
	Decision: Deferred Submission of Stability Study Results for next time point, including all tests mentioned in BP Monograph.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
445	**M/s Safina Pharmaceutical (Pvt) Ltd** 17 km. Sheikhupura Road, Lahore (**000654**) Tracking ID: (V4P-XS1-JJL1, 2024-02-23) Fee Paid: 30000.0 Paid Date: 2023-05-15 Case Category: New License **(Tahir Waqas)**	Proposed Name: **ESOSAF 20mg Capsule** Each capsule contains: Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 20mg United States Pharmacopeia RRA Status: NEXIUM 20mg Capsules (USFDA Approved) Me Too Status: NEXUM 20mg Capsules of M/s Getz Pharma (Pvt.) Limited. Pack Size(s): 14's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:

The case was deferred in 336th meeting of Registration Board for submission of reply to the following shortcomings, for which the response has been submitted as follows:

Sr. No.	Observations / Shortcomings	Response of the Firm
i.	Label claim needs to be corrected as per Innovator / Reference Product as follows: - *Each capsule contains:* *Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 20mg*	Firm have submitted revised label claim as follows: *Each capsule contains:* *Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole ... 20mg* **Fee for revision of label claim has not been submitted.**
ii.	2.3.P.2.1 Please provide GMP Certificate	Submitted

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Registration Board further decided that the Registration Letter will be issued after submission of requisite fee for revision of label claim.	
446	**Med Asia Pharmaceuticals (Pvt) Ltd** Plot No. 7, NowsheraIndustrial Estate (SIZ) Risalpur (**000690**) Tracking ID: (XVJ-UJM-P4X4, 2024-02-12) Fee Paid: 30000.0 Paid Date: 2023-11-10 Case Category: New License **(Tahir Waqas)**	Proposed Name: **AZOMED 250mg Capsule** Each hard Gelatin capsule contains: Azithromycin as Dihydrate … 250mg British Pharmacopeia RRA Status: ZITHROMAX 250mg CAPSULES, (MHRA Approved) Me Too Status: AZOMAX 250mg capsules of M/s AGP Limited Pack Size(s): 10's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The following observations / deficiencies have been communicated to the applicant: 01) Please provide GMP Certificate of API Manufacturer issued by relevant Regulatory Authority of Country of Origin. (Submitted) 02) 2.3.P.1, 2.3.P.3.2, 3.2.P.2.1, 3.2.P.3.2 Raw Material (Active) has been mentioned as 'Azithromycin as sodium sesquihydrate' whereas the same has been mentioned as 'Azithromycin as dihydrate' in rest of the application dossier. Please justify. (Typographic error) 03) 3.2.S.4.3 Verification of Analytical Method (of Drug Substance) by FPP Manufacturer has not been submitted. (Submitted) 04) 3.2.S.7.3 Submitted Stability Study Data Sheets are not endorsed / signed / verified by Drug Substance Manufacturer. Please justify. (Submitted) 05) 3.2.P.2.2.1 Please provide evidence & details of Reference / Innovator's Pack used for Pharmaceutical Equivalence and CDP. (Submitted) 06) Documents confirming loan of API from Importer have not been submitted. (Submitted)	
	Decision: Approved	
447	**Medevo (Pvt.) Limited** 94-Sundar Industrial Estate (**000962**) Tracking ID: (Y18-32Q-9J5W, 2024-01-10) Fee Paid: 30000.0 Paid Date: 2023-10-31 Case Category: New License **(Tahir Waqas)**	Proposed Name: **SURGILAST 0.05% Ophthalmic Solution** Each ml contains: Azelastine HCl ... 0.5mg United States Pharmacopeia RRA Status: USFDA Approved (**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**) Me Too Status: AZELAST Ophthalmic Solution (0.5%) of M/s Innvotek Pharmaceuticals Pack Size(s): 5ml-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The following deficiencies / shortcomings have been communicated to the firm: 1) Form 5-F and Undertakings have not been signed & stamped by applicant. (Submitted) 2) 2.3.P.5 Test for Osmolarity and Osmolality, as well as test for Antimicrobial / Preservative Effectiveness Test (as specified in USP Monograph) has not been conducted. Please justify. (Firm has submitted revised 2.3.P.5 including Test for Osmolarity and Osmolality. However, no information on Antimicrobial / Preservative Effectiveness Test (as specified in USP Monograph) has been submitted.) 3) Please provide valid GMP Certificate of API Manufacturer. The enclosed Certificate was valid till 10.2023. (Submitted) 4) 3.2.S.7.3 Stability Study Data of Drug Substance (API) have not been enclosed in this section. Please clarify / provide the same. (3.2.7.3 Stability Study Data of Drug Substance has been submitted. However, the Stability Study Data Sheets include optical rotation test for Hyoscyamine. Clarification is required.) 5) 3.2.P.2.2.1 Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence. (Submitted) 6) 3.2.P.8 In Accelerated Stability Study Results of at 3rd Month Testing Interval (Batch No. AZL Trial 003), Significant Change (>5%) has been observed from initial Assay results of Azelastine Hydrochloride. Please justify. (The firm have claimed that it was an Analyst Error and referred to the 6th Month Testing Interval results which are within specified limits.) 7) Please provide Clearance Certificate issued by AD (I&E) DRAP for concerned batch of API (Azelastine HCl). The enclosed document is a Drug Import License only and not the Clearance Certificate issued for import of concerned consignment. (Submitted)	
	Decision: Deferred 1) Clarification regarding 'optical rotation test for Hyoscyamine', mentioned in submitted stability study sheets for Drug Substance. 2) Stability Studies for newly formulated batches.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
448	**M/s Safina Pharmaceutical (Pvt) Ltd** 17 km. Sheikhupura Road, Lahore (**000654**) Tracking ID: (5DJ-35U-7MYG, 2024-07-09) Fee Paid: 30000.0 Paid Date: 2024-06-28 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Lansosaf 30mg capsule** Each Capsule contains: Lansoprazole as enteric coated pellets …… 30mg RRA Status: lansoprazole 30mg capsule by fda aprroved Me Too Status: lancerid 30mg capsule by bio-labs pvt.ltd Pack Size(s): 1x10's-As per SRO,2x7's-As per SRO,30's-As per SRO
	Evaluation Remarks: Submit reply of following observations at the earliest for further processing of your case. In section 3.2.P.8, 1- Submit the details of HPLC used for analysis. 2- Submit the evidence that chromatograms submitted has audit trail. 3- In the calculation sheets of assay, include weight taken of sample / reference standard, dilution and final concentration of the solution in mg/ml. 4- Submit SOP of integration of chromatograms of HPLC.	
	Decision: Deferred for submission of reply to the above cited shortcomings.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
449	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road (**000455**) Tracking ID: (HDL-1HL-JWPH, 2024-04-24) Fee Paid: 30000.0 Paid Date: 2023-09-22 Case Category: New Section **(Waqar Ahmed)**	Proposed Name: **Ezolite** Each capsule contains 20mg Esomeprazole United States Pharmacopeia RRA Status: FDA , USA / MHRA , UK Me Too Status: NABIQASIM INDUSTRIES (PVT) LTD. Pack Size(s): 14 capsule -As per SRO
	Evaluation Remarks: In section 3.2.P.8: Submit chromatograms for all the intervals of real time studies along with calculation sheets.	
	Decision: Deferred for submission of reply to the above cited shortcomings.	
450	**Elite Pharma (Pvt) Ltd** 9.5km Sheikupura Road (**000455**) Tracking ID: (UJZ-EM4-ALEV, 2024-05-21) Fee Paid: 30000.0 Paid Date: 2024-02-14 Case Category: New Section **(Waqar Ahmed)**	Proposed Name: **Montilite** Each sachet contains: Montelukast sodium equivalent to Montelukast Acid.....4mg United States Pharmacopeia RRA Status: MHRA, UK Me Too Status: Me-Too Status Pack Size(s): 14sachet/Pack-As per SRO
	Evaluation Remarks: In section 3.2.P.8: Submit chromatograms for all the intervals of real time studies along with calculation sheets.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred for submission of reply to the above cited shortcomings.	

Division of Biological Evaluation & Research

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Mr. Muhammad Kashif	DD-I	109
2.	H.M. Jawad Ali	DD-II	31
3.	Ms. Haleema Sharif	DD-III	18
4.	Ms. Anam Saeed	DD-IV	02
Total			**160**

CASES OF DD-I (MR. MUHAMMAD KASHIF)

Case. No.1 **For information and endorsement of the Registration Board**

A. Post Registration Variation cases decided in 1st PRVC for Biologicals held on held on 14th - 15th November, 2022.

Sr. No.	Applications	Decision of PRVC
1.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi has applied for the change in manufacturing site of their already registered biological products	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided as follows: a. Approved M/s Novo Nordisk (China) Pharmaceuticals Co., Ltd. No.99 Nanhai Road, TEDA, Tianjin, 300457 – People's Republic of China as manufacturing site of Insulatard HM Penfill 100 IU/ml (Reg. No. 010341). b. Approved the exemption from inspection of new manufacturing site abroad on the basis of Original legalized CoPP issued by Danish Medicines Agency which confirms GMP compliant status of the manufacturer and availability of the products as well.

2.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi has applied for the change in manufacturing site of their already registered products	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided as follows: a. Approved M/s Novo Nordisk Production SAS 45, Avenue d'Orléans, F-28000 Chartres, France as manufacturing site of Ryzodeg FlexTouch 100 U/ml Solution for Injection in Pre-Filled Pen (Reg. No. 087970). b. Approved the exemption from inspection of new manufacturing site abroad on the basis of Original legalized CoPP issued by Danish Medicines Agency which confirms GMP compliant status of the manufacturer and availability of the products as well.
3.	A. M/s Novartis Pharma (Pakistan) Limited has applied for change of Marketing Authorization Holder (MAH) of their already registered biological product	A. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved M/s Novartis Pharma Schweiz AG, 6343 Risch, Switzerland as Marketing Authorization Holder (MAH) of Fraizeron Solution for Injection 150mg Pre-Filled Pen (Reg. No 088713).
	B. M/s Novartis Pharma (Pakistan) Limited has applied for Extension of shelf life from 18 months to 24 months of their already registered biological product	B. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 24 months (2-8°C) of Fraizeron Solution for Injection 150mg Pre-Filled Pen (Reg. No 088713).
4.	. M/s Sanofi Aventis Pakistan Limited has applied for Change of MAH of their already registered biological product	**A.** The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved M/s Genzyme Europe BV Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands as Marketing Authorization Holder (MAH) of Cerezyme 400U (Powder for concentrate for solution for infusion) (Reg. No 107918) on the basis of Original legalized CoPP issued by Swiss medic.
	. M/s Sanofi Aventis Pakistan Limited has applied for Change (Extension) of shelf life of their already registered biological product	**B.** The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 36 months (Unopened vial) (2-8°C) of Cerezyme 400U (Powder for concentrate for solution for infusion) (Reg. No 107918).
5.	M/s Sanofi Aventis Pakistan Limited has	The Committee evaluated the case and decided to defer for following clarifications:

	applied for inclusion of shelf life of their already registered biological product	a. Manufacturing site in registration letter is M/s Sanofi Pasteur S.A France while in COPP is M/s Sanofi Pasteur, 14 Espace Henry Vallee 69007 Lyon France. Moreover, b. Strain 17D-204 and 1000 IU are mentioned in CoPP and not mentioned in the registration letter.
6.	M/s Galaxy Pharma (Pvt) Ltd has applied for change/Inclusion of specifications for their already registered Biological products	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the B.P Specifications for IVF-M Injection 150IU (Reg. No. 039814) and IVF-M Injection 75IU (Reg. No. 039813).
7.	A. M/s Getz Pharma (Pvt.) Ltd., Karachi applied to update the manufacturing site address (Site remains the same) of their already registered products. B. M/s Getz Pharma (Pvt.) Ltd. has applied for Extension of shelf life from 24 months to 48 months of their already registered biological product	A. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the updated address of M/s Biocon Biologics India Limited,Block No. B1, B2, Q13 of Q1 and W20 & Unit S18, 1st Floor, Block B4,Special Economic Zone Plot No. 2, 3, 4 & 5 Phase-IV Bommasandra-Jigani Link RoadBommasandra Post Bengaluru 560099, India for the above products. B. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 04 years (2-8°C) of above products.
8.	A. M/s Hoffmann Human Health Pakistan Ltd. 1st Floor, 32 Babar Block, New Garden Town, Lahore applied for change of MAH and manufacturing site of their already registered products. B. M/s Hoffmann Human Health Pakistan Ltd. 1st Floor, 32 Babar Block, New Garden Town, Lahore applied for the change in manufacturing site of their already registered products	A. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as under: **a.** Approved M/s LG Chem. Ltd. 151, Osongsaengmyeong-1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea as Marketing Authorization Holder and manufacturing site of Eutropin 4IU Injection (Reg. No. 039824). **b.** Approved combo pack (drug product and solvent) with shelf life of 36 months (2-8°C) with USP Specifications on the basis of COPP issued by the Ministry of Food and Drug Safety, South Korea. **c.** Approved the exemption from inspection abroad on the basis of PIC/s participating Authority.

		B. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as follows: Approved the M/s LG Chem. Ltd. 151, Osongsaengmyeong-1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea as Marketing Authorization Holder and manufacturing site of both the above products at (A) & (B). Approval of combo pack with shelf life of 36 months (2-8°C) with USP Specifications on the basis of COPP is issued by the by Ministry of Food and Drug Safety, South Korea and hence exempted from inspection abroad on the basis of COPP issued by PIC/s participating Authority. Approved the exemption from inspection abroad on the basis of PIC/s participating Authority
9.	M/s Roche Pakistan Limited has applied for Extension of shelf life from 30 months to 36 months of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved M/s Roche Pharma (Schweiz) AG Gartenstrasse 9, 4052 Basel Switzerland as MAH for the product for the products at S. No.1 & 2 and the shelf life of 36 months (2-8°C) of above products.
10.	M/s Grand Pharma (Pvt) Ltd has applied for correction in Brand Name of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the correction in brand name as GPVAC ND+ART Injectable (Reg. No. 111167) for the above product.
11.	M/s GlaxoSmithKline Pakistan Limited has applied for Extension of shelf life from 36 months to 48 months of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 48 months (2-8°C) of above product.
12.	M/s GlaxoSmithKline Pakistan Limited has applied for the change in name of Product License Holder and Manufacturer (site remains the same) of	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as follows: a. For S.No.01: approved M/s GlaxoSmithKline Biologicals S.A 89, Rue de I'Institut 1330 Rixensart, Belgium as Marketing Authorization Holder (MAH) and manufacturer.

	their already registered products	b. For S.No.02-04: deferred for clarification regarding difference in the composition of registration letter and CoPP.
13.	M/s Saadat International has applied for change of Name of the manufacturing site (Manufacturing site remains the same) with updated address and change of Legal entity (Marketing Authorization Holder)	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee deferred the case for a. Regularization of registration for the products at S. No. 1 & 2. b. Updating the address. c. Change in name of Marketing Authorization holder and manufacturer. d. Combo pack approval with detailed compositions as per CLIs for the products at S.No 1, 2 & 3 .
14.	M/s Saadat International has applied for Extension of shelf life from 24 months to 36 months of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as follows: a. approved the combo pack and shelf life of above product on the basis of Certificate of original and legalized Licensing and Inspection issued by United States Department of Agriculture and Animal and Plant Health Inspection Service Veterinary Service as per following details. "The expiration date of the combination package is the earliest expiration date of the individual product components. The combination package is composed of released product of codes 13D1.R1 and 2671.02. 13D1.R1(Freeze dried live vaccine); the expiration date is 18 months after the initiation of first potency test. 2671.02(Suspension part, killed vaccine): the expiration date is 36 months after the initiation of first potency test. b. Advised to inform the Registration Board.
15.	A. M/s Saadat International has applied for the change in name of manufacturing site(Site remains the same) & Marketing Authorization Holder (MAH) of	A. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as under: a. Deferred the product at S. No.1 for Regularization of registration by the Registration Board. b. Approved M/s Boehringer Ingelheim Animal Health France 29 Avenue Tony Garnier 69007, Lyon, France as Marketing Authorization Holder and M/s Boehringer Ingelheim Animal Health France Rue De L'Aviation, 69800 St. Priest, France as

	their already registered products. B. M/s Saadat International applied for the change in name of manufacturing site(Site remains the same) & Marketing Authorization Holder (MAH) of their already registered products	Manufacturer for the products at S. No. 2-11 as per Legalized COO/FSC issued by ANSES France. B. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee deferred the cases for following points: a. Regularization of registration by the Registration Board with composition as per COO/FSC for the products at S. No. 1 – 15. b. Status of Change in name of Marketing Authorization holder and manufacturer (site remains the same).
16.	M/s Hipra Pakistan(Pvt) Ltd has applied for additional packing of their already registered products	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the additional Packs of 1000 doses vial x 5 and 10ml of Solvent Vial x 5 for Hiprapox Vaccine (Lyophilisate and solvent for injectable suspension) (Reg. No. 101731) and 1000 doses vial x 5 for HIPRAVIAR-LT (Lyophilisate for suspension) (Reg. No. 094783)
17.	A. M/s Hilton Pharma (Pvt.) Ltd has applied for change of Brand name of their already registered biological product. B. M/s Hilton Pharma (Pvt.) Ltd has applies for change in Expression of Titer of their already registered biological product	A. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved Medivac ND G7 Emulsion (Inactivated vaccine) (Reg. No. 084989) as the new brand name of above product. B. The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee referred the case for deliberation in Registration Board along with status of innovator and other registered drug product.
18.	M/s Hilton Pharma (Pvt.) Ltd has applies for change in Expression of Titer of their already registered biological product	The Committee evaluated the case and Chairman Registration Boa the recommendations of the committee referred the case for delibera Registration Board along with status of innovator and other registere products
19.	M/s Haji Medicine Co., has applied for Inclusion of shelf life of 5 years in the registration letter of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life 5 years of HepaRotex on the basis of shelf life of 5 years in Reference Country's product i.e UK, and the country of origin approval i.e Germany.
20.	M/s Pfizer Pakistan (Pvt) Ltd has applied for	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee and on the basis

	extension of shelf life product of their already registered biological product	of approval of the demanded shelf life for Ixifi by Health Canada, approved the shelf life 5 years (2°C-8°C) of above product. Additionally, at the location of reconstitution, unopened Ixifi may be stored in the original carton at temperature up to a maximum of 30°C for a single period of up to 6 months not exceeding the refrigerated expiration date printed on the carton. Once removed from refrigerated storage, Ixifi cannot be returned to refrigerated storage
21.	M/s NIH, Islamabad has applied for Inclusion of parameters in Renewal letter	The Committee evaluated the case and the chairman RB referred the case for deliberation in Registration Board after submission of fee by M/s National Institute of Health Islamabad.

B. Post Registration Variation cases decided in 2nd PRVC for Biologicals held on held on 1st to 2nd February, 2023.

Sr. No.	Applications	**Decision of PRVC**
22.	M/s Lab Diagnostic System Private Limited has applied for change of name of Marketing Authorization Holder (MAH) and Manufacturer (site remains the same) of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the change of title of Marketing Authorization Holder and Manufacturer of M/s Jiangsu Hengrui Medicine Co., Ltd. to M/s Jiangsu Hengrui Pharmaceuticals Co., Ltd, for Pegaspargase (PEG-L_Asparaginase) Injection (Reg. No 105067).
23.	M/s Orient Animal Health (Pvt.) Ltd has applied for change of Brand Name of their already register	**The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the new brand names and correction of composition of the following products as per following details.**

S. No.	**Reg. No. and date**	**Name of Marketing Authorization Holder (MAH) & Manufacturer**	**Existing Brand Name and composition**	**Packing**	**New Approved Brand Name and Composition**

ed biologi cal product s	**1.**	**1110 94** (date d 17-01-2022)	M/s Genera Inc., Svetonedelj ska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**BRONHIKAL I SPF** (Lyophilisate for Suspension) Each dose contains: Attenuated live avian infectious bronchitis virus, strain H-120….. $\geq 10^{3.5}$ EID_{50} **(Ph. Eur. Specifications)**	**1's Vial** **(1000 doses)**	**Avishield IB H120** (Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bronchitis, Massachusetts serotype, strain H-120 …$10^{3.5}$- $10^{4.5}$ EID_{50} (**Ph. Eur. Specifications)**
	2.	**0886 66** (date d 24-04-2018)	M/s Genera Inc., Svetonedelj ska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**BRONHIKAL® I SPF** (Lyophilisate for Suspension) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H120…… $\geq 10^{3.5}$ EID_{50} **(Ph. Eur. Specifications)**	**10x250 0 Doses vials**	**Avishield IB H120** (Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bronchitis, Massachusetts serotype, strain H-120…….$10^{3.5}$- $10^{4.5}$ EID_{50} **(Ph. Eur. Specifications)**
	3.	**1110 93**	M/s Genera Inc.,	**BRONHOPEST B1 SPF**	**1's Vial**	**Avishield ND B1+IB H120**

	(dated 17-01-2022)	Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	(Lyophilisate for Suspension) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H-120…. ≥ $10^{3.5}$ EID_{50} Lentogenic Live virus of Newcastle disease, strain Hitchner B1.....≥ $10^{6.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**	**(1000 doses)**	(Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H-120, Massachusetts serotype, …$10^{3.5}$-$10^{4.5}$ EID_{50} Live, lentogenic virus of Newcastle disease, strain Hitchner B1…$10^{6.0}$- $10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
4.	**088661** (dated 24-04-2018)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**BRONHOPEST B1 SPF** (Lyophilisate for Suspension) Each dose of vaccines contains: Avian infectious bronchitis, strain H-120 …….≥ $10^{3.5}$ EID_{50} Newcastle disease, strain Hitchner	**10x2500 Doses vials**	**Avishield ND B1+IB H120** (Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H-120, Massachusetts serotype, …$10^{3.5}$-$10^{4.5}$ EID_{50}

			B1…….. ≥ $10^{6.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**		Live, lentogenic virus of Newcastle disease, strain Hitchner B1…$10^{6.0}$- $10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
5.	**111089** (dated 17-01-2022)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**BRONHOPEST SPF** (Lyophilisate for Suspension) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H-120… ≥ $10^{3.5}$ EID_{50} Live, lentogenic virus of Newcastle disease, strain LaSota ….≥ $10^{6.0}$ EID_{50} **(Ph. Eur. Specifications)**	**1's Vial** **(1000 doses)**	**Avishield ND+IB H120** (Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bronchitis, strain H-120, Massachusetts serotype….$10^{3.5}$- $10^{4.5}$ EID_{50} Live, lentogenic virus of Newcastle disease, strain La Sota……..$10^{6.0}$- $10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
6.	**088662** (dated 24-	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436,	**BRONHOPEST SPF** (Lyophilisate for Suspension)	**10x2500 Doses vials**	**Avishield** **ND+IB H120** (Lyophilisate for oculonasal

	04-2018)	Rakov Potok, Croatia	Each dose of vaccine contains: Live attenuated avian infectious bronchitis virus, strain H-120……. ≥ $10^{3.5}$ EID_{50} Live, lentogenic Newcastle disease virus, strain La Sota…... ≥ $10^{6.0}$ EID_{50} **(Ph. Eur. Specifications)**		Suspension/use in drinking water) Each dose of vaccine contains: Attenuated live virus of avian infectious bronchitis, strain H-120, Massachusetts serotype….$10^{3.5}$-$10^{4.5}$ EID_{50} Live, lentogenic virus of Newcastle disease, strain La Sota….$10^{6.0}$-$10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
7.	**111090** (dated 17-01-2022)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**Gumbokal IM Forte SPF** (Lyophilisate for Suspension) Each dose contains: Live Attenuated Gamboro disease virus (Infectious bursal disease), strain VMG91(intermediary type) …….≥$10^{4.0}$ $TCID_{50}$	**1's Vial** **(1000 doses)**	**Avishield IBD INT** (Lyophilisate for oculonasal Suspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bursal disease (Gamboro disease), intermediate strain VMG 91……$10^{4.0}$-$10^{5.0}$ $TCID_{50}$

			(Ph. Eur. Specifications)		**(Ph. Eur. Specifications)**
8.	**088665** (dated 24 - 04-2018)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**GUMBOKAL® IM FORTE SPF** (Lyophilisate for Suspension) Each dose contains: Attenuated live virus of Gamboro disease strain VMG 91…. $\geq 10^{4.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**	**10x2500 Doses vial**	**Avishield IBD INT** (Lyophilisate for oculonasalSuspension/use in drinking water) Each dose contains: Attenuated live virus of avian infectious bursal disease (Gamboro disease), intermediate strain VMG 91……$10^{4.0}$ - $10^{5.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
9.	**111092** (dated 17-01-2022)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**PESTIKAL B1 SPF** (Lyophilisate for Suspension) Each dose contains: Live lentogenic Newcastle disease virus, strain Hitchner B1..≥ $10^{6.0}$ EID_{50} **(Ph. Eur. Specifications)**	**1's Vial** **(1000 doses)**	**Avishield ND B1** (Lyophilisate for oculonasalSuspension/use in drinking water) Each dose contains: Live, lentogenic virus of Newcastle disease, strain Hitchner B1….$10^{6.0}$- $10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
10.	**088664**	M/s Genera Inc., Svetonedeljs	**PESTIKAL® B1 SPF**	**10x2500**	**Avishield ND B1**

	(dated 24-04-2018)	ka cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	(Lyophilisate for Suspension preparation) Each single dose vaccine contains: Lentogenic live Newcastle disease virus, strain Hitchner B1……≥ $10^{6.0}$ EID_{50} (embryo infective dose 50 =virus dose which infects 50% of inoculated chicken embryos **(Ph. Eur. Specifications)**	**Doses vial**	(Lyophilisate for oculonasalSuspension/use in drinking water) Each dose contains: Live, lentogenic virus of Newcastle disease, strain Hitchner B1….$10^{6.0}$- $10^{7.0}$ $TCID_{50}$ **(Ph. Eur. Specifications)**
11.	**111091** (dated 17-01-2022)	M/s Genera Inc., Svetonedeljska cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	**PESTIKAL LA SOTA SPF** (Lyophilisate for Suspension) Each dose contains: Live lentogenic Newcastle disease virus, La Sota strain……. ≥ $10^{6.0}$ EID_{50} **(Ph. Eur. Specifications)**	**1's Vial** **(1000 doses)**	**Avishield ND** (Lyophilisate for oculonasalSuspension/use in drinking water) Each dose contains: Live, lentogenic virus of Newcastle disease, strain La Sota……$10^{6.0}$- $10^{7.0}$$TCID_{50}$ **(Ph. Eur. Specifications)**
12.	**088663** (dated	M/s Genera Inc., Svetonedeljs	**PESTIKAL® LA SOTA SPF**	**10x2500**	**Avishield ND**

	24-04-2018)	ka cesta 2, Kalinovica, 10436, Rakov Potok, Croatia	(Lyophilisate for Suspension) Each single dose vaccine contains: Lentogenic live Newcastle disease virus, La Sota strain…… ≥ $10^{6.0}$ EID_{50} **(Ph. Eur. Specifications)**	**Doses vial**	(Lyophilisate for oculonasalSuspension/use in drinking water) Each dose contains: Live, lentogenic virus of Newcastle disease, strain La Sota……$10^{6.0}$-$10^{7.0}$$TCID_{50}$ **(Ph. Eur. Specifications)**

24. M/s Aster Life Sciences has applied for the change in manufacturing site of their already registered products

The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as under:

Approved M/s LG Chem. Ltd. 151, Osongsaengmyeong-1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea as Marketing Authorization Holder and manufacturer of Epotiv Prefilled Injection 4000IU/0.4ml (Reg. No. 087876) and Epotiv Prefilled Injection 10000IU/ml (Reg. No. 087877).

Approved the exemption from inspection abroad on the basis of PIC/s participating Authority.

Deferred the case of Epotiv Prefilled Injection 2000IU/0.5ml (Reg. No. 087875) for submission of Valid Legalized CoPP/FSC.

25. M/s Lab Diagnostic System Private Limited had applied for change of importer address

The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the new address of M/s Lab Diagnostic System Private Limited at Plot. No. 36-A, PSIC, SIE, Taxila with proprietor Mr.Muhammad Masood S/o Muhammad Dawood CNIC#37406-1570445-3 as per details mentioned in DSL for Pegaspargase (PEG-L-Asparaginase) Injection(reg. No. 105067) subject to storage facility verification.

26.	M/s Galaxy Pharma (Pvt) Ltd had applied for change of importer address	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as under: i. Deferred the case of product at S. No. 1, due to late submission of second (2nd) renewal application i.e. after 1st June 2015. ii. Referred the cases of products at S. No. 6 and 7 to PE&R, Division. iii. Approved the new address of M/s Galaxy Pharma (Pvt) Ltd at FD-35-36-A7 National Industrial Park Kyc (Korangi Creek) with proprietor Mr. Khalil ur Rehman S/o Rahim Bux CNIC#42201-7596532-5 for the above products at S. No. 2-5 & 8-12, subject to storage facility verification.
27.	M/s Novartis Pharma (Pakistan) Ltd has applied for change of importer address	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the new address of M/s Novartis Pharma (Pakistan) Limited, at C-21, S.I.T.E Manghopir Road, Karachi with proprietor Mr. Khalid Mehmood S/O Muhammad Yaqoob Shaikh CNIC#45501-1884977-5 for the above products.
28.	M/s Almed Laboratories has applied for Extension of shelf life from 24 months to 36 months of their already registered biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 36 months (2-8°C) for the above product.
29.	M/s Pfizer Pakistan (Pvt) Ltd has applied for extension of shelf life product of their already Emergency use authorized (EUA) biological product	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved the shelf life of 18 months (-90°C to -60°C) for the above product.
30.	M/s Sanofi Aventis Pakistan limited, Karachi applied for name change of Manufacturer (site address remains same) and approval of Marketing Authorization Holder	The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved M/s Opella Healthcare Italy S.r.l., Viale Luigi Bodio 37/b-20158 Milano (MI), Italy as Marketing Authorization Holder and M/s Opella Healthcare Italy S.r.l. Viale Europa 11- 21040 Origgio (VA), Italy as manufacturer of the above products.

(MAH) of their already registered biological products

31. M/s Bayer Pakistan (Pvt.) Ltd. has applied for change of specifications for their already registered biological product

The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee approved Innovator/Bayer In-House specification for the above product as per following details:

S. No.	Test Parameter	Product Specification
1.	Appearance	a. not greater than turbidity standard III
2.		b. essentially free form visible particulates
3.	Colour	not greater than reference standard BY5
4.	pH	5.9 – 6.5
5.	Identity by Western Blot (αR2)	conforms to reference standard
6.	Total Protein Content (A_{280})	36.0 – 44.0 mg/mL
7.	Potency by Cell-based Bioassay	60 – 140 % of reference IC_{50}
8.	Purity by CE-SDS	
	Non-reduced	
	% Purity	≥ 96.5 %
	Reduce	
	% Purity	≥ 91.5 %
	% LMW	≤ 8.5 %
9.	Purity by Size-exclusion UPLC	

	a. % main peak	a. aflibercept main peak ≥ 97 % total peak area
	b. % aggregate	b. ≤ 3 % aggregate
10.	Charge Variant Analysis by iCIEF	The test article profile should be qualitatively similar to the Reference Standard electropherogram in terms of intensity, number and pattern of peaks
	a. Region 1	a. 22-38 %
	b. Region 2	b. 39-50 %
	c. Region 3	c. 14-36 %
11.	Isoaspartate Content	≤ 0.30 mol isoaspartate/mol aflibercept
12.	Endotoxin Content	< 0.4 EU/mL
13.	Particulate Matter	≤ 2000 particles/mL (≥ 10 µm)
		≤ 50 particles/mL (≥ 25 µm)
14.	Sterility	meets USP, Ph. Eur. requirements
15.	Extractable Volume	≥ 0.1mL

C. Post Registration Variation cases decided in 3rd PRVC for Biologicals held on held on 30th March, 2023.

Sr. No	Applications	PRVC Decisions

32.	M/s Mustafa Brothers has applied for change of name of Marketing Authorization Holder (MAH) and Manufacturer (site remains the same) of their already registered biological products	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board approved: a. The change of Title/Name of Marketing Authorization Holder (MAH) and Manufacturer from M/s CZ Veterinaria, S.A to M/s CZ Vaccines, S.A.U for the products Dilphes Suspension for injection (Reg. No. 107956), RB-51 CZV (Reg. No. 096847) and Etadex Suspension for injection (Reg.No. 107957). b. The change of solvent from Phosphate saline buffer to water for injection for the product RB-51 CZV (Reg. No. 096847) as per CoPP**.**
33.	M/s ICI Pakistan limited has applied for change of name of Importer from ICI Pakistan Limited to Lucky Core Industries limited of their already registered biological product	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board decided to defer the case for submission of original and legalized Letter of Authorization/Sole Agency agreement duly issued by the Marketing Authorization Holder (MAH) for all the above products.
34.	M/s PharmEvo (Pvt.) Ltd. has applied for change of address of Product License Holder (name remain the same) of their already registered biological products	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board deferred the case for submission of: a. Application for change of name of Product License Holder/manufacturer with requisite fee. b. Original and legalized CoPP for the above products. c. Legalized GMP Certificate. d. Letter of Authorization/ Sole Agency agreement duly issued by the Marketing Authorization Holder (MAH).”
35.	M/s Muller and Phips Pakistan(Pvt) Ltd has applied for change of specifications for their already registered Biological product	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board rejected the case in the light of facts that manufacturer’s/In-house specifications are not stringent than the current Ph.Eur (B.P) Specifications for the product Heparin Sodium Fresenius 25000 IU/5ml (Solution for Injection) (Reg. No. 111175).
36.	M/s AJM Pharma (Pvt) Ltd has applied for extension of shelf life of their already Emergency use	The Committee evaluated the case in the light of approval of WHO for extension in shelf life and on the recommendation of the committee, the Chairman Registration Board approved the

	authorized (EUA) biological product	extension in shelf life from 6 Months (2°C-8°C) to 12 Months (2°C-8°C) for the above product as demanded by the firm.
37.	M/s GlaxoSmithKline Pakistan Limited has applied for change of specifications for their already registered Biological product	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board decided as under: i. No change in specification is warranted for the product at S. No. 1. as the current and demanded specifications of the product are same. ii. The cases for the product at S. No. 2 & 3 were deferred for submission of application in accordance with the approved SOP for change of specifications.
38.	M/s Marush Private Limited has applied for corrigendum/correction for their already registered Biological product	The Committee evaluated the case and on the recommendation of the committee, the Chairman Registration Board, deferred the case for submission of the following: a. Application for change of name of Product License Holder/manufacturer with requisite fee. b. Original and legalized CoPP for the above product. Legalized GMP Certificate/ Sole Agency agreement duly issued by the Marketing Authorization Holder (MAH). c. Legalized GMP/Sole Agency Agreement issued by Marketing Authorization Holder.

D. Post Registration Variation cases decided in 4th PRVC for Biologicals held on 12th June, 2023

Sr.	Applications	Decision of PRVC
39.	M/s BF Biosciences Limited has request to issue Corrigendum for mentioning "Source of API" of Filgen Injection in the registration letter	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to defer the case for submission of legalized CoPP / Registration letter or any other evidence, wherein the name of manufacturer of finished product i.e Bioprofarma Argentina and source of Bulk i.e M/s Gemabiotech S.A.U is mentioned for the Filgen (Filgrastim) 30MIU Injection (Reg. No. 028726).
40.	M/s. Sind Medical Stores, Karachi has applied for shelf-life extension from	On the recommendation of the Committee, the Chairman Registration Board (as per delegation of powers) after detailed deliberation &

	24 months to 30 months for their already registered WHO PQ vaccine	evaluation in the light of approval of WHO for extension in shelf life decided as under: i. Acceded to the request of the firm for the extension in shelf life from 24 Months (2°C-8°C) to 30 Months (2°C-8°C) of the product namely Measles and Rubella Vaccine, Live Attenuated (Freeze – dried Powder for Injection)- 1's Vial (10 doses) (Reg. No. 111098), keeping in view approval of WHO for extension in shelf life of said product.
41.	M/s Roche Pakistan Limited, 1st floor, 37-B, Block 6, P.E.C.H.S, 75400 Karachi has applied for the change in manufacturing site of their already registered biological products	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers), acceded to request of the firm for change of manufacturing site and Marketing Authorization Holder from M/s F. Hoffmann-La Roche AG, Wurmisweg 4303, Kaiseraugst, Switzerland to M/s Roche Pharma (Schweiz) AG Gartenstrasse 9, Ch-4052 Basel, Switzerland as Marketing Authorization Holder and M/s Roche Diagnostics GmbH Sandhofer Strasse 116, D-68305 Mannheim Germany as Manufacturer of the products namely Avastin 100 mg/4ml injection (Reg. No. 043004) and Avastin 400 mg/16ml injection (Reg. No. 043005).
42.	M/S HIPRA Pakistan have submitted the application applied for the addition of solvent part to their already registered biologicals products	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to defer the case for submission of application as per SOP for submission of composition of solvent of all the above products and submission of legalized FSC / CoPP stating composition of solvent.
43.	M/S HIPRA Pakistan have submitted the application applied for the addition of solvent part to their already registered biologicals products	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to defer the case for submission of revised application for all the applied products as per SOP indicating name of solvent with its composition to be supplied with the product(s) in combo pack.
44.	M/s. Pfizer Pakistan Limited, 12 Dockuard Road, West Wharf, Karachi has applied for change in Manufacturing site for their Solvent/NaCl Diluent only for the following already registered product	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to defer the case for submission of application by the firm for change of Marketing Authorization Holder of the solvent to be supplied with the product namely Nimenrix (Reg. No.091876).

45.	M/s Martin Dow Specialties (Pvt) Ltd. has applied for change of name of Manufacturer (Manufacturing site remains the same) **(a)** and change of address of Marketing Authorization Holder **(b)** of their already registered biological product	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) acceded to request of the firm for the product namely Crinone 8% Vaginal Gel (Reg. No. 104003) for: - 1. Change of address of Marketing Authorization Holder (MAH) from M/s Merck Serono Limited, Bedfont Cross, Stanwell Road, Feltham, Middlesex, TW14 8NX, United Kingdom to M/s Merck Serono Limited, 5 New Square Bedfont Lakes Business Park, Feltham, Middlesex, TW14 8HA, United Kingdom. 2. Change of Name of Manufacturer from M/s Fleet Laboratories Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, United Kingdom to M/s Dendron Brands Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, United Kingdom.
46.	M/s ICI Pakistan limited had applied for change of name of Importer from M/s ICI Pakistan Limited to M/s Lucky Core Industries limited of their already registered biological products. The case was placed in the 3rd PRVC meeting held on 30th March 2023	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to refer the case to legal affairs division for policy of Govt. of Pakistan for acceptance of Apostille and Notarial Certificates for consideration of the cases for their legal opinion.
47.	M/s Marush Private Limited has applied for corrigendum/correction for their already registered Biological product	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) decided to defer the case for provision of last three import invoices of the said product (preferably for the year 2022 & 2023) duly attested by I&E section DRAP, Lahore.
48.	M/s Muller and Phips Pakistan(Pvt) Ltd has applied for change of specifications for their already registered Biological product	On the recommendation of the Committee, after detailed deliberation, Chairman Registration Board (as per delegation of powers) acceded to the request of the firm for change in finished product specification from EP to BP.

E. Post Registration Variation cases decided in 5th PRVC for Biologicals held on 22nd September, 2023.

Sr.	Applications	Decision of PRVC
49.	M/s. Eli Lilly Pakistan (Pvt) Limited, Karachi has applied for the change in manufacturing site of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to refer the case to the Registration Board.
50.	M/s Bromed Animal Health has applied for change of name of Manufacturer of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided as under: Approved the change of name and updation in address of manufacturer from M/s Middle East for Veterinary Vaccines (MEVAC) Address Second Industrial Zone- Extention Part No.22,24. El Salhya El Gdeda, Elsharkya, Governorate to M/s Middle East for Vaccines (MEVAC) Address: Second Industrial Zone- Extention Part No. 21,22,24, 25. El Salhya El Gdeda, Elsharkya, Governorate for the products at Sr. No. 1 to 4. Approved the change of name of manufacturer from M/s Middle East for Veterinary Vaccines (MEVAC) Address: Second Industrial Zone-Extention Part No. 21,22,24, 25. El Salhya El Gdeda, Elsharkya, Governorate to M/s Middle East for Vaccines (MEVAC) Address: Second Industrial Zone- Extention Part No. 21,22,24, 25. El Salhya El Gdeda, Elsharkya, Governorate.
51.	M/s Getz Pharma (Pvt.) Ltd. has applied for change of manufacturing site of already registered imported biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided not to accede to the applications on following grounds: a. The CoPP submitted is not on WHO format. b. Manufacturer is not clearly mentioned in CoPP. c. No evidence is given that the product manufactured from the demanded site is Registered in any RRA or PIC/s member Authority.
52.	M/s Barrett Hodgson Pakistan (Pvt) Ltd. has applied for change of Marketing Authorization	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application for

	Holder of their already registered biological product	seeking the clarification of the existing Marketing Authorization Holder.
53.	M/s Novartis Pharma (Pakistan) Limited, Karachi has applied for the change of Manufacturing Site and Marketing Authorization Holder of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application for seeking the clarification of the following: a. Provide any evidence for the existing Manufacturer and Marketing Authorization Holder address. Marketing Authorization Holder in CoPP is different from the existing approved Marketing Authorization Holder
54.	M/s. Novartis Pharma Pakistan Limited, 15 West Wharf, Karachi, Pakistan, has applied for shelf-life extension from 15 months to 18 months	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application as the Marketing Authorization Holder in CoPP is different from the existing approved Marketing Authorization Holder.
55.	M/s Chiesi Pharmaceuticals (Pvt) Ltd has applied for Inclusion of Innovator's specifications for their already registered Biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approve the Innovator's Specifications (shelf life specs) for the product Curosurf Sterile Suspension in vials for intratracheal Instillation (Reg. No. 044899).
56.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the shelf life of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application as the approved Manufacturer is from France and the Manufacturer in CoPP is from Denmark.
57.	A. M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the inclusion of shelf life of their already registered product B. M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the	A. After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application as the approved Manufacturer is from France and the Manufacturer in CoPP is from Denmark. B. After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application as the approved Manufacturer is from France and the Manufacturer in CoPP is from Denmark.

	update in product specifications of their already registered product	
58.	M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi applied for the update in shelf life with storage conditions of their already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application as the approved Manufacturer is from France and the Manufacturer in CoPP is from Denmark.
59.	M/s Hilton Pharma (Pvt) Limited**,** has request to change the brand name of their already registration biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approve the change of brand name of the product from Taget Injection 180mcg (Reg. No. 061363) to Peghilo Injection 180mcg (Reg. No. 061363).
60.	M/s GlaxoSmithKline Pakistan Limited has applied for change of change of releasing site (importer address) for their already registered Biological products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application for the following: a. Submission of No Objection Certificate from previous proprietor. b. Submission of Legalized letter of Authorization/ Sole Agency Agreement for the new address.
61.	A. M/s. SMS Corporation has applied for change of name and address of manufacturer and marketing authorization holder for their already registered biological products. B. M/s. SMS Corporation has applied for change of Brand names of their already	A. After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approve the change of Name & Address of Marketing Authorization Holder (MAH) & Manufacturer of the products Albumin Biopharma 20%, (50mL vial) (Reg. No. 111123) and Albumin Biopharma 20%, (100mL vial) (Reg. No. 111124) from M/s BIOFARMA PLASMA Limited Liability Company 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.Secondary packaging & Batch Release:M/s BIOFARMA PLASMA Limited Liability Company to M/s LLC BIOPHARMA PLASMA *Legal Address:* 37-V, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.Address of the place of activity:*Production, primary packaging:9, M. Amosov St., Kyiv, 03680, Ukraine.Production, primary and Secondary packaging, Release of Series:37-V, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.Quality Control:37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.*9, M. Amosova St., Kyiv, 03680, Ukraine.

	registered biological products	B. After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board (as per delegation of powers) decided to approve the change of brand as per following details. a. From Albumin Biopharma 20%, (50mL vial) (Reg. No. 111123) to ALBUVEN - 20%, (50mL vial) (Reg. No. 111123). b. From Albumin Biopharma 20%, (100mL vial) (Reg. No. 111124) to ALBUVEN - 20%, (100mL vial) (Reg. No. 111124).
62.	M/s. Hospital Services & Sales has applied for change of manufacturing site for their already registered biological products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approved the change of Name & Address of Marketing Authorization Holder (MAH) & Manufacturer of the product BCG for Immunotherapy B.P SII-ONCO-BCG (Lyophilized) Powder for Intravesical Instillation (Reg. No. 053818) from M/s. SERUM INSTITUTE OF INDIA PVT. LTD., 212/2 Hadapsar, Pune 411028, Maharashtra state, INDIA to M/s. SERUM INSTITUTE OF INDIA PVT. LTD., S. No. 105-110, Manjari BK.PUNE 412307, Maharashtra State, INDIA.
63.	M/s. Hospital Services & Sales, Karachi has submitted a request for Correction in the registration letter of their following WHO PQ products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approve the correction of packing in Registration letter as tabulated below:

Sr. No.	Reg. No	Product Name	Previous Packing	New approved Packing
1.	107974	ROTASIIL single dose (Rotavirus Vaccine, Live Attenuated – Oral (Freeze-Dried) + Diluent 2.5 ml (WHO PQ product)	Two vial set (1 Dose Vaccine Vial + 1 Diluent 2.5ml Vial)	1 Dose Vial + 1 Diluent Vial (2.5 mL), 1 Adapter & Sterile Disposable Syringe.
2.	108975	ROTASIIL two dose (Rotavirus Vaccine, Live Attenuated - Oral (Freeze-Dried) + Diluent 5 ml (WHO PQ product)	Two vial set (2 Dose Vaccine Vial + 1 Diluent 5 ml Vial)	2 Dose Vial + 1 Diluent Vial (5 mL), 1 Adapter & Sterile Disposable Syringe.

64.	M/s Vety Care has applied for change of primary packing from Glass Vials to Sealed Aluminum Laminate Cups of their following already registered biological products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided not to accede to the application as all the above stated products are changed from vials to tablets.
65.	M/s HUZAIFA INTERNATIONAL has applied for Extension of shelf life of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the case for provision of registration trail for all the above mentioned products.
66.	M/s Golden Harvest has applied for change of name of Manufacturer and Marketing Authorization Holder (MAH), of their already registered biological products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to refer the case to the Registration Board.
67.	M/s Gene-tech laboratories has applied for change of name and address of Manufacturer and Product License Holder of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to refer the case to the Registration Board.
68.	M/s. Macter International Limited, has applied for change of name /Title of Bulk Manufacturer (Manufacturing site remains the same) of their already registered biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the case for submission of original CoPP, DML and Letter of Authorization.
69.	M/S HIPRA Pakistan have submitted the application	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the case for

	applied for the addition of solvent part to their already registered biologicals products	submission of legalized FSC / CoPP stating composition of solvent for all the above stated products.
70.	M/S HIPRA Pakistan have submitted the application applied for the addition of solvent part to their already registered biologicals products	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to refer the application to Registration Board.
71.	M/s BF Biosciences Limited has request to issue Corrigendum for mentioning "Source of API" of Filgen Injection in the registration letter	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the case for submission of Original Legalized GMP/Free sale certificate.
72.	M/s. Pfizer Pakistan Limited, 12 Dockuard Road, West Wharf, Karachi has applied for change in Manufacturing site for their Solvent/NaCl Diluent only for the following already registered product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to approve the change in Manufacturing site of Solvent/NaCl Diluent for the product Nimenrix (Powder & Solvent for Solution for Injection) (Reg. No. 091876) from M/s Catalent Belgium SA Font saint Landry, 10 1120 Brussels Belgium to M/s Pfizer Manufacturing Belgium NV Rijksweg 12 2870 Puurs Belgium.
73.	M/s Marush Private Limited has applied for corrigendum/correction for their already registered Biological product	After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the case for submission of full Fee of Registration.
74.	M/s ICI Pakistan limited had applied for change of name of Importer from M/s ICI Pakistan Limited to M/s Lucky Core Industries limited of their already registered biological products	The committee evaluated the case keeping in view of the opinion of the Legal Affairs Division of DRAP on policy of Govt. of Pakistan for acceptance of Apostille and Notarial Certificates and the decision of the 166th meeting of Authority, where in Authority decided that all relevant Division shall accept the Foreign Apostille Certificates issued by the member /contracting states of the convention without any requirement of attestation from ministry of Foreign Affairs OR Pakistan Mission

Abroad except Germany, Czech Republic, Poland, Australia, Austria, Finland, Netherland, Denmark and Hellenic Republic and as per reservation / declaration of the Government of Pakistan while acceding the Convention, it shall not apply to India, and/or entities not recognized by Pakistan *(like Israel).*

On the recommendation of the Committee, the Chairman Registration Board, decided as under:

a. Approved the Change of name of importer from M/s ICI Pakistan limited 5 West Wharf, Road Karachi to M/s Lucky Core Industries Limited 5 West Wharf, Road Karachi for the products at Sr. No. 2-7 and 17- 18 on the basis of Apostille and Notarial Certificate issued by the Law Firm CHORUS 15, Mugyo-ro, Jung-gu, Seol, Korea for Letter of Authorization.

b. Approved the Change of name of importer from M/s ICI Pakistan limited 5 West Wharf, Road Karachi to M/s Lucky Core Industries Limited 5 West Wharf, Road Karachi for the products at Sr. No. 8-15 and 19 on the basis of Apostille and Notarial Certificate submitted by the firm which Bears seal/stamp of Dona E. Falk, Notary Public, Dilaware USA for Letter of Authorization.

c. Approved the Change of name of importer from M/s ICI Pakistan Limited Pharma Distributor 32/1. 2A, Phase III Industrial Estate Hattar, KPK to M/s Lucky Core Industries Limited, 32/2A, Phase III Industrial Estate Hattar, KPK for the products at Sr. No. 20 on the basis of Legalized Letter of Authorization submitted by the firm.

d. Deferred the case for the product at Sr. No.1 and 16 for submission of original and legalized Letter of Authorization/Sole Agency agreement duly issued by the Marketing Authorization Holder (MAH).

F. Post Registration Variation cases decided in 8th (A) PRVC for Biologicals held on 01st July, 2024.

Sr.	Applications	Decision of PRVC
75.	M/s Ghazi Brothers**,** has applied issuance	**After detailed deliberation it was decided to defer the case for the following deficiencies/clarifications:**

	of variation certificate for finished product specification (Inclusion of specification in registration letter) and address of storage facilities	**i. Marketing Authorization Holder is not mentioned on your registration letters, submit applications for addition of Market Authorization Holder with required fee as per S.R.O as per approved PRV guidelines of DRAP.** **ii. The applicant has applied for two variations for which separate applications are required as per approved PRV guidelines of DRAP with fee as per S.R.O are required.** **iii. The applicant has not submitted the registration trails (All renewals, all approved PRVs) of their above products.** **iv. One registration number has been issued to more than one Packing of your products mentioned at Sr. No.1,3,4,5,6,8,9,11,13,14,16,17,18,19,20 and 22 as per practice only one registration number is allotted to one packing.** **v. Undertaking that no case is pending in any official forum of any of the above products.**
76.	M/s Ghazi Lifesciences, has applied issuance of variation certificate for finished product specification and address of storage facilities	**After detailed deliberation it was decided to defer the case for the following deficiencies/clarifications:** **i. Marketing Authorization Holder is not mentioned on the registration letter, applications for addition of Market Authorization Holder with required fee as per S.R.O as per approved PRV guidelines of DRAP is required to be submitted.** **ii. The applicant has applied for two variations for which separate applications are required as per approved PRV guidelines of DRAP and fee as per S.R.O are required.** **iii. The applicant has not submitted the registration trails of the above stated product.** **iv. Undertaking that no case is pending in any official forum of any of the above products.**
77.	M/s Allmed Laboratories has applied for updation of detection test for mycoplasmas for their already	**After detailed deliberation it was decided to approve the change of Test for mycoplasmas as per Ph. Eur. 2.6.7 on agarose gel-based PCR method to qualitative PCR (qPCR) technique while Detection limit will remains the same i.e ≤ 10 CFU/ml (Ph. Eur. 2.6.7 requirement).**

	registered Biological product	
78.	M/s Allmed Laboratories has applied for to make the specifications more stringent for their already registered Biological product	**After detailed deliberation it was decided to approve to make the Bacterial endotoxins test specifications more stringent from ≤ 20 IU/mL to ≤ 6 IU/mL.**
79.	M/s. Calory Pharma, has applied for shelf-life extension from 24 months to 36 months for their already registered biological drug	**In the light of the data submitted by the applicant and approval of the Regulatory Authority of the country of Origin after detailed deliberation it was decided to approve the extension of shelf-life from 24 months (≤ 25°C) to 36 months (≤ 25°C) of the products at Sr. No. 26 to 28.**
80.	M/s Lab Diagnostic Systems (SMC) Pvt Ltd has applied for ***change in name of manufacturer*** & Product license Holder of their already registered biological product	**After detailed deliberation it was decided to approve the change of name of manufacturer & Product license Holder at same premises from M/s Incepta Vaccine Ltd.,Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-Bangladesh to M/s Incepta Pharmaceuticals Ltd., Vaccine Division, Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341 Bangladesh of the product Ingovax ACWY Vaccine Inj. (Reg. No. 115100).**
81.	M/s Hipra Pakistan (Pvt) Ltd has applied for change of address of Firm/Importer for their following registered biological products	**After detailed deliberation it was decided to approve the change of address of Firm/Importer from M/s Hipra Pakistan (Pvt) Ltd Office Address:3rd Floor, Plot No. 8, Block CCA, Phase 6-C, D.H.A., Lahore. Warehouse Address:2nd warehouse on left side, street no 5, Gajjumata, Nadir Chowk, Hazara Chowk, Industrial Area, Ferozepur Road, Lahore to M/s Hipra Pakistan (Pvt) Ltd Office & Warehouse Address: House No. 86-88, J-1, Sunflower Society, M.A Johar Town, Lahore for the product HIPRAPOX Vaccine 1000 ds (Reg. No. 101731).**

82.	M/s Helix Pharma (Pvt)., Ltd, A-56, S.I.T.E, Karachi, Pakistan, has applied for shelf-life extension from 24 months to 36 months for their already registered biological drug	**After detailed deliberation it was decided to approve the extension of shelf-life from 24 months (2°C-8°C) to 36 months (2°C-8°C) of the products XIMAB Injection 100mg/10ml (10mg/ml) (Reg.No.107953) and XIMAB Injection 500mg/50ml (10mg/ml) (Reg.No.107954).**

F. Post Registration Variation cases decided in 8th (C) PRVC for Biologicals held 25th July, 2024.

Sr.	Applications	Decision of PRVC
83.	M/s. SMS Corporation, Karachi has applied for the A. Correction ***in name of manufacturer and address of manufacturing site***	**After detailed deliberation and on recommendation of Committee, the Chairman Registration Board acceded to request of the firm change in correction in name of manufacturer & MA Holder and change in address of Manufacturer and Marketing Authorization Holder (MAH) as per following details:**

Reg. No. and date	**Brand Name and Composition**	**Existing Name & Address of Manufacturer and Marketing Authorization Holder (MAH)**	**Corrected Names and address of Manufacturer and Marketing Authorization Holder (MAH)**
111087 Dated 13-01-2022	**BIOVEN MONO** Solution for Injection Each mL contains: Human Normal Immunoglobulin (≥95%IgG) …… 50mg	**M/s BIOFARMA PLASMA Limited Liability Company** 37 Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.	**M/s LLC BIOPHARMA PLASMA** ***Legal Address:*** 37-V, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine. **<u>Address of the place of activity:</u>**

		(Ph. Eur. Specifications) **Pack:** 1's Vial (50mL)	**Secondary packaging & Batch release:** M/s Biofarma Plasma Limited Liability Company, 9M. Amosova Str., Kyiv, 03680, Ukraine.	***Production, primary packaging:*** *9, M. Amosov St., Kyiv, 03680, Ukraine.* ***Secondary packaging, Release of Series:*** *37-V, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.* ***Quality Control:*** *37, Kyivska St., Bila Tserkva, Kyiv region, 09100, Ukraine.*
84.	M/s. SMS Corporation, Karachi has applied for the ***Extension of shelf life*** of their already registered biological product as per following details:	After detailed deliberation, keeping in view the CoPP issued by the country of origin and on recommendation of committee, the Chairman Registration Board acceded to request of the firm for increase in shelf life of BIOVEN MONO (Reg. No. 111087) from 2 Years (2°C-8°C) and 3 Years (2°C-8°C).		
85.	M/s. Sind Medical Stores, Karachi has applied for A. the ***correction of product name and B. storage condition*** in the registration letter of "diluent for measles and rubella	After detailed deliberation, keeping in view the CoPP issued by the country of origin and on recommendation of committee, the Chairman Registration Board decided as under: 1. Brand name of diluent shall remain same as per CoPP. 2. Approved the correction in shelf life from 05 Years (2 to 8°C) to 05 Years (To be stored at room temperature, not to be frozen).		

	vaccine" Reg. No. 111099.	
86.	M/s. Sind Medical Stores, Karachi, has applied for the ***change in address of manufacturing site*** of their already registered biological product	After detailed deliberation, keeping in view the CoPP issued by the country of origin and on recommendation of committee, the Chairman Registration Board acceded to request of the firm for change in address of Manufacturer M/s Changchun BCHT Biotechnology Co., at 138 Zhuoyue Street, High Tech Zone, Changchun – Jilin, P. R. CHINA as per current import policy of DRAP.
87.	M/s. Sind Medical Stores, Karachi, has applied for **.** Change in packaging material from **"Low Borosilicate vials"** to **"medium Borosilicate vials"**of their already registered biological product	After detailed deliberation and on recommendation of committee, the Chairman Registration Board did not acceded to request of the firm for Primary packaging material from Low Borosilicate vials to medium Borosilicate vials.
88.	**M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to M/s **Jovac Global Pak** of their already registered biological product	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product PESTEVAC Vaccine (Reg. No. 097374).
89.	**M/s Jovac Global Pak** Lahore Pakistan has applied for the	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area,

	transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product	Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Lumpy Sheild-N vaccine (Reg. No. 115107).
90.	**M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Jovac NDV Clone Vaccine (Reg. No. 039938)
91.	**M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Jovac IBD (Gumboro) Vaccine (Reg. No. 028575).
92.	M/s Hilton Pharma (Pvt) Ltd. has applied for change in brand name of their already registered biological product	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided acceded to request of the firm for change in brand name of the product: **1.** Gluwell-Base 3ml Injection (Reg. No. 079553) to Gluwell 3ml Injection (Reg. No. 079553).

		2. Gluwell-Base 10ml Injection (Reg. No. 079554) to Gluwell 10ml Injection (Reg. No. 079554).
93.	M/s. Eli Lilly Pakistan (Pvt) Limited, has applied for a change in container-closure system of their already registered biological product Humalog (Insulin lispro 100IU/ml) Solution for Injection (Reg. No. 111119)**.**	After detailed deliberation, keeping in view CoPP issued by EMA and on recommendation of committee, the Chairman Registration Board acceded to request of the firm for change in container-closure system i.e. to add off-white halobutyl stopper supplied by Datwyler Pharma packaging of Insulin Lispro Injection drug product.
94.	M/s. Eli Lilly Pakistan (Pvt) Limited, has applied for a change in container-closure system of their already registered biological product Forsteo (Teriparatide) 20mcg/80mcl Solution for Injection in pre-filled pen (Reg. No. 043009).	After detailed deliberation, keeping in view CoPP issued by EMA and on recommendation of committee, the Chairman Registration Board acceded to request of the firm for change in container-closure system i.e. to add a new disc seal component and change in immediate packaging of the finished product to change the silicon emulsion formulation used for cartridge.
95.	M/s Zam Zam corporation has applied for change in brand name of their already registered biological product	After detailed deliberation, keeping in view CoPP & letter of authorization issued by M/s Zam Zam Corporation and on recommendation of committee, the Chairman Registration Board decided to place the case before Registration Board.
96.	M/s A.J.Mirza Pharma (Pvt) Ltd., Karachi. Pakistan has applied on 26-06-2023 for the ***transfer of registration/***	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to provide personal hearing to M/s AA Pharma 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi, in 339th meeting of Registration Board.

	change of importer /Change of Importer from M/s AA Pharma to M/s A.J.Mirza Pharma (Pvt) Ltd of their already registered biological product	
97.	M/s. OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi, having valid DSL No:024, applied for the ***change Importer in Pakistan***.	After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to provide personal hearing to M/s Hakimsons (impex) (Private) Ltd., Hakimson building, 19 West Wharf Road Karachi in 339th meeting of Registration Board.

Decision: **The Board after detailed deliberation decided to endorse all the above decisions of the PRVC.**

Cases Referred by PRVC of Biologicals:

Case No.2. M/s Zam Zam corporation has applied for change in brand name of their already registered biological product as per following details:

Sr.	Reg. No.	Brand Name	Manufacturer	Demanded/suggested Brand Name
98.	000854 dated 14 April 1984 Transfer dated 14th June 1994	Heparin Injection (5000IU) (5ml) Each ml contains: Heparin Sodium …5000IU	M/s Leo Pharmaceutical Products, Denmark	Heparin Mucous

The case has been evaluated as per approved SOPs in the PRV Guidelines and tabulated below:

Documents required as per SOP	Documents submitted by the firm	Remarks
Application with Required fee as per relevant SRO.	Application on company letterhead and Fee Rs 30,000/- for the product is submitted	
Copy of registration letter and last renewal status.	Copy of Registration Letters dated 14 April 1984 and transfer dated 14th June 1994 has been submitted all renewals are submitted.	

Information approvals of change of brand name since registration of drug product.	Not submitted
Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured / imported.	Last invoice is submitted
An undertaking that the proposed names do not resemble with already registered brands and in case of resemblance /similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter. Line extension	Submitted
Legalized CoPP where applicable in case of imported drug products.	Apostilled CoPP is Submitted on Eapp.
For establishing brand name resemblance with any other registered drug product, a unit carton/ any other information as evidence of resemblance shall be provided.	Submitted

Registration Board in its 307th meeting delegated its power/functions for Change Brand Name of already registered products to the Chairman Registration Board.

Detail of case: M/s Leo Pharma was sent an email on 24.07.2024 to verify Letter of Authorization issued in favor of M/s Zam Zam Corporation, Karachi. M/s Leo Pharma through email on 25.07.2024 confirm the LOA as Annexure-A.

Decision of 8th (C) PRVC: ***After detailed deliberation, keeping in view CoPP & letter of authorization issued by M/s Zam Zam Corporation and on recommendation of committee, the Chairman Registration Board decided to place the case before Registration Board.***

Decision: The Board after detailed deliberation decided to approve the change of brand name from Heparin Injection (Reg. No. 000854) to Heparin Mucous (Reg. No. 000854) manufactured by M/s Leo Pharmaceutical Products, Denmark.

Case No.3. M/s A.J.Mirza Pharma (Pvt) Ltd., Karachi. Pakistan has applied on 26-06-2023 for the ***transfer of registration/ change of importer /Change of Importer*** from M/s AA Pharma to M/s A.J.Mirza Pharma (Pvt) Ltd of their already registered biological product as per following details:

Sr. No.	Reg. No. and date	Brand Name and Composition	Existing MA Holder/ Importer	Demanded/ New MA Holder/ Importer
99.	092407 Dated 28.11.2018 Renewal 10-07-2023	**EPIAO 10000IU/mL PFS** Each PFS (1ml) contains: Human erythropoeitin (CHO Cell) …..10000IU (BP specification)	M/s AA Pharma **Address:** 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan	M/s A.J.Mirza Pharma (Pvt) Ltd **Address:** 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan
100.	092405 Dated 12.10.2018 Renewal 10-07-2023	**EPIAO 2000IU/mL PFS** Each PFS (1ml) contains: Human erythropoeitin (CHO Cell) …..2000IU (BP specification)		
101.	092406 Dated 12.10.2018 Renewal 10-07-2023	**EPIAO 4000IU/mL PFS** Each PFS (1ml) contains: Human erythropoeitin (CHO Cell) …..4000IU (BP specification)		

The case has been evaluated as per approved Guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. 150,000/- Online Slip Number: 0087691366 dated 22.06.2023 has been submitted for **EPIAO 10000IU/mL PFS** Online Slip Number: 3341854835 dated 22.06.2023 has been submitted for **EPIAO 2000IU/mL PFS** Online Slip Number: 39521234 dated 22.06.2023 has been submitted for **EPIAO 4000IU/mL PFS**	
Copy of registration letter and last renewal status	Copy of Registration letter, dated 28.11.2018 & Renewal dated 10-07-2023 for the product at Sr. No. 1 is submitted.Copy of Letters, Dated 12.10.2018Renewal	

	10-07-2023 for the products at Sr. No. 2 & 3 is Submitted
Termination letter (original) from marketing authorization holder/ manufacturer for previous importer.	Submitted
Legalised Authority letter/sole agent letter (original) from marketing authorization holder/ manufacturer in name of new importer.	Original LOA is submitted Firm has Submitted Original Letter of Authorization. M/s Shenyang Sunshine Pharmaceutical Co. Ltd., No.3 A1, Road 10, Economy and Technology Development Zone, Shenyang 110027, P.R. China, authorizes M/s A.J.Mirza Pharma (Pvt) Ltd. to register, Import & Distribute EPIAO 2000IU/ml, 4000IU/ml & 10000IU/ml PFS.
No Objection Certficate (issued within last 6 Months) from existing registration holder in name of applicant for registration of drug product.	Original NOC is submitted.
Revised drafts of the package insert and labeling incorporating the proposed variation.	Submitted
Legalized Certificate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Legalized GMP with copies of CoPP for All the stated products.

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer (A.J. Mirza Pharma (Pvt) Ltd.) and manufacturer/ manufacturing site abroad remains unchanged which is already registered in the Chairman Registration Board.

Decision of 7th PRV: After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board deferred the case and advised to issue show cause notice under section 42 of the Drugs Act, 1976 to M/s AA Pharma 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan, as the Market Authorization Holder has terminated their Sole Agency Agreement for the products mentioned at Sr. No.1 & 3 and give them personal Hearing for transfer of their above mentioned products to M/s A.J. Mirza Pharma (Pvt) Ltd Address:1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan in the light of their NOC for the transfer.

Decision *of 8th(C) PRVC*: After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to provide personal hearing to M/s AA Pharma 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi, in 339th meeting of Registration Board.

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm M/s AA Pharma appeared through their representative Ali Abbas Innayatullah (Director of M/s AA Pharma) S/o M. Hussain Innayatullah CNIC# 42201-6534290-3, who stated that both of the companies are the same i.e sister concerns and they have no objection on transfer of their products EPIAO 10000IU/mL PFS (Reg. No. 092407), EPIAO 2000IU/mL PFS (Reg. No. 092405) and EPIAO 4000IU/mL PFS (Reg. No. 092406) to M/s A.J.Mirza Pharma (Pvt) Ltd.

Decision: The Board after detailed deliberation decided to approve the change of market authorization holder Pakistan for the products EPIAO 10000IU/mL PFS (Reg. No. 092407), EPIAO 2000IU/mL PFS (Reg. No. 092405) and EPIAO 4000IU/mL PFS (Reg. No. 092406) from M/s AA Pharma to M/s A.J. Mirza Pharma (Pvt) Ltd.

Case No.4. M/s. OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi, having valid DSL No:024, applied for the ***change Importer in Pakistan***. Details are provided below.

Sr. No.	Reg. No. and date	Brand Name and Composition	Existing Name of Manufacturer and Marketing Authorization Holder (MAH):	Demanded Name of Manufacturer and Marketing Authorization Holder (MAH):
102.	111142 dated 27-June-2022	**HuCoG-5000 HP (Combo Pack)** (Chorionic Gonadotrophin Injection B.P) (freeze Dried) Each vial contains: Chorionic Gonadotrophin BP…..5000 IU **Solvent:** One ml of sodium chloride injection B.P	**MA holder in Pakistan** M/s Hakimsons (impex) (Private) Ltd., Hakimson building, 19 West Wharf Road Karachi. **Name of MA Holder & Manufacturer**: Bharat Serums and Vaccines Limited Plot No K-27, Jambivili Village, Anand Nagar, Additional MIDC, Ambernath (East) Thane-421506, Maharashtra state, India.	**MA holder in Pakistan** M/s OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi **Name of MA Holder & Manufacturer**: Bharat Serums and Vaccines Limited K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East)Thane-421506, Maharashtra, India.
103.	**111143** dated 27-June-2022	**BSV Humog 75 HP** Menotrophin for injection B.P (freeze Dried) Each vial contains: Menotrophin B.P. equivalent to activity of Follicle Stimulating Hormone ,75 I.U. Luteinizing Hormone ..... 75 I.U. **Solvent:** One ml of sodium chloride injection B.P		

The case has been evaluated as per approved Guidelines: Post Registration Variation Guidelines and tabulated below:

Requirements as SOP	**Documents submitted by the firm**	**Remarks**
Application with required fee as per relevant SRO.	Application on company letter head and fee of Rs. 150,000/- for change of name & address of MA holder in Pakistan has been submitted.	
Copy of registration letter and last renewal status.	Copy of Registration Letter for Sr. No. 1 (HuCoG-5000 HP (Combo Pack) dated 27-June-2022 has been submitted. Copy of Registration Letter for Sr. No. 2 (BSV Humog 75 HP) dated 27-June-2022 has been submitted.	
Termination letter (original) from marketing authorization holder/ manufacturer for previous importer.	submitted	
Legalised Authority letter/sole agent letter (original) from marketing authorization holder/ manufacturer in name of new importer.	Submitted	
No Objection Certficate (issued within last 6 Months) from existing registration holder in name of applicant for registration of drug product.	Submitted	
Revised drafts of the package insert and labeling incorporating the proposed variation.	Submitted	
Legalized Certficate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Submitted	

Registration Board in its 3th meeting delegated its power/functions for Change of importer of already registered products to the Chairman Registration Board.

Decision of 7th PRV: *After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board deferred the case for personal hearing to M/s Hakimsons (impex) (Private) Ltd., Hakimson building, 19 West Wharf Road Karachi, under section 42 of the Drugs Act, 1976. As the Market Authorization Holder has terminated their Sole Agency Agreement for the products mentioned at Sr. No.49 & 50 for transfer of their above mentioned products to M/s OBS AGP (Private) Limited, B-23-C, 2nd Floor S.I.T.E., Karachi.*

Decision of 8th *(C)* PRVC: After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to provide personal

hearing to M/s Hakimsons (impex) (Private) Ltd., Hakimson building, 19 West Wharf Road Karachi in 339th meeting of Registration Board.

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm M/s Hakimsons (impex) (Private) Ltd., appeared through their representative Mr. Humayun Malik S/o Muhammad Saleem Awan holding CNIC # 37405-6483158-1, who submitted the authority letter on company letter Head and stated that they have no objection on transfer of their products HuCoG-5000 HP (Reg. No. 111142) and BSV Humog 75 HP (Reg. No. 111143) to M/s OBS AGP (Private) Limited.

Decision: The Board after deliberation decided to approve the change of market authorization holder Pakistan for the products HuCoG-5000 HP (Reg. No. 111142) and BSV Humog 75 HP (Reg. No. 111143) from M/s Hakimsons (impex) (Private) Ltd., to M/s OBS AGP (Private) Limited.

Case No.5. **M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to M/s **Jovac Global Pak** of their already registered biological product as per following details

Sr. No.	Reg. No. and Date	Brand Name and composition	Manufacturer and PLH	Existing MA Holder/ Importer	Demanded/ New MA Holder/Importer
104.	097374 23-09-2019 **Addition of Diluent part** Dated 04-07-2022	**PESTEVAC Vaccine** (live attenuated freeze-dried pellet for injection) (100 doses vial) Each Dose of vaccine contains at least $10^{2.5}$ $TCID_{50,}$/dose of live attenuated PPR Virus strain Nig.75/1. Diluent of **PESTEVAC Vaccine** Each ml Contains Sodium Chloride….137 M Potassium Chloride…2.7 M	M/s Jovac "Jordan Bio Industries Center" Yajouz, near the Agriculture Nursery, Amman-Jordan.	**M/s EROS Pharmaceuticals** (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi.	**M/s Jovac Global Pak**, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore.

Potassium Dihydrogen Phosphate…1.5 M
Sodium Dihydrogen Phosphate…6.5 M
Water for injection…. qs to 1 ml

The case has been evaluated as per approved guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. **150,000/-** Online slip Number: **73391281** Dated: **13-11-2023** has been submitted for PESTEVAC Vaccine 100 doses Vial.	
Copy of registration letter and last renewal status	Copy of Registration letter, dated **23-09-2019 and Addition of Diluent Part** Dated 04-07-2022 is submitted.	
Termination letter (original) from marketing authorization holder/manufacturer for previous importer.	Submitted.	
Legalized Authority letter/ Sole Agent letter(original) from marketing authorization holder/manufacturer in name of new importer	Original LOA is submitted.	
No Objection Certificate (issued within last 6 months) from existing registration holder in name of applicant for registration of drug product.	Original NOC dated 22-August 2023 is submitted	
Revised drafts of package insert and labeling incorporating the proposed variation.	Submitted	
Legalized Certificate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Legalized CoPP and Free Sales Certificate (Country of origin) Submitted.	

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer (manufacturer/

manufacturing site abroad remains unchanged) to the Chairman Registration Board.

Decision *of 8th (C) PRVC:* ***After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product PESTEVAC Vaccine (Reg. No. 097374).***

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm **M/s EROS Pharmaceuticals** appeared through their representative Mr. Zia Khalid S/o Mr. Khalid Akhtar (Director of **M/s EROS Pharmaceuticals**) who stated that they have no objection on transfer of their product **PESTEVAC Vaccine (Reg. No. 097374) to M/s Jovac Global Pak**,

Decision: The Board after deliberation decided to approve the change of market authorization holder Pakistan for the product PESTEVAC Vaccine (Reg. No. 097374) from M/s EROS Pharmaceuticals to M/s Jovac Global Pak.

Case No.6. **M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product as per following details

Sr. No.	Reg. No. and Date	Brand Name and composition	Manufacturer and PLH	Existing MA Holder/ Importer	Demanded/ New MA Holder/Importer
105.	115107 dated 20th March 2023	**Lumpy Sheild-N vaccine** (Live attenuated freeze-dried pellets of lumpy Skin disease virus) (**25 Doses Vial.**) **Freeze-Dried pellet**; Each dose contains live attenuated Lumpy Skin Disease Virus (Neethling strain) ….at least $10^{4.0}$ $TCID_{50}$ **Solvent** Each ml Contains	M/s Jovac "Jordan Bio Industries Center" Yajouz, near the Agriculture Nursery, Amman-Jordan.	**M/s EROS Pharmaceuticals** (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi .	**M/s Jovac Global Pak**, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore.

Sodium Chloride….8.5 mg
Water for injection…. qs to 1 ml

The case has been evaluated as per approved guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. **150,000/-** Online slip Number: **9697861429** Dated: **13-11-2023** has been submitted for Lumpy Sheild-N vaccine	
Copy of registration letter and last renewal status	Copy of Registration letter, dated **16-03-2022** is submitted.	
Termination letter (original) from marketing authorization holder/manufacturer for previous importer.	Submitted.	
Legalized Authority letter/ Sole Agent letter(original) from marketing authorization holder/manufacturer in name of new importer	Original LOA is submitted.	
No Objection Certificate (issued within last 6 months) from existing registration holder in name of applicant for registration of drug product.	Original NOC dated 22-August 2023 is submitted	
Revised drafts of package insert and labeling incorporating the proposed variation.	Submitted	
Legalized Certificate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Legalized GMP, CoPP and Free Sales Certificate (Country of origin) Submitted.	

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer (manufacturer/ manufacturing site abroad remains unchanged) to the Chairman Registration Board.

Decision *of 8th (C) PRVC:* ***After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Lumpy Sheild-N vaccine (Reg. No. 115107).***

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm **M/s EROS Pharmaceuticals** appeared through their representative Mr. Zia Khalid S/o Mr. Khalid Akhtar (Director of **M/s EROS Pharmaceuticals**) who stated that they have no objection on transfer of their product **Lumpy Sheild-N vaccine (Reg. No. 115107) to M/s Jovac Global Pak**,

Decision: The Board after deliberation decided to approve the change of market authorization holder Pakistan for the product Lumpy Sheild-N vaccine (Reg. No. 115107) from M/s EROS Pharmaceuticals to M/s Jovac Global Pak,.

Case No.7. **M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product as per following details

Sr. No.	**Reg.** No. And Date	**Brand Name and composition**	**Manufacturer and PLH**	**Existing MA Holder/ Importer**	**Demanded/ New MA Holder/Importer**
106.	039938 15-06-2005	**Jovac NDV Clone Vaccine 25**00 doses vial Each Dose of vaccine contains: SPF Freeze dried live Newcastle disease virus clone strain not less than 10^6 $EID_{50,}$	M/s Jovac "Jordan Bio Industries Center" Yajouz, near the Agriculture Nursery, Amman-Jordan.	**M/s EROS Pharmaceuticals** (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi .	**M/s Jovac Global Pak**, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore.

The case has been evaluated as per approved guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. **150,000/-** Online slip Number: **703458518556** Dated: **13-11-2023** has been submitted for Jovac NDV Clone Vaccine	
Copy of registration letter and last renewal status	Copy of Registration letter, dated: 15-06-2005 Copy of Last Renewal Date:18-05-2020 is submitted.	
Termination letter (original) from marketing authorization holder/manufacturer for previous importer.	Submitted.	
Legalized Authority letter/ Sole Agent letter(original) from marketing authorization holder/manufacturer in name of new importer	Original LOA is submitted.	
No Objection Certificate (issued within last 6 months) from existing registration holder in name of applicant for registration of drug product.	Original NOC is submitted	
Revised drafts of package insert and labeling incorporating the proposed variation.	Submitted	
Legalized Certificate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Legalized CoPP and Free Sales Certificate (Country of origin) Submitted.	

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer (manufacturer/ manufacturing site abroad remains unchanged) to the Chairman Registration Board.

Decision *of 8th (C) PRVC:* ***After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under***

Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Jovac NDV Clone Vaccine (Reg. No. 039938)

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm **M/s EROS Pharmaceuticals** appeared through their representative Mr. Zia Khalid S/o Mr. Khalid Akhtar (Director of **M/s EROS Pharmaceuticals**) who stated that they have no objection on transfer of their product **Jovac NDV Clone Vaccine (Reg. No. 039938) to M/s Jovac Global Pak**,

Decision: The Board after deliberation decided to approve the change of market authorization holder Pakistan for the product Jovac NDV Clone Vaccine (Reg. No. 039938) from M/s EROS Pharmaceuticals to M/s Jovac Global Pak,

Case No.8. **M/s Jovac Global Pak** Lahore Pakistan has applied for the transfer of registration / change of importer from M/s **EROS Pharmaceuticals (Pvt) Ltd** to **Jovac Global Pak** of their already registered biological product as per following details:

Sr. No.	Reg. No. and Date	Brand Name and composition	Manufacturer and PLH	Existing MA Holder/ Importer	Demanded/ New MA Holder/Importer
107.	028575 13-08-2002	**Jovac IBD (Gumboro) Vaccine** Each Dose of vaccine contains: Freeze dried Infectious Bursal disease virus D-78 strain not less than 10^3 $TCID_{50}$.	M/s Jovac "Jordan Bio Industries Center" Yajouz, near the Agriculture Nursery, Amman-Jordan.	**M/s EROS Pharmaceuticals** (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi .	**M/s Jovac Global Pak**, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore.

The case has been evaluated as per approved guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. **150,000/-**	

	Online slip Number: **90798599** Dated: **13-11-2023** has been submitted for Jovac IBD (Gumboro) Vaccine 2500 doses vial.
Copy of registration letter and last renewal status	Copy of Registration letter 13-08-2002 Copy of last Renewal Date:18-05-2020 is submitted.
Termination letter (original) from marketing authorization holder/manufacturer for previous importer.	Submitted.
Legalized Authority letter/ Sole Agent letter(original) from marketing authorization holder/manufacturer in name of new importer	Original LOA is submitted.
No Objection Certificate (issued within last 6 months) from existing registration holder in name of applicant for registration of drug product.	Original NOC is submitted
Revised drafts of package insert and labeling incorporating the proposed variation.	Submitted
Legalized Certificate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Legalized GMP, CoPP and Free Sales Certificate (Country of origin) Submitted.

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer (manufacturer/ manufacturing site abroad remains unchanged) to the Chairman Registration Board.

Decision of 8th (C) PRVC: ***After detailed deliberation and on recommendation of committee, the Chairman Registration Board decided to issue show cause notice to M/s EROS Pharmaceuticals (Pvt) Ltd 94 Sector 23, Korangi Industrial area, Karachi under Section 42 of the Drugs Act, 1976 and provide them personal Hearing in 339 th meeting of Registration Board Meeting for transfer of their above mentioned products to M/s Jovac Global Pak, 4th floor, Plaza no 17, Block D, EME, DHA Phase 12, Lahore Pakistan Godown address: 1C, Shadman Chowk, Jail Road, Lahore. in the light of their NOC for the transfer, as the Market Authorization Holder has terminated their Sole Agency Agreement for the product Jovac IBD (Gumboro) Vaccine (Reg. No. 028575).***

Letter for Personnel hearing has been issued to the firm.

Proceeding in the Meeting:

The firm M/s EROS Pharmaceuticals appeared through their representative Mr. Zia Khalid S/o Mr. Khalid Akhtar (Director of M/s EROS Pharmaceuticals) who stated that they have no objection on transfer of their product Jovac IBD (Gumboro) Vaccine (Reg. No. 028575) to M/s Jovac Global Pak,

Decision: The Board after deliberation decided to approve the change of market authorization holder Pakistan for the product Jovac IBD (Gumboro) Vaccine (Reg. No. 028575) from M/s EROS Pharmaceuticals to M/s Jovac Global Pak,

Case No.9. <u>ADDITION OF MANUFACTURING SITE</u>

M/s Novo Nordisk Pharma (Pvt.) Limited, Karachi has applied for the addition of a manufacturing site for their already registered biological products as per the following details:

Sr. No.	**Reg. No. and date**	**Brand Name and Composition**	Existing Manufacturing Site and Marketing Authorization Holder	**Demanded Additional Manufacturing Site**
108.	010348 Dated 11-11-2005	**Mixtard® 30 HM 100 IU/ml, 10 ml Vial** Suspension for injection in 10ml Vial. Each ml contains; Insulin Regular (Human) 100 IU, Insulin Human (rDNA) Ph.Eur (30% as soluble insulin and 70% as isophane insulin)	M/s Novo Nordisk Production SAS, 45 Avenue d' Orleans, F-28000 Chartres, France.	Eskayef Pharmaceuticals Limited, 400 Squibb Road, Tongi Industrial Area, Tongi, Ghazipur 1711, Bangladesh.

Documents required as per SOP	**Documents submitted by the firm**	**Remarks**
Application on Form-5F	Submitted	
Required fee as per relevant SRO.	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 4906016017	
Copy of registration letter and last renewal status	Registration letter: dated 11-11-2005 Renewal application 13-05-2010 Renewal application 16-04-2015	

	Site change approval 06-03-2016 Copy of last renewal submission dated 04-05-2020
Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	The firm has submitted legalized copy of CoPP (No. DA/6-39/05/2409) dated 19-01-2023 issued by the Directorate General of Drug Administration Mohakhali, Dhaka-1212. The CoPP specifies free sale status of the product in the exporting country. The CoPP also confirms the GMP status of the firm.
Site master file of new manufacturing site in case of change of manufacturing site/ source	Submitted
Revised Sole Agency Agreement when there is change in MAH	Submitted
Undertaking that provided information/ documents are true & correct.	Submitted

Form 5F Assessment report is as follows:

FORM 5-F ASSESSMENT REPORT

Mixtard® 30 HM 100 IU/ml, 10 ml Vial

Documents required as per SOP	**Documents submitted by the firm**	**Remarks**
Name, address of Applicant / Marketing Authorization Holder	M/s Novo Nordisk Pharma (Private) Limited, 113, Shahrah-e-Iran, Clifton, Karachi-75600 Pakistan	
Details of Drug Sale License of Importer	Novo Nordisk Pharma (Pvt.) Limited **Address:** 113, Shahrah-e-Iran, Clifton, Karachi, Pakistan. **Address of go-down:** 208/1, Sector 23, KIA, Karachi	

	Validity: 08-04-2028 Status: License to sell drugs by way of Wholesale.	
Name and address of marketing authorization holder/ Product License Holder (abroad)	M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.	
Name, address of manufacturer(s)	Eskayef Pharmaceuticals Limited 400 Squibb Road, Tongi Industrial Area, Tongi, Gazipur 1711, Bangladesh	
Name of exporting country	Bangladesh	
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** • Firm has submitted legalized copy of CoPP (No. DA/6-39/05/2409) dated 19-01-2023 issued by Directorate General of Drug Administration Mohakhali, Dhaka-1212. The CoPP specifies free sale status of the product in the exporting country. The CoPP also confirms the GMP status of the firm.	
Details of letter of authorization / sole agency agreement	Firm has submitted attested and legalized letter of product specific authorization from Senior Vice President (Submissions and Life Cycle Management) of Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute and sale the registered product Mixtard® 30 HM Vial 100IU/ml 10 ml Vial. The letter was issued on 07-February-2023.	
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)	
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐Domestic and Export sales	

For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only	
Dy. No. and date of submission	Dy. No. 1706 dated 11 Dec 2023	
Details of fee submitted	PKR 150,000/-: dated 03/02/2023 Deposit Slip No. 4906016017	
The proposed proprietary name / brand name	**Mixtard® 30 HM 100 IU/ml, 10 ml Vial** Suspension for injection	
Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Active ingredient(s)** Insulin Human (rDNA) Ph.Eur. (30% as soluble insulin and 70% as isophane insulin) **Human insulin is produced in Saccharomyces cerevisiae by recombinant DNA technology*	
Dosage form of applied drug	Solution for injection	
Pharmacotherapeutic Group of (API)	Drugs used in diabetes. Insulins and analogues for injection, Intermediate or long acting combined with fast-acting, insulin (human). ATC code: A10AD01.	
Reference to Finished product specifications	Ph. Eur Specs	
Proposed Pack size	Each Pack contains: 1 x 10ml Vial	
Proposed unit price	MRP already available Mixtard 30 HM Vial Reg.No.010348	
Shelf Life	30 Months	
Storage Conditions	Store in refrigerator (2°C – 8°C).	
The status in reference regulatory authorities	Novo Nordisk A/S holds registration in Reference Regulatory Authorities. Eg: EMA & FDA Novo Nordisk A/S, Denmark. According to the letter, the firm Novo Nordisk A/S, Denmark has a contract manufacturing site in Bangladesh in name of Eskayef Pharmaceuticals. Further, Novo Nordisk A/S has provided sole authorization to Novo Nordisk Pharma (Private) Limited" to import, Distribute and sale the registered product Insulatard®. The letter was issued on 07-February-2023	

<table>
<tr><td>For generic drugs (me-too status)</td><td colspan="2">Not Applicable</td><td></td></tr>
<tr><td>Module-II (Quality Overall Summary)</td><td colspan="2">Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, manufacturer, description of manufacturing process and process controls, control of materials, control of critical steps and intermediates, process validation and/or evaluation, manufacturing process development, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material ,container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries</td><td></td></tr>
<tr><td rowspan="3">Name, address of drug substance manufacturer</td><td>Address</td><td>Activity</td><td rowspan="3"></td></tr>
<tr><td>M/s Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark</td><td>Production of Master cell bank and working cell bank.
Storage of Master Cell Bank and Working Cell Bank.</td></tr>
<tr><td>M/s Novo Nordisk A/S, Hallas Allé, 4400 Kalundborg, Denmark.</td><td>Storage and stability testing of Master Cell Bank and Working Cell Bank.
Recovery from fermentation broth.
Purification of insulin human
Quality control of in-process samples and drug substance.</td></tr>
<tr><td>Module-III Drug Substance:</td><td colspan="2">Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical state, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard or material, container closure system and stability studies of drug substance.</td><td></td></tr>
</table>

Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at long term and accelerated time conditions. The long term stability data is conducted at -18°C±2°C for 60 months with 3 batches as per claim shelf life of 60 months. The accelerated study conducted at +5 °C±3°C for 12 months.	
Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, no change statement concerning to Mixtard® 30 100IU/ml,10 ml, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.	
Analytical method validation/verification of product	The firm has submitted analytical methods as per specifications/Ph. Eur. The methods are validated as per SOPs. The Analytical methods are listed below • Macroscopy (Ph. Eur.) • Microscopy (Ph. Eur.) • Identity of Human insulin (Ph. Eur.) • Assay of insulin (Ph. Eur.) • pH (Ph. Eur. / USP / JP) • Insulin in the supernatant (Ph. Eur.) • High molecular weight proteins (Ph. Eur. / USP) • A21 Desamido insulin (Ph. Eur.) • Other related impurities (Ph. Eur.) • Zinc total (Ph. Eur. / USP / JP) • Bacterial endotoxins (Ph. Eur. Method D) • Sterility (Ph. Eur. / USP / JP) • Total dissolved insulin (A2619a)	

	• Isophane confirmation (A2361a) • Identity of preservatives (A2461a) • Phenol (A2461a) • Metacresol (A2461a) • Particulate matter (Ph. Eur. / USP / JP)	
Container closure system of the drug product	The container closure system consists of following: 1. The closure system, consisting of a rubber closure with a cap. 2. The rubber plunger The vial is made of colorless glass with a hydrolytic resistance as defined in Ph Eur and USP (type I glass). The plunger is made of bromobutyl rubber.	
Stability study data of drug product, shelf life and storage conditions	Firm has submitted comparability report for 3 PPQ batches of stability manufactured at site Chartres and at Contract Manufacturing Site Eskayef stored for 30 months at long term conditions at 5°C±3°C.	
Module 4 & Module 5 (Non-Clinical & Clinical Documentation)	No change Statement concerning to Module 4 and Module 5.	

Decision: Approved subject to the opinion of Secretary Appellate Board regarding the applicability of decision of the Appellate Board about the addition of the manufacturing facility.

CASES OF DD-II (DR.H.M. JAWAD ALI)

BIOLOGICAL CASES DISCUSSED IN 3RD MEETING OF SUB-COMMITTEE ON VETERINARY DRUGS.

The following cases has been discussed in Registration Board and decided to refer the case for the expert opinion of expert working group (EWG) on veterinary drugs. The previous decision for each case has been placed below: -

Sr. No.	Importer & Manufacturer's Name	Composition	Dy. No. Date of Application; Fee Status Pack Size
109.	M/s. BroMed Animal Health,	**MEVAC ND+IB+EDS** Each dose (0.5ml) contains:	Dy. No. 31877: Dated

246-A, West Wood Colony, Lahore. **Manufacturer's Name** M/s. Middle East for Veterinary Vaccines (MEVAC), Second Industrial Zone-Extension part No. 21, 22, 24, 25 El Salhya El Gadeda, Elsharkya Governate, Egypt.	1- Inactivated NDV LaSota strain "NDV/Chicken/Egypt/11478AF/11" $\geq 10^{8.5}$ EID_{50}/dose before inactivation 2- Inactivated infectious bronchitis virus "IBV classical (IBV-EG/M41-ME01/2011)" $\geq 10^{7}$ EID_{50}/dose before inactivation (BI) 3- Inactivated infectious bronchitis virus "IB Variant type 1 (ME/IBV-VAR1/2017)" $\geq 10^{7}$ EID_{50}/dose before inactivation (BI) 4- Inactivated infectious bronchitis virus "IB Variant type 2 (EG/1212B)" $\geq 10^{7}$ EID_{50}/dose before inactivation (BI) 5-Inactivated Egg Drop Syndrome 76 Virus avian "ADV-1 N/ME/EDS-76/ L/2016" $\geq 10^{9}$ EID_{50}/dose before inactivation	19-11-2021. Rs.100,000/- Dated 18-11-2021

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee: After deliberation, the Sub-committee on Veterinary Drugs decided that Multicomponent composition is relevant and vaccine is required to control related poultry diseases found in Pakistan.

Product is Recommended.

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

110. M/s. Saadat International
Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore

Valid till: 12-Jun-2022

Marketing Authorization Holder:
M/s. Boehringer Ingelheim Vetmedica GmbH, Binger Strabe 173, 55216 Ingelheim am Rhein, Germany.

Manufacturer of Drug:
M/s Boehringer Ingelheim Animal Health USA Inc. 2621 North Belt hwy, Saint Joseph, MO 64506-USA.

Lyophilizate for suspension for chicken

Each dose (2ml) of lyophilizate vaccine contains:
Modified live BVDV*-1 non cytopathic parent strain KE-9….≥ $10^{4.0}$ $TCID_{50}$ **
Modified live BVDV*-2 non cytopathic parent strain NY-93….≥ $10^{4.0}$ $TCID_{50}$ **
*Bovine viral diarrhea virus
**Tissue culture infective dose 50%

Diluent part:
Each one dose of 2ml contains:

Sodium chloride ……16mg

Potassium Chloride……0.4mg

Potassium dihydrogen phosphate……...2.3mg

Disodium hydrogen phosphate…….. 2.3mg

Water for Injection q.s. ……. 2ml

Dy. No. 1315 R&I Dated 14-01-2022

Rs. 150,000/- (Slip No. 14457036611)

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that BVD is a long-neglected animal disease in Pakistan; now being increasingly found; some of good scientific work on BVD in Pakistan stay at NVL and COMSATS, Islamabad. **Product is relevant and required and is therefore Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

111. M/s. Saadat International

Gallivac IBD S706 NEO (2000 doses)

Each dose of vaccine contains:

Dy. No. 20796 R&I Dated 30-07-2021

Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore	Live attenuated avian infectious bursal disease virus, strain S706…..≥ $4\log_{10}$ $CCID_{50}$ -5.3log10 $CCID_{50}$.	Rs. 75000/- (Slip No. 0430941720)
Valid till: 12-Jun-2022	Dosage Form: Effervescent tablet	

Marketing Authorization Holder:
M/s. Boehringer Ingelheim Vetmedica GmbH

Binger Strabe 173, 55216 Ingelheim am Rhein, Germany.

Manufacturer of Drug:
M/s Boehringer Ingelheim Animal Health

Rue De L aviation, 69800 ST PRIEST-France

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that Infectious Bursal Disease is a major challenge for broiler sector in Pakistan; IBD S706 will be a good addition to the repertoire of control for this disease in poultry sector. **Product is Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

112.

-do-	**Gallivac IBD S706 NEO (5000 doses)** Each dose of vaccine contains: Live attenuated avian infectious bursal disease virus, strain S706≥ $4\log_{10}$ $CCID_{50}$ -5.3log10 $CCID_{50.}$ Dosage Form: Effervescent tablet	Dy. No. 31673R&I Dated 17-11-2021 Rs. 75,000/- (Slip No. 2322179827)

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that Infectious Bursal Disease is a major challenge for broiler sector in Pakistan; IBD S706 will be useful for control of this disease in the poultry sector. **Product is Recommended**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

113.

M/s. QAS International, GT Road, Gujranwala **Manufacturer of drug:** M/s. Veterinarski zavod SUBOTICA doo Adress: Beogradski put 123, 24000 Subotica, Serbia	**Poliovin** Each dose contains: *Cl perfringens* type A and alpha toxoid anti-alpha….. 2.5 IU *Cl perfringens* type C and beta toxoid….. anti-beta…. 2.5 IU *Cl perfringens* type D and beta toxoid. anti-epsilon…… 5 IU *Cl novyi* type B, …. Anti-novyi……. 3.5IU *Clostridium Septicum* and toxoid….. anti-septicum….2.5 IU. *Fusobacterium necrophorus*…….... 40AU.	Dy. No.29406 R&I Dated 28-10-2021 Rs. 150,000/- (Slip No 964611009823)

Staphylococcus aureus ……..…..
0.5AHU.

Arcanobacterium pyogenes…….
80AU

Previous Decision in M-320:

Registration Board deferred the case for evidence of availability of vaccine (formulation) in RRAs and for the comments of Expert Working Group on Veterinary Drugs regarding immunological relevance and need of applied strains in Pakistan. Registration Board further advised DBE&R to take the comments of Expert Working Group on Veterinary Drugs for all the veterinary vaccines having new strains, before placing the case in Registration Board.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that this is a need for European high milk producing cattle now reared in a substantial number in Pakistan; **Vaccine is relevant and required. Product is Recommended**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

114.	M/s. Huzaifa International, Address: Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. **Manufacturer** M/s Komipharm International Co., Ltd. Address:17, Gyeongje-Ro, Siheung-Si, Gyeonggi-Do, South Korea [Before Address System Change: 1236-6, Chongwang-Dong,	**Pro-Vac AB** Each 2ml dose contains: Anthrax (Stern Strain) spore...: ≥ 0.8 X $I0^7$ CFU Blackleg spore------ ≥ 0.8 X $I0^7$ CFU	Dy. No.32626 Dated 8-12-2020, Dy No. dated 21-06-2022 Rs. 100,000/- dated 08-12-2020

Shihung-Si, Kyonggi-
Do, South Korea]

Previous Decision in M-320:

Registration Board deferred the case for evidence of availability of vaccine (formulation) in RRAs and for the comments of Expert Working Group on Veterinary Drugs regarding immunological relevance and need of applied strains in Pakistan. Registration Board further advised DBE&R to take the comments of Expert Working Group on Veterinary Drugs for all the veterinary vaccines having new strains, before placing the case in Registration Board.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that It is a bivalent bacterial vaccine; public sector in Pakistan produces these in their monovalent form; **Vaccine is relevant and could be useful for Pakistan. Product is Recommended**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

115.	M/s. Hivet Animal Health Business, Lahore 1 st Floor,667-P.M.A, Johar Town, Lahore, Pakistan **Manufacturer** M/s. Beijing Sinder-Vet Technology Co., Ltd. Address: Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Shunyu Road No.118, Shunyi District, Beijing, China.	**Sinvac IBD** Each dose contains: Infectious Bursal Disease Antigen (B87 strain)…..≥10(3.0)ELD50/dose before freeze drying (0.0012ml/dose)	Form-5A Dy. No.18491 Dated 01-07-2021, Dy No. 9412 dated 13-04-2022 Rs. 150,000/- dated 08-12-2021

Previous Decision in M-320:

Registration Board referred the case to Expert Working Group on Veterinary Drugs for their comments regarding immunological relevance and need of applied strain in Pakistan. Registration Board further advised DBE&R to take the comments of Expert Working Group on Veterinary

Drugs for all the veterinary vaccines having new strains, before placing the case in Registration Board.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that Infectious Bursal Disease (IBD) is major challenge for Broiler segment of poultry industry in Pakistan. In China, a strict vaccine immunization program is applied to prevent and control IBD; B87 is the most widely used live-attenuated vaccine strain. **Vaccine will be useful for poultry sector in Pakistan. Product is therefore Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

116.	M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14, Sector-15, Korangi, Industrial Area, Karachi **Manufacturer** M/s. PT MEDION FARMA JAYA, JI Babakan Ciparay No 282, Babakan Ciparay, Bandung-Indonesia. Plant: JI. Raya Batujajar No 29, Cimareme, Ngamprah, Bandung Barat-Indonesia.	**Medivac IB Variant Vaccine** Each dose of dose contains: Infectious Bronchitis Virus M02 Strain ≥ $10^{3.5}$ EID_{50}	Form-5A Dy. No.15310 Dated 02-06-2021, Dy. No.22447 Dated 05-08-2022 Rs. 75,000/- dated 26-05-2021, Rs. 75,000/- dated 03-08-2022

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that Infectious bronchitis virus (IBV) is avian coronavirus and is ubiquitous in most parts of the world where poultry are reared. It spreads very rapidly in non-protected birds and exists in the form of many different antigenic or genotypic types, commonly referred to as variants. Antibodies to several European IBV variants have been demonstrated in Pakistan; **Vaccine could be useful for control of IBV in Pakistan. Product is Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

117.	M/s. Bromed Animal Health 246-A, West Wood Colony, Lahore. **Product License Holder:** Middle East for Veterinary Vaccine. Second Industrial Zone -Extention Part No. 21,22,24,25 El Salhya El Gdeda Elsharkya Governate, Egypt.	**MEVAC Eli Var2 (2000 doses)** (Live Vaccine) Each dose contains: Live attenuated Avian Infectious Bronchitis Variant 2 Virus (EG/IBV 12) $\geq 10^3$ EID_{50} Live attenuated New Castle Disease Virus (NDV2)$\geq 10^6$ EID_{50}.	Form-5A Dy. No. 31086 R&I Dated 23-11-2020 Rs. 100,000/- Dated 23-11-2020
118.	-do-	**ME VAC Eli Var2 ((5000 doses))** (Live Vaccine) Each dose contains: Live attenuated Avian Infectious Bronchitis Variant 2 Virus (EG/IBV 12) $\geq 10^3$ EID_{50} Live attenuated New Castle Disease Virus (NDV2)$\geq 10^6$ EID_{50}.	Form-5A Dy. No. 31085 R&I Dated 23-11-2020 Rs. 100,000/- Dated 23-11-2020

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that IBV and ND pose major economic threat worldwide, especially due to reduced egg quality and quantity in layer chickens and predisposition to bacterial infections in broilers. IBV initially targets the epithelium of the respiratory tract, but depending on the viral strain it can also infect other organs, mostly the reproductive tract and the kidneys. New IBV variants, resulting in different genotypes, serotypes and pathotypes, are continuously reported; similarly, ND is evolving to bring up new genotypes, now Genotype VII prevails much in the country. Evolving viruses therefore need similarly approach for their control; **product is therefore Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

119.	-do-	**ME VAC ND 7 Plus** (Inactivated Vaccine) Each dose contains: Inactivated vNDV Genotype VII "rgNDV1/ME-G7/2017" $\geq 10^{8.5}$ EID_{50}/dose before inactivation. Inactivated NDV LaSota strain, "NDV/chicken/Egypt/11478/11" $\geq 10^{8.5}$ EID_{50}/dose before inactivation	Form-5A Dy. No. 31088 R&I Dated 23-11-2020 Rs. 100,000/- Dated 23-11-2020

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that ND Genotype VII is in Pakistan since last one decade and need continuous control to reduce spread. Vaccine is relevant and required. **Product is Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

120.	-do-	**Mefluvac H9+ND7 0.3** <u>Inactivated Bivalent Virus Vaccine Against New Castle Disease</u> Each dose contains: Low pathogenic Avian Influenza H9N2 $\geq 10^{8.5}$ EID_{50}/dose before inactivation Recombinant Newcastle Disease Virus $\geq 10^{8.5}$ EID_{50}/dose before inactivation	Form-5A Dy. No. 13954 R&I Dated 24-05-2021 Rs. 150,000/- Dated 21-05-2021

Firm M/s. Bromed Animal Health has submitted following response/ relevancy: -

Sr.	Product Name	Virus strain as per FSC/ CoPP	Same/ circulating strain in Pakistan	Already registered products of same strain	Manufacturer/ agent name
121.	MEVAC Eli Var 2	*NDV2* EG/IBV12	VG/GA ND60 NDV2-NDV60 E/IBV12 Pak973	Avinew MEVAC ND Elite MEVAC IBVAR2 GPVAC IB Plus	Marial/ Saadat MEVAC/ Bromed MEVAC/ Bromed Grand Pharma
122.	MEVAC Eli Var2	*NDV2* EG/IBV12	VG/GA ND60 NDV2-NDV60 EG/IBV12 Pak973	Avinew MEVAC ND Elite MEVAC IB Var2 GPVAC IB Plus	Marial/ Saadat MEVAC/ Bromed MEVAC/ Bromed Grand Pharma
NOTE: MEVAC Eli Var2 is a bivalent vaccine and it is a combination of already approved two vaccines MEVAC ND Elite & MEVAC IB Var2 in Registration Board Meeting No.312					
123.	MEVAC ND7 Plus	vNDV Genotype vii, "rg NDV1/ME-G7/2017"} NDV/chicken/Egypt/11478 AF/2011* *Lab number in Egypt	ND G7 Lasota	Medivac ND G7B Emulsion Reg.No.0884989 MEVAC ND Broiler	Hilton Pharma MEVAC/ Bromed
124.	MEFLUVAC H9+ND7 0.3	H9N2 (A/chicken/ Egypt/ ME 543V/ 2016) * vNDV genotype vii, "rg NDV1/ME-G7/2017"}	AI H9N2	MEVAC Multi IB+H9+ND MEFLUVAC H9 0.3	MEVAC/ Bromed MEVAC/ Bromed

		*Lab Number in Egypt	ND G7	Medivac ND G7B Emulsion Reg.No.084989	Hilton Pharma
Note: MEVAC ND7 strain used in MEVAC ND7 Plus and MEFLUVAC H9+ND7 has shown highest identity with Pakistani isolates reported recently.					
Evaluation by DBE&R: *For product at serial i & ii virus strain on FSC is NDV2 and the firm claimed in their letter that it is NDV2-NDV60 strain.*					

Previous Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs in M-320 for comments regarding immunological relevance and need of applied strains in Pakistan.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that H9 is low-path Avian influenza (AI); In Pakistan vaccination is opted for the control of AI and ND. **Vaccine is a dual virus vaccine and is Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

Sr. No.	Name of Importer and Manufacturer	Brand Name & Composition	Dy. No. Date of Application Fee Status	Remarks of BE&R Division
125.	M/s. UM Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900 **Manufacturer of Drug:** M/s. Phibro Animal Health Limited. Address: Finisklin Buiseness park, Sligo F91 R772, Ireland.	**Phivax IB VAR 206** Each dose contains:- Live attenuated Avian infectious bronchitis virus, variant 206 strain … $10^{3.2}EID_{50.}$ Dosage Form: Effervescent tablet	Dy. No. 31963 R&I Dated 22-11-2021. Rs. 75000/- (Slip No. 506012933)	No already registered product for Live Attenuated Avian infectious bronchitis virus, **variant 206 strain** $10^{3.2}EID_{50}$ *Product (Phivax IB VAR 206) is not marketed in country of origin because variant 206 strain of avian infectious bronchitis virus is not found in Ireland as per clarification provided by firm.

Decision(M-336): Registration Board, after detailed deliberation, referred the product to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan.

Moreover, the Board advised BE&R Division to ask the applicant to submit following data;

• Notrised COPP indicating free sale status, details of manufacturer and MA Holder.

• Submission of specifications, analytical procedures and COAs as per official pharmacopoeia.

• Detail about pack size of the applied product and stability data of that pack size at recommended time intervals.

Recommendation of Sub-committee:

After deliberation, the Sub-committee on Veterinary Drugs decided that It is a live attenuated virus vaccine for avian Infectious Bronchitis developed from a field strain belongs to the unique IBV Genotype variant 2. It provides early protection against variant 2 field viruses found in Europe, the Middle East, Asia, Gulf States and the Africa. **Product is Recommended.**

Decision: -

On the basis of recommendations of Sub-committee on Veterinary Drugs, Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of legalized GMP certificate along with legalized CoPP.

CASES OF IMPORT REGISTRATION OF BIOLOGICAL PRODUCTS.

126.	**Name of Applicant**	**M/s Vety Care (Pvt.) Ltd., plot #77-A, Street-06, I-10/3, Islamabad.**
	DSL details	DSL No. DHO.ICT/883 dated 15-02-2024 valid till 14-02-2025
	Name of Manufacturer & **Product License Holder:**	**Product License Holder:** M/s Intervet International Nederland B.V. Wim de Korverstraat 35 5831, AN Boxmeer, The Netherlands. GMP expired. (conducted on 16-07-2020 for three years)
	Brand Name +Dosage	Nobivac Puppy DP Plus Lyophilisate and solvent for suspension for injection; **reconstituted vaccine**
	Composition	**Each dose (1 ml) of reconstituted vaccine contains:** **Active substances:** Live canine distemper virus strain Onderstepoort: $10^{5.1}$ -$10^{6.5}$ TCID50*

		Live recombinant canine parvovirus strain 630a: $10^{5.1}$ -$10^{6.7}$ TCID50* * Tissue culture infective dose 50%. (Strain strength on label and form-5A is not matching for FSC)
	Description	The canine parvovirus vaccine is considered a core vaccine by the World Small Animal Veterinary Association (WSAVA) Vaccination Guidelines Group as well as the American Animal Hospital Association (AAHA), indicating that all dogs should receive this vaccine as part of a routine wellness program. Two types of CPV-2 vaccines are currently available: a modified live virus (MLV) and an inactivated (killed) vaccine.
	Finished Product Specifications	Ph. Eur. Specifications.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2°C - 8°C)
	Pack size & Demanded Price	5 x 1's glass vial / Decontrolled; (Plastic box with 5 x 1 dose vial vaccine and 5 vials containing 1ml of solvent).
	International Availability	EMA (CPP Certificate: 05/22/169734)
	Alternate Products already registered in Pakistan	Product Name: Primodog (Reg.No. 018497) Mfd. by: Boehringer Ingelheim; Distributor: Saadat International. Product Name: Biocan Puppy (Reg.No 087881) Distributor: SNAM Pharma; Mfd. by : Bioveta a.s. Czech Republic.
	Type of Form; Dy. No., Date, Fee submitted	Form-5A; Dy. No. 21769 Date: 27-07-2022; Rs. 150000/-
	Demanded Price /Pack size	5 x 1 Dose (Decontrolled)
	Remarks of the Evaluator	COPP with strain of applied vaccine provided from Netherland, i.e., reference regulatory authority (RRA); Strain strength on label and form-5A is not matching for FSC. GMP expired. (latest inspection conducted on 16-07-2020 for three years validity)

Decision:

Registration Board after detailed deliberation deferred the product due to following deficiencies: -

- Submit the legalized valid GMP certificate.
- Submit clarification that strain strength on label and form-5A is not matching with FSC.

127.	**Name of Importer**	**M/s Hipra Pakistan (Private) Limited,** House no 86-88, J-1, Sunflower Society, M.A, Johar Town , Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0058-050528D valid till 19-Feb-2029
	Name of Manufacturer	**Laboratorios HIPRA, S.A, Avda. La Selva, 135** **17170 Amer (Girona) Spain**
	Brand Name + Dosage	**STARTVAC (Emulsion For Imjection)**

Form + Strength	25 doses glass bottle
Composition	Active substances and amount per unit dose or unit volume: Composition per dose (2 ml): Escherichia coli J5 inactivated ..... > 50 RED_{60*} Staphylococcus aureus (CP8) strain SP140 inactivated, expressing Slime Associated Antigenic Complex (SAAC) ..... > 50 RED_{80*} * RED60: Rabbit effective dose.
Finished product specifications	European Pharmacopeia.
Pharmacological Group	Inactivated vaccine against Bovine Mastitis
Shelf life	18 Months
International availability	Spain
Products already registered in Pakistan	No
Type of Form; Dy. No.	Form 5-A; Dated:12-07-2021.
Date;, Fee submitted	Fee Submitted: Rs. 150,000 /- dated 09-07-2021.
Demanded Price / Pack size	1's x 25 doses glass bottle Decontrollered
General Documentation	Legalized Certificate of Pharmaceutical Product (CoPP) No. 04/21/157404 issued by European Medicines Agency • Domenico Scarlattilaan 6 • 1083 HS Amste1 ciarn • The Netilerluncls. Dated 04-05-2021.
Remarks	• Product Monograph not attached • Form-5A revision is required for composition and drug product as per legal documents submitted.
Recommendation of Sub-committee of Expert on Veterinary Drugs:	Due to new strain, It was directed to present the case in Sub-committee of EVD, where it is deed as follows; "After deliberation, the Sub-committee on Veterinary Drugs decided that Mastitis is most important dairy problem usually looked after using antibiotics; product will help bio-control and will assist managing the AMR challenge. **Product is Recommended"**

Decision:

Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of product monograph as per applied specifications and revised form-5A alongwith applicable fee.

128.	**Name of Importer &** Address	**M/s Hi-Tech Pharmaceuticals (Pvt) Ltd** 1-C, Shadman Chowk, Jail Road, Lahore
	DSL Details	License to Sell Drugs as Distributor No: 05-352-0063-066935D valid till 03 Mar 2028.

Name of Manufacturer & Address	**Jordan Bio Industries Center "Jovac"** Yajouz Road, Near The Agriculture Nursery, Amman-Jordan
Brand Name; Dosage Form Strength	**Jova Zeit 4 Vaccine** (Emulsion for injection)
Composition	Each 0.3 mL dose contains: Inactivated Egg drop syndrome (EDS) virus Strain 76…… At least 1000 HA units
Description	Egg drop syndrome (EDS) is an **infectious disease caused by an adenovirus which mainly affects laying hens**. The disease results in egg quality defects in the eggs laid by infected hens. The virus is transmitted through any of the conventional means of viral disease spread and is also transmitted on and in the egg (horizontal and vertical transmission). Egg drop syndrome virus (EDSV) or Duck adenovirus-1 (DAdV-1), originated in waterfowl and likely introduced to commercial chickens through a contaminated vaccine.
Finished Product Specifications	Ph. Eur. Specification
Pharmacological Group	Veterinary Vaccine
Shelf Life & Storage	24 Months (2^o – 8^o C)
International Availability (RRA)	Jordan (Registration No. 52/23, Registration Date: 22/01/2001)
Product (s) already Registered in Pakistan	Nobilis EDS (Reg. No. 014160); Izovac EDS (Reg. No. 020051)
Type of Form Dy. No & Date Fee Submitted	Form – 5A; dated 17 Apr, 2023 Rs. 150,000.00 *vide* Slip No. 283322579153, dated 12-04-2023
Demanded Price Demanded Pack Size	Decontrolled Bottles of 300 mL (1000 Doses) (The product dose is 0.3 mL).
General Documentation	Legalized Free Sale Certificate o. 52/69 dated 09 Nov 2021 valid until 11 Feb 2031. GMP Certificates of License No. 52/1997 issued to the manufacturer by Ministry of Agriculture vide Jordanian directive No. (Z/10) 2022, valid till 03-10-2025.
Remarks:	• Form-5A revision is required for composition and drug product as per legal documents of Jordan.
Decision: Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of revised form-5A alongwith applicable fee.	

129.	**Name of Importer &** Address	**M/s Hi-Tech Pharmaceuticals (Pvt) Ltd** 1-C, Shadman Chowk, Jail Road, Lahore
	DSL Details	License to Sell Drugs as Distributor No: 05-352-0063-066935D valid till 03 Mar 2028.
	Name of Manufacturer & Address	**Jordan Bio Industries Center "Jovac"** Yajouz Road, Near The Agriculture Nursery, Amman-Jordan
	Brand Name Dosage Form Strength	**Combivac C Vaccine** At least $10^{6.0}$ EID_{50} of live attenuated Newcastle Disease Virus Strain Clone and at least $10^{3.0}$ EID_{50} Infectious Bronchitis Virus Strain H120.
	Composition	Composition per Dose **Composition** — **Quantity / Dose** **1)** Live Newcastle Disease Virus Strain Clone — At least $10^{6.0}$ EID_{50} / dose **2)** Live Infectious Bronchitis Virus Strain Massaachusetts H120 — At least $10^{3.0}$ EID_{50} / dose **3)** Lactose — 5 % **4)** Non-fat dried milk powder — 3 %
	Finished Product Specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf Life & Storage	24 Months (2^o – 8^o C)
	International Availability (Reference Regulatory Authority)	Jordan, Egypt, Lebanon, Iraq, Sudan, Syria, Taiwan, Tunis & Yemen
	Product(s) already Registered in Pakistan	IB+ND VACCINE NOBILIS MA5+ (Reg. No. 013232)
	Type of Form; Dy. No & Date of Fee	Form – 5A; dated 12 Apr.-2023, 17 Apr, 2023; Rs. 150,000.00 *vide* 4740706172, dated 12 Apr 2023
	Demanded Price & Pack Size	Decontrolled; Demanded Pack Size 1000 dose/vial
	General Documentation	Legalized Free Sale Certificate o. 53/69 dated 09 Nov 2021 valid until 11 Feb 2031. GMP Certificates of License No. 52/1997 issued to the manufacturer by Ministry of Agriculture vide Jordanian directive No. (Z/10) 2022, valid till 03-10-2025.
	Remarks:	• Form-5A revision is required for composition and drug product as

		per legal documents of Jordan.
	Decision. Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of revised form-5A alongwith applicable fee.	
130.	**Name of Importer &** Address	**M/s Hi-Tech Pharmaceuticals (Pvt) Ltd.,** 1-C, Shadman Chowk, Jail Road, Lahore.
	DSL Details	License to Sell Drugs as Distributor No: 05-352-0063-066935D valid till 3 Mar 2028
	Name of Manufacturer & Address	**Jordan Bio Industries Center "Jovac"** Yajouz Road, Near The Agriculture Nursery, Amman-Jordan.
	Brand Name Dosage Form Strength	**Combivac L Vaccine** Each contains at least $10^{6.0}$ EID_{50} of live attenuated Newcastle Disease Virus Strain LaSota and at least $10^{3.0}$ EID_{50} Infectious Bronchitis Virus Strain H120
	Composition	Composition per Dose **Composition** — **Quantity / Dose** **1)** Live Newcastle Disease Virus Strain LaSota — At least $10^{6.0}$ EID_{50} / dose **2)** Live Infectious Bronchitis Virus Strain Massaachusetts H120 — At least $10^{3.0}$ EID_{50} / dose **3)** Lactose — 5 % **4)** Nonfat dried milk powder — 3 %
	Finished Product Specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf Life & Storage	24 Months (2^o – 8^o C)
	International Availability (Reference Regulatory Authority)	Jordan, Egypt, Malaysia, Tanzania, Syria, Vietnam & Yemen
	Product(s) already Registered in Pakistan	IZOVAC H120 LaSota, 1000 dose vial Reg. No. 020059
	Type of Form; Dy. No & Date with Fee	Form – 5A; dated DRAP on 17 Apr, 2023 & Rs. 150,000.00; Slip No. 58787767, dated 12 Apr 2023.
	Demanded Price Demanded Pack Size	Decontrolled Available in 1000 and 2500 doses / vial Demanded Pack Size 1000 dose/vial

	General Documentation	Legalized Free Sale Certificate o. 54/69 dated 09 Nov 2021 valid until 11 Feb 2031. GMP Certificates of License No. 52/1997 issued to the manufacturer by Ministry of Agriculture vide Jordanian directive No. (Z/10) 2022, valid till 03-10-2025.
	Remarks:	• Form-5A revision is required for composition and drug product as per legal documents of Jordan.
	Decision: Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs and provision of revised form-5A alongwith applicable fee.	

131. **Name of Importer** M/s Huzaifa International, Commercial area, aziz bhatti town, Sargodha

DSL details DSL No. 08-384-0120-022405D, valid till. 20-11-2028

Product License Holder & Manufacturer Vetal Hayvan Sagligi Urunleri A.S (Vetal Animal Health Products S.A), Organize sanayi bolgesi, Petrol Mah.14 cad. No.1, Adiyaman /,Turkey.

Brand Name + Dosage Form + Strength **ABORVAC R SHEEP** vaccine with Diluent (Live attenuated Freeze dried Brucella melitensis Rev.1 vaccine with diluent)

Composition Each 1ml contains:

Active agents:

Live Attenuated Brucella melitensis Rev.1 $\geq$ 1-2 x10^5 CFU / dose

Diluent for ABORVAC R SHEEP Vaccine: (As per form-5A)

Components	**Concentration (mg/ml)**
Sodium chloride (NaCl)	……0,8 mg
Potassium chloride (KCl)	…….0,2 mg
Disodium hydrogen phosphate (Na_2HPO_4)	……...1,15 mg
Potassium hydrogen phosphate (KH_2PO_4)	……..0,2 mg
Water for Injection	…….q.s 1 ml

Description Brucellosis in cattle, water buffalo, and bison is caused almost exclusively by *Brucella abortus/ melitensis*. *It* is occasionally isolated from seropositive cows but does not appear to cause clinical signs and is not transmitted between cows. Infection spreads rapidly and causes many abortions in a herd of unvaccinated cattle. In a herd in which disease is endemic, an infected cow typically aborts only once after exposure. Subsequent gestations and lactations appear normal; however, organisms can still be shed in the placenta, amniotic fluid, and milk.

Live attenuated *Brucella melitensis* strain Rev.1 (Rev.1 vaccine) is th

		most effective vaccine against caprine and ovine brucellosis. Although these two vaccines provide good immunity for animals against brucell osis, the expense of persistent serological responses is one of the main problems of both vaccines.
	Finished product specifications	European Pharmacopoeia.
	Pharmacological Group	Biological Product- Veterinary vaccine
	Shelf life	12 Months; Store at 2-8°C
	International availability	CZV Rev-1 vaccine , manufactured by; CZ vaccines; Spain
	Products already registered in Pakistan	N/A
	Type of Form Dy. No.	Form 5-A; . Dy. No.15-06-2023
	Date , Fee submitted	Fee Submitted: Rs. 75,000 -/ dated: 04-08-2023
	Demanded Price / Pack size	Decontrolled for Veterinary products/ 20 doses of vaccine with 20 ml of diluent
	General Documentation	• Original Legalized Free Sale certificate from Turkey dated 10-11-2004 doc. No. B029984 , attested on 10-10-2022. • Copy of legalized Authorization letter;.. • GMP certificate date of validity 29-12-2026.

Decision:

Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs.

132.	**Name and address of Importer**	**M/s SNAM PHARMA 61-G, Phase-1, Commercial Area, DHA, Lahore**
	Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cantt, District Lahore. DSL # 05-352-0058-036985D; Valid till: 14-11-2027.
	Name of Manufacturer & MAH/PLH	**Manufacturer:** Tianjin Ringpu Bio-Technology Co., Ltd. Address: Airport Economic Zone Branch, No.168, Huanhe South Road, Airport Economic Zone, Tianjin, China, Postal code: 300381 **MAH:** Tianjin Ringpu Bio-Technology Co., Ltd. Address: No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin
	Brand Name + Dosage Form + Strength	RINVAC ND+IB+AI. Injectable Emulsion Newcastle disease virus in chickens before inactivation is $\geq 3x10^{8}$ EID_{50}/0.1ml, Infectious bronchitis virus…… $\geq 3x10^{6.0}$ EID_{50}/0.1ml. H9 subtype avian influenza virus content ……..$\geq 3x10^{7}$ EID_{50}/0.1ml.

Composition	The Vaccine contains inactivated Newcastle Disease Virus (La Sota strain), Infectious Bronchitis Virus (M41 strain) and H9 subtype Avian Influenza (Hp strain) Excipient(s): Oil adjuvant
Finished product specifications	As per innovators specifications
Pharmacological Group	
Shelf life	24 months (Store at 2-8°C)
International availability	Available in China
Products already registered in Pakistan	Brand Name: Meilan K. ND + IB + H9
Type of Form	Form-5A
Dy. No. Date of Application, Fee submitted	Date of Application: 17 March 2023 Fee submitted Date: 15-02-2023, Challan No. 346904330
Demanded Price / Pack size	De-controlled; 500 ml/Bottle
Remarks:	• FSC does not contains the strength of the applied product. • Safety studies and stability data is considered for small number and should be submitted in accordance of V-ICH guidelines. (Safety and stability studies brief data provided) • Label should be legible and contains all pre-requisites of labelling as per rules.

Decision: Registration Board after detailed deliberation deferred the product to comply with following deficiencies: -

- FSC does not contains the strength of the applied product.
- Safety studies and stability data is considered for small number and should be submitted in accordance of V-ICH guidelines. (Safety and stability studies brief data provided)
- Label should be legible and contains all pre-requisites of labelling as per rules.

133.	**Name and address of Importer**	**M/s. Mustafa Brothers** **186-D Peoples Colony No. 1, Faisalabad**
	Detail of DSL	M/s. Mustafa Brothers; 186-D Peoples Colony No. 1, Faisalabad. Valid Up to 21.06.2027.
	Name and address of Manufacturer	Bimeda biologicals, Inc 1702 North Bell Street San Angelo, TX 76903 (800) 284-8403. US

	Marketing Authorization Holder	Bimeda Animal Health Limited Unit 2/3/4 Airton Close,tallaght, Dublin 24, Ireland. Airton Road, Tallaght, Dublin 24, Ireland.
	Name of exporting country	United States of America
	Brand Name +Dosage Form + Strength	**MYCO-BAC.** Cattle Vaccine
	Diary No. Date of R& I & fee	1127; 14-07-2023; 75,000/- 02-06-2023.
	Composition	Each Dose contains: Mycoplasma bovis Bacterin
	Pharmacological Group	Biological product
	Type of Form	Form-5A
	Finished Product Specification	USP specifications
	Shelf Life	24 months (2 ^{0}C-8 ^{0}C)
	Document Details	
	Pack size	50 dose / 100ml
	Reference Regulatory Authority Availability	Approved in USDA
	Products already registered in Pakistan	**Not available.**
	Remarks of Evaluator	• Form-5 needs revision, no strength of active ingredient. • Composition and strength not mentioned.
	Decision: Registration Board after detailed deliberation deferred the product to comply with following deficiencies: - • Form-5 needs revision, no strength of active ingredient. • Composition and strength not mentioned, clarification required as per application form in accordance to the FSC.	
134.	**Name and address of Importer**	**M/s. Mustafa Brothers** **186-D Peoples Colony No. 1, Faisalabad**
	Detail of DSL	M/s. Mustafa Brothers 186-D Peoples Colony No. 1, Faisalabad. Valid Up to 21.06.2027
	Name and address of Manufacturer	Bimeda biologicals, Inc 1702 North Bell Street San Angelo, TX 76903 (800) 284-8403

	Marketing Authorization Holder	Bimeda Animal Health Limited Unit 2/3/4 Airton Close, Tallaght, Dublin 24, Ireland. Airton Road, Tallaght, Dublin 24, Ireland.
	Name of exporting country	United States of America
	Brand Name +Dosage Form + Strength	**STIMULATOR 5**
	Diary No. Date of R& I & fee	1128; 14-07-2023; 75,000/- 02-06-2023.
	Composition	**Each Dose contains:** 1. Bovine Herpesvirus Type 1 (BHV-1) (Cooper (Colorado) strain) 2. Bovine Viral Diarrhea Virus Type 1a (BVDV-1a) (Singer strain) 3. Bovine Viral Diarrhea Virus Type 2 (BVDV-2) (125 strain) 4. Parainfluenza Type 3 Virus (PI3) Reisinger SF4 (strain) 5. Bovine Respiratory Syncytial Virus (BRSV) (N375 strain) Excipients: Neomycin, Nystatin, Sucrose solution , DMEM
	Pharmacological Group	Biological product
	Type of Form	Form-5A
	Finished Product Specification	USP specifications
	Shelf Life	18 months (2 -8 ^{0}C)
	Document Details	
	Pack size	50dose / 100ml, 10 dose / 20mL
	Reference Regulatory Authority Availability	Approved in USDA
	Products already registered in Pakistan	**Not available**
	Remarks of Evaluator	• Form-5 needs revision, no strength of active ingredient. • Composition and strength not mentioned.
	Decision: Registration Board after detailed deliberation deferred the product to comply with following deficiencies: - • Form-5 needs revision, no strength of active ingredient. • Composition and strength not mentioned, clarification required as per application form in accordance to the FSC.	

DEFERRED CASE OF IMPORT REGISTRATION OF BIOLOGICAL PRODUCTS.

DEFERRED IN M-336 OF REGISTRATION BOARD		
135.	**Name of Importer**	M/s Huzaifa International, Commercial area, aziz bhatti town, Sargodha
	DSL details	DSL No.. .08-384-0120-022405D, valid till. 20-11-2028
	Name of Manufacturer	**Product License Holder & Manufacturer (As per CoPP)**: JILIN ZHENGYE BIOLOGICAL PRODUCTS CO., LTD.Address: : No.1 Lian Meng Street Economic and technological Development Zone Of Jilin City, China
	Brand Name + Dosage Form + Strength	POLY-VAC ND.IB.H9 Inactivated viral vaccine for the prevention of Newcastle disease, Infectious Bronchitis and Avian Influenza in poultry.
	Composition	Contains Newcastle disease virus LaSota strain (before inactivation the virus content≥$3*10^{8.0}EID_{50}$/0.1ml), Chicken infectious bronchitis virus M41strain（before inactivation the virus content≥$3*10^{6.0}EID_{50}$/0.1ml) and Avian influenza (H9N2 subtype) virus （before inactivation the virus content≥$3*10^{8.0}EID_{50}$/0.1ml）
	Finished product specifications	Specifications; Innovator's specifications
	Pharmacological Group	Biological Product- Inactivated Veterinary vaccine
	Shelf life	12 Months)Store at 2~8°C)
	International availability	MEVAC Multi IB+H9+ND (In United kingdom)
	Products already registered in Pakistan	Pro-vac ABBN Vaccine; Registration holder; Huzaifa International, commercial area, aziz Bhatti town, Sargodha. Reg. no. 088167
	Type of Form Dy. No. Date of Application, Fee submitted	Form5-A Dy. No. Date:02-12-2022 Fee Submitted: Rs. 75,000, -/ dated: 11-11-2022
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 500 ml vaccine bottle
	General Documentation	• Original Legalized Free Sale certificate , GMP certificate and Authorization letter submitted
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • Provide valid GMP certificate and attach the last inspection report of the manufacturer.	

	• Clinical data is not complete, so provide the clinical studies data as per VICH guidlines. • Provide the label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Submit the differential fee in the light of fee SRO.	
	Decision: The registration board deferred the case for submission of following deficiencies; • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Kindly Submit the differential fee in the light of fee SRO.	
	Now, the firm submitted followings: • Online paid challan for 75,000/- Rs. (Differential fee), Challan no.688826228 • Copy of valid legalized GMP certificate (valid till 30-05-2027). • Clinical/ Safety studies data on 20-SPF and 50-Layers Chicken. • Stability studies data of 3-batches of vaccine in recent years, according to ICH guidelines, Zone IV-A. • Label of vaccine approved & being used in country of origin.	
	Decision: Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs.	
136.	**Name of Importer**	M/s Huzaifa International, Commercial area, aziz bhatti town, Sargodha
	DSL details	DSL No.. **.022405-0120-384-08 D**, valid till. 20 –11-2028.
	Name of Manufacturer	**Product License Holder & Manufacturer (As per CoPP)**: JILIN ZHENGYE BIOLOGICAL PRODUCTS CO.,LTD.Address: : No.1 Lian Meng Street Economic and technological Development Zone Of Jilin City, China
	Brand Name + Dosage Form + Strength	POLY-VAC ND.IB.EDS Inactivated viral vaccine for the prevention of Newcastle disease, Infectious Bronchitis and Egg drop syndrome in poultry.
	Composition	Each dose contains: Contains the Inactivated Newcastle disease virus(Clone 30 strain),before Inactivated at least $3.0*10^{8.0}EID_{50}$/0.1ml; Chicken infectious bronchitis virus (M41 strain),before Inactivated at least $3.0*10^{6.0}EID_{50}$/0.1ml; Egg Drop Syndrome virus (AV127 strain),before Inactivated virus liquid HA at least 1:30720.

	Finished product specifications	Specifications; European Pharmacopoeia specifications
	Pharmacological Group	Biological Product- Inactivated Veterinary vaccine
	Shelf life	12 Months)Store at 2~8°C)
	International availability	VAXXON ND-IB-EDS (In Netherlands)
	Products already registered in Pakistan	ITA ND.IB.EDS Vaccine; Registration holder; Vet line International, Lahore. Reg. no. 062005 (…….)
	Type of Form Dy. No. Date of Application, Fee submitted	Form5-A .; Dy. No. Date:02-12-2022 Fee Submitted: Rs. 75,000, -/ dated: 11-11-2022
	Demanded Price / Pack size	Decontrollered for Veterinary products/ 500 ml vaccine bottle
	General Documentation	• Original Legalized Free Sale certificate , GMP certificate and Authorization letter submitted
	Remarks OF Evaluator: The application has been evaluated and shortcomings are as follows: • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Kindly Submit the differential fee in the light of fee SRO.	
	Decision: The registration board deferred the case for submission of following deficiencies; • Provide valid GMP certificate and attach the last inspection report of the manufacturer. • Clinical data is not complete, so provide the clinical studies data as per V-ICH guidelines. • Provide label of the product approved in country of origin. • Stability studies data is too old to consider (2016), hence submit sufficient data to consider for stability studies in the light of Zone-IVA. • Firm submitted fee of 75,000/- Kindly Submit the differential fee in the light of fee SRO.	
	Now, the firm submitted followings: • Online paid challan for 75,000/- Rs. (Differential fee), Challan no.688826228 • Copy of valid legalized GMP certificate (valid till 30-05-2027). • Clinical/ Safety studies data on 20-SPF and 50-Layers Chicken. • Stability studies data of 3-batches of vaccine in recent years, according to ICH guidelines, Zone IV-A. • Label of vaccine approved & being used in country of origin.	
Decision: Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs.		

MISCELANEOUS CASES

EXPERT OPINION ON EXEMPTION OF PHASE-III FROM PHARMACY SERVICES DIVISION/ CSC OPINION ON CLINICAL TRIAL AND DATA NECESSITY FOR REGISTRATION OF BIOSIMILAR (BIOLOGICAL) PRODUCT.

The below mentioned case was referred to the Pharmacy Services Division for expert opinion and the comments of is paced here for consideration of the board: -

Imported Human Biological product from non-Reference countries:

137.	Name, address of Applicant / Importer	M/s AMGOMED, Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue arejn a Islamabad Pakistan
	Details of Drug Sale License of importer	License No: DSL-002-ICT/2013 Address: Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. Validity: 30-01-2024 Status: Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Gennova Biopharmaceuticals Limited, Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
	Name, address of manufacturer(s)	M/s Gennova Biopharmaceuticals Limited,
		Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP**: Firm has submitted original CoPP certificate (CoPP/CERT/PD/110860/2022/11/39406/ 191298) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 14-07-2022.

	Details of letter of authorization / sole agency agreement	The firm submitted notarized letter of authorization whereby M/s Gennova Biopharmaceuticals Limited, India authorized M/s Amgomed to apply for registration, for marketing, distribution and sale of below mentioned product; Hamsyl 3750 IU / 5ml Injection Each 5 ml vial contains: Pegasparagase (Pegylated L- Asparaginase) HIS 3750 IU The authorization letter is valid till 06-05-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	
	Intended use of pharmaceutical product	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	For imported products, specify one the these	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26085 Dated: 30-07-2018
	Details of fee submitted	PKR 100,000 (Slip number : 0778294)
	Proposed proprietary name / brand name	Hamsyl 3750 IU / 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Pegaspargase (Pegylated L-Asparginase)....3750 IU
	Pharmaceutical form of applied drug	Solution for IV / IM Administration
	Pharmacotherapeutic Group of (API)	Antineoplastic agents ATC-code: 01XX24
	Finished product specifications	In-house
	Proposed Pack size	1's vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 2 °C to 8 °C

	The status in reference regulatory authorities	Oncaspar Injection 3,750 IU / 5ml vial of M/s Sigma Tau (USFDA approved).
	For generic drugs (me-too status)	Pegaspargase (Peg-L-Asparaginase of LDS (Reg#105067)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	DMF Holder Address: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China. Name and Address of the manufacturer: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Gennova Biopharmaceuticals limited do not intend to store the API manufactured. It is immediately transfer for fill finish activities. Hence formal stability study for Pegaspargase Bulk is not intended as there is no change in the composition of Bulk and Finished product. Its only containerization process. Hence, we have carried out hold time study for bulk and finished product stability study is reflective for API stability as well.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of Pharmaceutical Equivalence: Hamsyl 3750 IU /5ml Injection and reference product Oncaspar by Sigma Tau Corporation, USA.
	Analytical method validation / verification of product	The firm has submitted relevant data including analytical method validation for the drug product including the impurities.
	Container closure system of the drug product	Pegaspargase Injection is filled in USP Type I Glass vial. One such labelled vial is placed in Plastic Tray and which is packed in Monocarton along with leaflet. Primary packaging materials conform to specifications.

	Stability study data of drug product, shelf life and storage conditions	Real time stability (Long term) studies have been conducted at 5°C ± 3°C for 24 months of 3 batches. Accelerated stability studies is conducted at 25 °C ± 2 °C / 60% ± 5% RH for 6 months of 3 batches. 431401H01 431402H02 431403H03
	Non-Clinical (Module IV)	**Single dose toxicity** Acute Intravenous toxicity study in Swiss Albino mice Acute Intravenous toxicity study in Sprague Dawley rat **Multiple Dose** Subchronic intravenous toxicity study in the Swiss Albino Mouse Subchronic intra venous toxicity study in the Sprague Dawley Rat

	Module V	**1.** A prospective, open label, randomized, active control, parallel design, comparative pharmacokinetics study of intramuscular pegaspargase (Hamsyl) of M/s Gennova Biopharmaceuticals Ltd versus intramuscular Oncaspar in pediatric patients with **relapsed cases** of Acute Lymphoblastic Leukemia (ALL). **Twenty-four** (24) Pediatric patients diagnosed with Acute Lymphoblastic Leukemia (ALL) in relapsed stage enrolled in 1:1 ratio in two arms randomly. 2. To demonstrate the pharmacokinetic comparability of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase) given intramuscularly during induction in patients with ALL therapy. 3. To compare the immunogenicity and toxicity of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase).
Remarks of Evaluator: The submitted original CoPP is not legalized however, the firm has submitted undertaking that we will submit legalized original copy of CoPP after attestation. Meanwhile, we request you to please include our product in DRB meeting.		
Evaluation by BE&R:		

Sr.No.	**Decision of 324th meeting**	**Response by the firm**
138.	Submission of Phase I, II, III clinical study data for the proposed indication since already submitted study is a pharmacokinetic comparison of applied product with reference product.	Hamsyl is a pegylated version of native- asparaginase. Hamsyl was approved as an 'Orphan drug' in India in the second line of treatment of relapsed Acute Lymphoblastic Leukemia (ALL). This approval was based on a bioequivalency study (PK) against the reference product (Oncaspar) in patients with ALL in India. The serum asparaginase activity (> 100 IU/L) has been considered as a surrogate marker for efficacy1 and has been used for the approval of asparaginase formulations worldwide. For instance, *Erwinia asparaginase* US-FDA approval was based on the nadir serum asparaginase activity >100 IU/L. Hamsyl was found to be 'Bioequivalent' to Oncaspar. Importantly, both drugs maintained a

		nadir serum L-asparaginase activity> 100 IU/L. The secondary endpoints of the study included comparison of the L• asparaginase antibodies response profile and changes in L-asparagine and glutamine amino acids levels. No statistically significant differences were observed in the secondary endpoints. Based on these results, Hamsyl was approved and Phase III study was waived off. Hamsyl has been available in India for therapeutic use since 2014. Various independent investigators have published their experience of treatment with Hamsyl as retrospective studies with no new significant concerns.	
2.	Details of pharmaceutical comparison with reference product Oncaspar Injection 3750 IU / 5ml.	The firm has submitted comparability evaluation report of Oncaspar (ON3066X2) and Hamsyl injection (3750 IU/vial) for the identified critical quality attributes.	
3.	Legalization of CoPP	**CoPP**: Firm has submitted original Legalized CoPP certificate (CoPP/CERT/PD/1108776/2022/11/41643/ 204858) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 09-07-2025.	
Decision: Registration Board decided to refer the case to Pharmacy Services Division for opinion on firm's justification for exemption of Phase III clinical study data.			

The subject matter was placed before Clinical Studies Committee (CSC) in its 50th meeting held on 11th July 2024. The Committee decided the case as follows:

The CSC after detailed deliberation and discussion advised to forward following decision to the BE&R Division:

i. *The CSC notified and work under the Bio-Study Rules, 2017 for Clinical Trial Oversight in the country and instant application is not for the conduct of any clinical trial / study hence its not the mandate of CSC.*
ii. *However, the Committee is of the view that Pharmacokinetic study is one of the parts of the Phases of the Clinical Trials and can't substitute Phase-I, II and III studies, as already mentioned in the Registration Board. Moreover, Registration Board may decide the application as per merit of the case.*

Decision:

- Registration board after detailed deliberation decided on the recommendation of pharmacy services division deferred the case and give the final opportunity to submit the complete pharmacokinetic studies as it is the parts of the phases of the clinical studies.

CASE NO .139 <u>APPROVAL OF DILUENT FOR ALREADY REGISTERED BIOLOGICAL PRODUCT "TEYLOVAC VACCINE" I.E., INTEND TO IMPORT FROM TURKEY BY M/S HUZAIFA INTERNATIONAL, SARGODHA.</u>

M/s. **Huzaifa International, commercial area aziz bhatti town, Sargodha** submitted the request of for registration of subject product alongwith solvent as mentioned below: -

TEYLOVAC Vaccine

Live attenuated Freeze dried Theileria Annulata cells based

vaccine with diluent

Each dose of vaccine contains Theileria annulata…....$1x10^7$ cells;

Composition of Diluent for Teylovac vaccine;	
Each 10 ml diluent contains will be;	
NaCl	115 mg
KCl	1.92 mg
Na2HPO4.2H2O	16.54 mg
KH2PO4	9.23 mg
Phenol red	8.46 mg
Deionized Water	q.s upto 10 ml

manufactured by; **M/S Vetal Animal Health Products S.A., Address: Organize Sanayi Bolgesi, Petrol Mah.14 Cad. No.1/1, Adiyaman, Turkey**.

<u>Case History:</u>

The above product was discussed in M-307th of RB with solvent and Registration Board referred the case to Expert Working Group (EWG) on Veterinary Drugs. Then it was placed in M-313rd of RB with recommendation of EWG and approved for grant of registration. The registration letter was issued on request of firm after codal formalities on 20th May, 2024, without solvent because its composition was not presented on Free Sale certificate of country of origin (that doesn't contain composition of solvent) as per following details of the product: -

Regn. No.	***Name of Drug and Composition***	***Packing***	***MRP***	***Approved Shelf Life***

120502	TEYLOVAC Vaccine Theileria Annulata vaccine. Each dose vaccine contains: - Theileria annulata……1x10^7 cells. **(As per Innovator's Specs.)**	4 doses vaccine vial.	Decontrolled	60-months. (-196°C) in liquid nitrogen tank.

Now, the firm has requested to issue the approval of registration of diluent of 10ml as combo pack and submitted following documents: -

1. Application on the form-5A;
2. Free Sale certificate presenting the composition of solvent;
3. Challan Slip of 15000/-
4. Scanned copy of Agency agreement;
5. Undertaking.

Decision

Registration Board after detailed deliberation approved the diluent as per free sale certificate and issuance of letter in conjunction with registration certificate of TEYLOVAC Vaccine Reg. no. 120502.

CASES OF DD-III (Ms. HALEEMA SHARIF)

Imported Human Biologicals from Non-Reference Countries:

140.	Name, address of Applicant / Importer	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan,** 2nd floor plaza 60, Commercial Block-K, Phase-1 DHA, Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0058-104514D **Validity**: 08-05-2028 **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore **Status**: License to sell drugs by way of whole sale. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. No.97 Zhuzhou Road, Laoshan District, Qingdao city Shandong province, China.
	Name, address of manufacturer(s)	M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. No.97 Zhuzhou Road, Laoshan District, Qingdao city Shandong province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized **copy** of CoPP (No. Shandong20210018) dated 01-12-2021 issued by The Second Regional Inspection Bureau Branch of Shandong Province Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 30-11-2023.

	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. China. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	17335(R&I) Dated 11-07-2023
	Details of fee submitted	Rs. 150,000/- Dated 07-07-2023
	The proposed proprietary name / brand name	**Urokine Injection 100,000 IU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Urokinase…..….100,000 Units
	Dosage form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Thrombolytic drug
	Finished product specifications	Chinese Pharmacopoeia Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO/DPC
	Shelf life	36 months
	Storage conditions	Store below 25 °C.
	The status in reference regulatory authorities	Syner-KINASE 100,000 IU powder for solution for injection of Syner-Medica **(MHRA Approved**)
	For generic drugs (me-too status)	Not confirmed.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Address 1: M/s Qingdao Kangyuan Pharmaceutical Co., Ltd. Yinghai Industrial Area, Jiaozhou, Shandong, China.

		Address 2: Shandong Hailong Biotechnology Co., Ltd. North of huaihi Road Middle Part, Economic and Technology. Address 3: Yishui Longteng Biotechnology Co., Ltd Economic & Technology Development Area County, Shangdong. Only Urokinase Crude is manufactured in site 2,3.
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of following 3 batches of drug substance conducted at 5 ± 3°C for 36 months: KU150901 KU150902 KU151001
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Injection vials made of low borosilicate glass tubing • Halogenated butyl rubber plugs for freeze drying • Aluminum plastic cover
	Stability study data of drug product	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C/75% ± 5% RH for 6 months. The real time stability study data is conducted at 25°C ±2°C / 60% ± 10% RH for 24 months. 170303 170304 170305
	Non-clinical (Module-IV)	The firm has submitted following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion

		Toxicology • Single dose toxicity • Repeated dose toxicity
	Clinical (Module-V)	Urokinase is a naturally occurring enzyme have same indications as streptokinase. While streptokinase is derived from bacteria. Study reports of Controlled Clinical Studies pertinent to the claimed Indications: **Treatment of acute cerebral infarction with urokinase** From September 2019 to April 2020, **56** patients with acute cerebral infarction were admitted to the Second Affiliated Hospital of Shaoyang College. The control group was treated with routine comprehensive therapy, and the observation group was treated with intravenous thrombolytic therapy of urokinase. Conclusion: Intravenous thrombolytic therapy with urokinase is effective in the treatment of acute cerebral infarction. **Treatment of cerebral thrombosis with urokinase** **42** patients with cerebral thrombus were treated with Urokinase in Internal Medicine Department of Kaiyuan, Liaoning Central Hospital of Liaoning Province. The clinical efficacy, safety, neurological function, limb function, mobility and quality of life were observed. Conclusion: Urokinase thrombolytic therapy is effective and safe in the treatment of patients with cerebral thrombosis.
	Remarks of evaluator	Variation in relative humidity in submitted stability data is ±10% RH, please provide reference of guideline for this variation. The firm has clarified that their relative humidity is accordance to Chinese Pharmacoepea.
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.		
141.	Name, address of Applicant / Importer	M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan, 2nd floor plaza 60, Commercial Block-K, Phase-1 DHA, Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0058-104514D **Validity**: 08-05-2028 **Address of Godown:** House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore **Status**: License to sell drugs by way of whole sale. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. No.97 Zhuzhou Road, Laoshan District, Qingdao city Shandong province, China.
	Name, address of manufacturer(s)	M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. No.97 Zhuzhou Road, Laoshan District, Qingdao city Shandong province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized **copy** of CoPP (No. Shandong20210019) dated 01-12-2021 issued by The Second Regional Inspection Bureau Branch of Shandong Province Drug Administration. The CoPP confirms free sale status of the product

		in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP is valid till 30-11-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from M/s Qingdao Guanlong Biopharmaceutical Co., Ltd. China. The letter specifies that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	(R&I) Dated 11-07-2023
	Details of fee submitted	Rs. 150,000/- Dated 07-07-2023
	The proposed proprietary name / brand name	Urokine Injection 250,000 IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Urokinase…..….250,000 Units
	Dosage form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Thrombolytic drug
	Finished product specifications	Chinese Pharmacopoeia Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO/DPC
	Shelf life	36 months
	Storage conditions	Store below 25 °C.
	The status in reference regulatory authorities	Syner-KINASE 250,000 IU powder for solution for injection of Syner-Medica **(MHRA Approved**)
	For generic drugs (me-too status)	Not confirmed.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and

		drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Address 1: M/s Qingdao Kangyuan Pharmaceutical Co., Ltd. Yinghai Industrial Area, Jiaozhou, Shandong, China. Address 2: Shandong Hailong Biotechnology Co., Ltd. North of huaihi Road Middle Part, Economic and Technology. Address 3: Yishui Longteng Biotechnology Co., Ltd Economic & Technology Development Area County, Shangdong. Only Urokinase Crude is manufactured in site 2,3.
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of following 3 batches of drug substance conducted at 5 ± 3°C for 36 months: KU150901 KU150902 KU151001
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Injection vials made of low borosilicate glass tubing • Halogenated butyl rubber plugs for freeze drying • Aluminum plastic cover
	Stability study data of drug product	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C/75% ± 5% RH for 6 months. The real time stability study data is conducted at 25°C ±2°C / 60% ± 10% RH for 24 months. 170306 170307 170308
	Non-clinical (Module-IV)	The firm has submitted following study reports: Pharmacology • Primary pharmacodynamics • Secondary pharmacodynamics • Safety pharmacology

		Pharmacokinetics • Absorption • Distribution • Metabolism • Excretion Toxicology • Single dose toxicity • Repeated dose toxicity
	Clinical (Module-V)	Urokinase is a naturally occurring enzyme have same indications as streptokinase. While streptokinase is derived from bacteria. Study reports of Controlled Clinical Studies pertinent to the claimed Indications: **Treatment of acute cerebral infarction with urokinase** From September 2019 to April 2020, **56** patients with acute cerebral infarction were admitted to the Second Affiliated Hospital of Shaoyang College. The control group was treated with routine comprehensive therapy, and the observation group was treated with intravenous thrombolytic therapy of urokinase. Conclusion: Intravenous thrombolytic therapy with urokinase is effective in the treatment of acute cerebral infarction. **Treatment of cerebral thrombosis with urokinase** **42** patients with cerebral thrombus were treated with Urokinase in Internal Medicine Department of Kaiyuan, Liaoning Central Hospital of Liaoning Province. The clinical efficacy, safety, neurological function, limb function, mobility and quality of life were observed. Conclusion: Urokinase thrombolytic therapy is effective and safe in the treatment of patients with cerebral thrombosis.
	Remarks of evaluator	Variation in relative humidity in submitted stability data is ±10% RH, please provide reference of guideline for this variation. The firm has clarified that their relative humidity is accordance to Chinese Pharmacoepea.
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.		

142.	Name, address of Applicant / Importer	**Neutro Health Care**, 22-A, M, Gulberg III, Lahore- Pakistan
	Details of Drug Sale License of importer	License No: **05-352-0062-103478D** Address: Hazrat Ali Road Sagian ByPass Opp by Aligee Garments District Lahore Validity: 28.03.2028
	Name and address of marketing authorization holder	**Neutro Health Care** 22-A, M, Gulberg III, Lahore- Pakistan

Name, address of manufacturer(s)	**Tonghua Dongbao pharmaceutical Co. Ltd.,** Dongbao Xincun, Tonghua County, Jilin Province, China.
Name of exporting Country	**China**
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. **Jilin20220048** issued on 23rd August 2022. Firm has attached GMP Certificate No. **JL20190079** issued on 9th December 2019, issued by State Food and Drug Administration, China.
Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. **HWBA202201005** signed by both the parties.
Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No; 1748 Dated: **14th December 2023**
Details of fee submitted	Rs: 150,000/-

	Dated: 01-12-2023 (Slip No. 65754663)
The proposed proprietary name / brand name	**Insulin Glargine Cartridge 3ml**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Cartridge contains: 3ml solution for injection of Insulin Glargine…. equivalent to 300 units **(100units/ml)**
Dosage form of applied Drug	Injectable
Pharma co therapeutic Group of (API	Anti-Diabetic Insulin Analogues
Reference to Finished product specifications	USP Specifications
Proposed unit price	As per DPC
Shelf Life	30 Months
Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
The status in reference regulatory authorities	Lantus Cartridge 3ml…...300 Units/3ml (100units/ml) Sanofi Aventis U.S. LLC U.S. License No. 1752
For generic drugs (me-too status)	Lantus Cartridge 3ml Sanofi-Aventis (Pvt.) Ltd,
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

	process validation protocols and validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
Name, address of drug substance manufacturer	Tonghua Dongbao Pharmaceutical Co., Ltd. Dongbao Xincun, Tonghua County, Jilin Province, China
Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The stability studies of three commercial batches of insulin Glargine GL201512007, GL201512008 and GL201512009 for 6 months at (2 - 8°C) under accelerated conditions and for 36 months at -20°C ± 5°C under long term conditions have been completed. (Insulin Glargine is sensitive to temperature. The storage temperature of the drug substance is usually at below -15ºC. So, the accelerated test is conducted at between 2ºC to 8ºC)
Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
Container closure system of the drug product	The insulin glargine injection, will be filled into a cartridge made of neutral borosilicate glass tubing, with a brominated butyl rubber plunger and an aluminium plastic cap. The secondary packaging is designed with a plastic container inside a paper box with basic product information printed following marketing regulations.

Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The real time stability study data is conducted at 05°C ± 3°C for 36 months.
Module-IV Non-Clinical	Firm has submitted toxicity studies
Module-V Clinical	Efficacy and Safety of Insulin Glargine Injection in the Treatment of Type 2 Diabetes Mellitus by Multi-center, randomized, Open, Parallel and Lantus referenced Phase III Clinical Study The main efficacy indicator HbA1c, secondary efficacy indicator FPG and 2hr-GLU changes relative to baseline of Insulin Glargine Injection group and the Lantus group, all had no significant difference. The incidence of hypoglycemia of the two groups were also similar, clearly demonstrated that the Insulin Glargine Injection developed by Tonghua Dongbao Pharmaceutical Co., Ltd was equivalent in terms of safety and efficacy of the marketed innovator Lantus.

Remarks:

- Clarification for difference in address of importer in Form 5F, DSL & Sole agency agreement is required.

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and the clarification as per remarks of evaluator.

143.	**Name, address of Applicant / Importer**	**Neutro Health Care, 22-A, M, Gulberg III, Lahore-Pakistan**
	Details of Drug Sale	License No: **05-352-0062-103478D**
	License of importer	Address: Hazrat Ali Road Sagian ByPass Opp by Aligee Garments District Lahore. Validity: 28.03.2028
	Name and address of marketing authorization holder	**Neutro Health Care** 22-A, M, Gulberg III, Lahore- Pakistan
	Name, address of manufacturer(s)	**Tonghua Dongbao pharmaceutical Co. Ltd.,** Dongbao Xincun, Tonghua County, Jilin Province, China.

Name of exporting Country	**China**
Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. **Jilin20220047** issued on 23rd August 2022. By Jilin Medical Products Administration. Firm has attached GMP Certificate No. **JL20190079** issued on 9th December 2019, issued by State Food and Drug Administration, China.
Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. **HWBA202201005** signed by both the parties.
Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No; 1746R&I dated 14th December 2023
Details of fee submitted	Rs: 150,000/- Dated: 01-12-2023 (Slip No. 5924605731)
The proposed proprietary name / brand name	Insulin Glargine Vial 10ml
Strength / concentration of drug of Active	Each Vial contains:

Pharmaceutical ingredient (API) per unit	10ml solution for injection of Insulin Glargine…. equivalent to 1000 units (100units/ml)
Dosage form of applied Drug	Injectable
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin Analogues
Reference to Finished product specifications	USP Specifications
Proposed unit price	As per DPC
Shelf Life	24 Months
Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
The status in reference regulatory authorities	Lantus Vial 10ml….. 1000 Units/10ml (100units/ml) Sanofi Aventis U.S. LLC U.S. License No. 1752
For generic drugs (me-too status)	Lantus Vial 100units/ml (U-100) Sanofi-Aventis (Pvt.) Ltd
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
Name, address of drug	Tonghua Dongbao Pharmaceutical Co., Ltd.

substance manufacturer	Dongbao Xincun, Tonghua County, Jilin Province, China
Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The stability studies of three commercial batches of insulin Glargine GL201512007, GL201512008 and GL201512009 for 6 months at (2 - 8°C) under accelerated conditions and for 36 months at -20 ± 5°C under long term conditions have been completed. (Insulin Glargine is sensitive to temperature. The storage temperature of the drug substance is usually at below -15ºC. So, the accelerated test is conducted at between 2ºC to 8ºC)
Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
Container closure system of the drug product	Injection vials made of neutral borosilicate glass tube closed with a butyl rubber stopper and covered with an aluminium plastic combinatorial cap for antibiotic glass vial.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The real time stability study data is conducted at 5°C ± 3°C for 24 months.
Module-IV Non-Clinical	Firm has submitted toxicity studies
Module-V Clinical	Efficacy and Safety of Insulin Glargine Injection in the Treatment of Type 2 Diabetes Mellitus by Multi-centre, randomised, Open, Parallel and Lantus referenced Phase III Clinical Study with following conclusion: **Conclusion**

		The main efficacy indicator HbA1c, secondary efficacy indicator FPG and 2hr-GLU changes relative to baseline of Insulin Glargine Injection group and the Lantus □ group, all had no significant difference. The incidence of hypoglycemia of the two groups were also similar, clearly demonstrated that the Insulin Glargine Injection developed by Tonghua Dongbao Pharmaceutical Co., Ltd was equivalent in terms of safety and efficacy of the marketed innovator Lantus□. • Clarification for difference in address of importer in Form 5F, DSL & Sole agency agreement is required.

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and the clarification as per the remarks of evaluator.

144.	Name, address of Applicant / Importer	**Neutro Health Care**, 22-A, M, Gulberg III, Lahore- Pakistan
	Details of Drug Sale License of importer	License No: **05-352-0062-103478D** Address: Hazrat Ali Road Sagian ByPass Opp by Aligee Garments District Lahore. Validity: 28.03.2028
	Name and address of marketing authorization holder	**Neutro Health Care** 22-A, M, Gulberg III, Lahore- Pakistan
	Name, address of manufacturer(s)	**Tonghua Dongbao pharmaceutical Co. Ltd.,** Dongbao Xincun, Tonghua County, Jilin Province, China.
	Name of exporting Country	**China**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has attached CoPP No. **Jilin20220045** issued on 23rd August 2022, subject to inspection after two years.

	Firm has attached GMP Certificate No. **JL20190079** issued on 9th December 2019, issued by State Food and Drug Administration, China.
Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. **HWBA202201005** signed by both the parties.
Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No; 1749 Dated: **14th December 2023**
Details of fee submitted	Dy. No; N/A Rs: 150,000/- Dated: 01-12-2023 (Slip No. 55788413737)
The proposed proprietary name / brand name	Insulin Glargine Prefilled Pen 3ml
Strength / concentration of drug of Active Pharmaceutical ingredient	Each Prefilled Pen contains: 3ml solution for injection of Insulin Glargine……. Equivalent to 300 units (100units/ml)

(API) per unit	
Dosage form of applied	Injectable
Drug	
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin Analogues
Reference to Finished	USP Specifications
product specifications	
Proposed unit price	As per DPC
Shelf Life	30 Months
Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
The status in reference	Lantus SoloStar Prefilled Pen
regulatory authorities	300 Units/3ml (100units/ml) Sanofi Aventis U.S. LLC U.S. License No. 1752
For generic drugs (me-too	Lantus SoloStar Prefilled Pen.
status)	Sanofi-Aventis (Pvt.) Ltd
Module-II (Quality	Firm has submitted QOS as per WHO. Firm has summarized
Overall Summary)	information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
Name, address of drug	Tonghua Dongbao Pharmaceutical Co., Ltd.

substance manufacturer	Dongbao Xincun, Tonghua County, Jilin Province, China
Module-III Drug Substance:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The stability studies of three commercial batches of insulin Glargine GL201512007, GL201512008 and GL201512009 for 6 months at (2 - 8°C) under accelerated conditions and for 36 months at below -15ºC under long term conditions have been completed. (Insulin Glargine is sensitive to temperature. The storage temperature of the drug substance is usually at below -15ºC. So, the accelerated test is conducted at between 2ºC to 8ºC)
Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
Container closure system of the drug product	The insulin glargine injection, will be filled into a cartridge made of neutral borosilicate glass tubing, with a brominated butyl rubber plunger and an aluminum plastic cap.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The real time stability study data is conducted at 05°C ± 3°C for 36 months.
Module-IV Non-Clinical	Firm has submitted following: Single dose toxicity studies Repeat dose toxicity studies
Module-V Clinical	Firm has submitted Multicenter, randomisedized, open, parallel and positive drug controlled safety and efficacy studies in 578 subjects with following findings:

Insulin Glargine Injection group and the Lantus® group, the baseline at selection, body weight at 24th week, BMI, systolic blood pressure, diastolic blood pressure are basically similar; the two groups had no significant statistical difference after 24 weeks treatment.

The heart rate of Insulin Glargine Injection group and the Lantus® group at baseline selection and 24 weeks of treatment are similar; after 24 weeks of treatment, the average heart rate of the Insulin Glargine Injection group was 77.01 (8.62) beats/minute which decreased 0.69(9.29) beats/minute comparing to the baseline, the average heart rate of Lantus® group was 78.60 (9.21) beats/minute and increased 1.25(10.1) beats/minute comparing to the baseline, the heart rates of the two groups were in the normal range with good index, although there was a statistical significance between the two groups (P=0.034) but no clinical significance.

	Remarks of Evaluator	• Clarification for difference in address of importer in Form 5F, DSL & Sole agency agreement is required.

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and the clarification as per the remarks of evaluator.

145.	Name, address of Applicant / Importer	**M/s. Neutro Health Care**, 22-A, M, Gulberg III, Lahore-Pakistan
	Details of Drug Sale License of importer	License No: **05-352-0062-103478D** Address: Hazrat Ali Road Sagian ByPass Opp by Aligee Garments District Lahore. Validity: 28.03.2028
	Name and address of marketing authorization holder	**Neutro Health Care** 22-A, M, Gulberg III, Lahore- Pakistan
	Name, address of manufacturer(s)	**Tonghua Dongbao pharmaceutical Co. Ltd.,** Dongbao Xincun, Tonghua County, Jilin Province, China.
	Name of exporting Country	**China**
	Detail of certificates attached (CoPP, Free sale certificate, GMP	Firm has attached CoPP No. **Jilin20220041** issued on 23rd August 2022, subject to inspection after two years.

certificate)	Firm has attached GMP Certificate No. **JL20190079** issued on 9th December 2019, issued by State Food and Drug Administration, China.
Details of letter of authorization / sole agency agreement	Firm has attached sole Agency agreement No. **HWBA202201005** signed by both the parties.
Status of the applicant	☐Manufacturer ☒**Importer** ☐Is involved in none of the above (contract giver)
Status of application	☐New Drug Product (NDP) ☒**Generic Drug Product (GDP)**
Intended use of pharmaceutical product	☒**Domestic sale** ☐Export sale ☐Domestic and Export sales
For imported products, specify one the these	☒**Finished Pharmaceutical product import** ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	CTD Dossier Dy. No; 1747 dated 14 December 2023
Details of fee submitted	Rs: 150,000/- Dated: 01-12-2023 (Slip No. 561092563)
The proposed proprietary name / brand name	Regular Human Insulin (Recombinant) Vial 10ml
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: 10ml solution for injection of Regular Human Insulin….. equivalent to 1000 units (100units/ml)

Dosage form of applied Drug	Injectable
Pharma co therapeutic	Anti-Diabetic
Group of (API	Insulin Analogues
Reference to Finished product specifications	USP Specifications
Proposed unit price	As per DPC
Shelf Life	24 Months
Storage Conditions	- Store at 2 °C to 8 °C - Avoid freezing - Keep medicine out of reach of children
The status in reference regulatory authorities	Humulin R Vial 10ml. Eli Lilly and Company, Indianapolis, IN 46285, USA
For generic drugs (me-too status)	Humulin R Vial 10ml Elli Lilly and Company Ltd.,
Module-II (Quality Overall Summary)	Firm has submitted QOS . Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability
Name, address of drug substance manufacturer	Tonghua Dongbao Pharmaceutical Co., Ltd. Dongbao Xincun, Tonghua County, Jilin Province, China
Module-III Drug	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process,

Substance:	Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The stability studies of three commercial batches of human insulin for 6 months at (2 - 8°C) under accelerated conditions and for 36 months at -20°C± 5°C under long term conditions have been completed.
Module-III Drug Product:	Firm has submitted details drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Analytical method validation of Product	Firm has submitted analytical method validation report of insulin injection Assay.
Container closure system of the drug product	The Regular recombinant human insulin injection, will be filled into Insulin exclusive antibiotic vials made of neutral borosilicate glass, with a butyl rubber stopper for medical use and an aluminium plastic combinatorial cap for antibiotic glass vial
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The real time stability study data is conducted at 05°C ± 3°C for 24 months.
Module-IV Non-Clinical	Toxicity studies are submitted by the firm
Module-V Clinical	Firm has submitted single blinded, cross over Positive controlled safety and efficacy studies in 100 subjects with following conclusion:
Remarks of Evaluator	• Clarification for difference in address of importer in Form 5F, DSL & Sole agency agreement is required.

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and the clarification as per the remarks of evaluator.

146.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan**

	73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt
Details of Drug Sale License of importer	**License No:** 05-352-0068-029407D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 07.04.2027 **Status:** License to sell drugs as a distributor
Name and address of marketing authorization holder (abroad)	**M/s. VINS Bioproducts Limited, India** Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village, Kothur Mandal, Ranga Reddy District, Pin code 509325, Telangana State, India
Name, address of manufacturer (s)	**M/s. VINS Bioproducts Limited, India** Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village, Kothur Mandal, Ranga Reddy District, Pin code 509325, Telangana State, India
Name of exporting country	India
Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**Free Sale Certificate:** Firm has submitted copy of Free Sale Certificate (No. 110372/TS/2023) dated 10/02/2023 issued by Drugs Control Administration Government of Telangana for **Vinrab 1000 IU I.H.S.** **(5 mL liquid vial).** The Free Sale Certificate states that the product is **on free sale in exporting country**. **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (No. 104134/TS/2023) dated 04/01/2023 issued by Drugs Control Administration Government of Telangana valid until 03/01/2024.
Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **VINS Bioproducts Limited, India.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to register their products in Pakistan. The authorization letter is valid till 30th May, 2024.

Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No: 17340 Date of submission: 11-07-2023
Details of fee submitted	Rs: 150,000 Slip number: 267883909840 Dated :19/06/2023
The proposed proprietary name/ brand name	**Vinrab 1000 IU I.H.S.** **(5 mL liquid vial)**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Enzyme Refined, Equine Antirabies Immunoglobulin fragments Not less than ….200 IU
Pharmaceutical form of applied drug	Liquid for Injection
Pharmacotherapeutic Group of (API)	Immune sera and immunoglobulin- Equine Antirabies immunoglobulin ATC Code: J06AA06- Rabies serum

Reference to Finished product specifications	**I.H.S.**
Proposed Pack size	1's (5ml liquid vial)
Proposed unit price	Rs. 3500/Vial
Shelf Life	24 months (2 years)
Storage Conditions	The liquid Tetanus antitoxin should be stored at 2°C to 8°C. It should not be allowed to freeze.
The status in reference regulatory authorities	ANSM (France) Approved FAVIRAB by SANOFI PASTEUR
For generic drugs (me-too status)	**Reg. No:** 052223 **Company Name:** Hakimsons (Impex) (Pvt.)Ltd **Brand Name:** Equirab 1000 IU/5 ml **Formulation:** Anti-Rabies Serum (Equine) **Pack Size:** (1's pack)
Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	**VINS Bioproducts Limited** Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist., Telangana, India
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form,manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 5± 3°C for 24 months

Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
Container closure system of the drug product	**Glass Vial:** 5 mL flint 20mm moulded glass vials **Rubber stoppers :** 20 mm plain grey bromobutyl rubber stoppers **Flip off seals:** 20 mm aluminium flip off seals
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted at 5± 3°C the real time stability study data for 24 months as per ICH guidelines.
Module-IV Non-Clinical	2.6.6 Toxicology data is presented with title "Determination of potency of the Test Item Rabies Antiserum-1000 IU after administration Subcutaneously in Mice".
Module-V Clinical	5.3 Clinical Study Report is presented with title "Evaluation of the immunogenicity and safety of Equine Rabies Immunoglobulin in obese patients with WHO Rabies category III of exposure." The study was single centered, open labeled.
Remarks of Evaluator	• Evidence of ICH/WHO/EMA guideline that single dose and repeat dose toxicity is not required/ for this product. • Evidence of ICH/WHO/EMA guideline supporting open labeled clinical trial. • Finished product specifications in the light of decision of 267th Registration Board meeting. • What does I.H.S in Brand name Stands for?

Decision: The board after detailed deliberation decided to approve the product subject to current import policy of DRAP.

147.	**Name, address of Applicant/Importer**	**M/s Bristol Mayer Biotech Pakistan** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt.
	Details of Drug Sale License of importer	**License No:** 05-352-0068-029407D **Address:** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt **Address of Godown:** NA **Validity:** 07.04.2027 **Status:** License to sell drugs as a distributor
	Name and address of marketing authorization holder (abroad)	**M/s. VINS Bioproducts Limited, India** Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village, Kothur Mandal, Ranga Reddy District, Pin code 509325, Telangana State, India
	Name, address of manufacturer (s)	**M/s. VINS Bioproducts Limited, India** Office Address: 806, Essjay house, Road No.03, Banjara hills, Hyderabad-500034, Telangana, India. Site Address: Sy. No. 117, Thimmapur, Thimmapur Village, Kothur Mandal, Ranga Reddy District, Pin code 509325, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP , Free Sale certificate, GMP certificate)	**Free Sale Certificate:** Firm has submitted original, legalized copy of Free Sale Certificate (No. 110372/TS/2023) dated 10/02/2023 issued by Drugs Control Administration Government of Telangana for **Tetanus Antitoxin 1500 IU BP (1.0 ml liquid ampoule).** The Free Sale Certificate states that the product is **on free sale in exporting country**. **GMP Certificate:** Firm has submitted original, legalized copy of GMP certificate (No. 104134/TS/2023) dated 04/01/2023 issued by Drugs Control Administration Government of Telangana valid until 03/01/2024.
	Details of letter of authorization/sole agency agreement	Firm has submitted copy of letter of authorization from **VINS Bioproducts Limited, India.** The letter specifies that the manufacturer appoints M/s Bristol Mayer Biotech Pakistan to

	register their products in Pakistan. The authorization letter is valid till 30th May, 2024.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one of these	For imported products, specify one the these ☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No: 67341 Date of submission: 11-07-2023
Details of fee submitted	Rs: 150,000 Slip number: 1581129621 Dated :19/06/2023
The proposed proprietary name/ brand name	**Tetanus Antitoxin 1500 IU BP** **(1 ml liquid ampoule)**
Strength / concentration of drug of Active	Tetanus Antitoxin 1500 IU (1ml liquid ampoule)
Pharmaceutical ingredient (API) per unit	Each ml contains Enzyme Refined, Equine Tetanus Antitoxin Immunoglobulin fragments NLT 1500 IU
Pharmaceutical form of applied drug	Liquid for Injection

Pharmacotherapeutic Group of (API)	Immune sera and immunoglobulin- Equine Tetanus antitoxic immunoglobulin ATC Code: J06AA02-Tetanus antitoxin
Reference to Finished product specifications	B.P.
Proposed Pack size	Tetanus antitoxin is supplied as 1ml liquid in a glass ampoule.
Proposed unit price	Rs. 600/Ampoule
Shelf Life	24 months (2 years)
Storage Conditions	The liquid Tetanus antitoxin should be stored at 2°C to 8°C. It should not be allowed to freeze.
The status in reference regulatory authorities	ANSM (France) Approved TETANEA 1500 IU/ml by SANOFI PASTEUR
For generic drugs (me-too status)	**Reg. No:** 059003 **Company Name:** Hospital Services & Sales **Brand Name:** Tetanus Antitoxin 1500 IU **Formulation:** Each ml contains: - Tetanus Antitoxin….1500IU **Pack Size:** 1 Dose Amp /1ml
Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	**VINS Bioproducts Limited** Survey No.117, Thimmapur (V) Kothur (M), Rangareddy Dist., Telangana, India
Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions.

(Conditions & duration of Stability studies)	The accelerated stability data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability data is conducted at 5± 3°C for 24 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product
Container closure system of the drug product	2 ml USP Type – 1 Flint ampoule
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 25°C ± 2°C, RH 60 ± 5% for 6 months. The real time stability study data is conducted at 5± 3°C the real time stability study data as per ICH guidelines.
Module-IV Non-Clinical	Study Report for Toxicology (4.2.3) is presented with title "Determination of potency of the test item Tetanus Antitoxin-1500 IU after administration subcutaneously in Mice."
Module-V Clinical	Under 5.3 Clinical Study Report section, Report of Post-Marketing Experience (5.3.6) is presented with title "Safety of Equine Tetanus Antitoxin For Prophylactic Use In Ethiopia: A Multicenter Retrospective Study (TAT-Safe)". **Conclusion:** VINS Bioproducts Limited's equine tetanus antitoxin (TAT) is safe and well tolerated in adult patients with tetanus-prone wounds for prophylactic use in Ethiopia.
Remarks of Evaluator	• Evidence of ICH/WHO/EMA guideline that single dose and repeat dose toxicity is not required for this product. • Finished product specifications in the light of decision of 267th Registration Board meeting.

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and the clarification as per the remarks of evaluator.

Human Biological Local Manufacture:

148.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind , Lahore-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s BF Biosciences Ltd 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000655 Address: 5km Sundar Raiwind Road, Raiwind, Lahore-Pakistan Evidence of section: Parentals (Liquid & Lyophilized) For Biologicals & Non-Biologicals GMP: Last GMP conducted on 13-09-2023 valid up to 13-09-2025
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Manufacturing
	Dy. No. and Date of submission	Tracking.ID. XLQ-DAS-3RG1 / Serial No. 3313 Submission Date : 04-03-2024
	Details of fee submitted	PKR.30,030/- (Slip # 5516897862)
	The proposed proprietary name / brand name	**HEPRIN INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains Heparin Sodium …. 25000IU
	Pharmaceutical form of applied drug	Solution For Injection/Infusion (For Intravenous or Subcutaneous use)
	Pharmacotherapeutic Group of (API)	Antithrombotic agent ATC Code: B01AB01

	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Condition	Store below 30°C
	The status in reference regulatory authorities	Heparin Sodium Injection (B-Braun) FDA Approved
	For generic drugs (me-too status)	Hepagusan Injection (Searle Pakistan Limited)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	Hebei Changshan Biochemical Pharmaceutical Co., Ltd. No. 71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhending Area of China (Hebei) Pilot Free Trade Zone.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **i) For Bulk Concentrate Import/Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of	GMP Issue Dated : 11th June, 2019 GMP Certificate No. : HE20190057 Firm has submitted the GMP issued by : China

	biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Food and Drug Administration
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that COPP is not applicable since the product is not imported in finished form/Bulk. Applicant will be manufacturing finished product at their own facility from API.
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of drug substance at accelerated and real time conditions. The real time stability data is conducted at 30℃ ± 2℃ and 75%± 5% for 48 months, and the accelerated stability data is conducted Under 40℃ ± 2℃ and 75%± 5% for 6 months. Batch No: NHS151001 Batch No: NHS151002 Batch No: NHS151003
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Not Applicable**
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.

	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	N/A
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	6mL USP Type 1 clear glass vial
	Documents for the procurement of API with approval from DRAP	Submitted
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40±2°C, 75%±5% RH for 6 months. The real time stability study data is conducted at 30°C±3°C, 65%±5% for 6 months. Batch No. / Batch Size / Manufacturing date 040D02 / 200 vials / October-2023 040D03 / 2000 vials / October-2023 040D04 / 2000 vials / October-2023
	Module IV	Not Applicable
	Module V	Not Applicable
	Remarks By Evaluator	
	Decision: Approved	

Imported Human Biologicals from Reference Countries:

149.	**Name, address of Applicant / Importer**	M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E., Karachi.
	Details of Drug Sale License of importer	**License No: 008** **Address:** M/s GlaxoSmithKline Pakistan Limited F-268, S.I.T.E., Karachi **Address of Godown: -** **Validity:** 04-10-2024.

		Status: Drug License by way of wholesale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	**GlaxoSmithKline Biologicals SA** Rue de I'Institut 89, B-1330 Rixensart, Belgium
	Name, address of manufacturer(s)	**GlaxoSmithKline Biologicals SA** Rue de I'Institut 89, B-1330 Rixensart, Belgium
	Name of exporting country	Belgium
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Legalized CoPP issued by EMA confirming Free sale, EUDRA GMP certificate is submitted by firm,
	Details of letter of authorization / sole agency agreement	Letter of authorization from **GlaxoSmithKline Biologicals SA (MAH)** to **GlaxoSmithKline Pakistan Limited**
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	February 2nd, 2024,
	Details of fee submitted	**Deposit Slip no**. 31325019718 **PKR** 75,000: **Dated** 01-02-2024 62511744133 **PKR** 225,000: **Dated** 01-03-2024
	The proposed proprietary name / brand name	Shingrix
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	After reconstitution, one dose (0.5 mL) contains: Varicella Zoster Virus[1] glycoprotein E antigen[2,3] : 50 micrograms 1 Varicella Zoster Virus = VZV 2 adjuvanted with AS01B containing: plant extract Quillaja saponaria Molina, fraction 21 (QS-21) : 50 micrograms 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from Salmonella minnesota : 50 micrograms 3 glycoprotein E (gE) produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology
	Dosage form of applied drug	Intramuscular injection

	Pharmacotherapeutic Group of (API)	Vaccines, varicella zoster vaccines, ATC code: J07BK03
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's vial
	Proposed unit price	To be confirmed later
	Shelf life	3 Years
	Storage conditions	Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package in order to protect from light.
	The status in reference regulatory authorities	The product is registered by FDA, EMA, TGA and Health Canada etc.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	GlaxoSmithKline Biologicals SA Parc de la Noire Epine Avenue Fleming, 20 1300 Wavre Belgium
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• The storage of gE Purified Bulk batches at -45°C ± 10 °C for up to 74 months in PETG bottles closed with HDPE screw caps; • The stability of gE Purified Bulk batches under stress conditions (i.e. exposure for 7 days at +37°C ± 2°C); • The stability of gE Purified Bulk batches manufactured from WCB A4430W020B at -45°C +/- 10°C in PETG bottles closed with HDPE screw caps.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the PPQ batches demonstrate that the FDC drug product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and that the in-process tests are suitable to monitor the manufacturing process.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Powder for 1 dose in a vial (type I glass) with a stopper (butyl rubber) • Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber). • Shingrix is available in a pack size of 1 vial of powder and 1 vial of suspension
	Stability study data of drug product, shelf life and storage conditions	• Long-term stability studies (for up to 60 months at +2°C to +8°C); • Accelerated stability studies (for up to 193 days at +25°C ± 2°C and for up to 6 months at +37°C ± 2°C),
	Module-IV Non-Clinical	Submitted
	Module-V Clinical	Multicenter, Double blind, Phase III clinical trial (America, Australia, Canada) Submitted
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Case. No.150. M/s. Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector-27, Korangi, Industrial Area, Karachi for export purposes only.

M/s. Getz Pharma will bulk import labelled vials of ADALIMAB(adalimumab) solution for injection 40mg/0.8mL from M/s. Shangai Henlius Biopharmaceuticals Co., Ltd., situated at Building 1 (Building D) No. 1289 Yishan Road, Shangai, China for local Repacking at Getz Pharma (Pvt.) Ltd. facility situated at Plot No. 29-30, Sector-27, Korangi, Industrial Area, Karachi.

Requirements as per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML is provided.

GMP Status	GMP Inspection by FID dated 17.01.2023, concluded that firm is operating at good level of current GMP
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr. No.	**Name of Drug(s) with composition**	**RRA Status**	**Dy. No. /Fee with date**
I	**II**	**III**	**IV**
1.	**ADALIMAB (adalimumab) solution for injection 40mg/0.8mL** Each vial contains: Adalimumab …..... 40mg	Humira Solution for Injection 40mg/0.8mL (M/s AbbVie Inc., USA. USFDA Approved).	Dy No. 7894 R&I 20March 2020 Fee challan of Rupee 75000/-(Slip No., 1621789964) is submitted by firm

The application is evaluated and the following deficiencies are observed:

i. Evidence of section approval of required manufacturing facility is required.
ii. Either valid GMP certificate of Source of API or any web link of issuing authority to verify the GMP status of source of API is required.
iii. Either CoPP of finished product manufactured from applied bulk in country of origin or CoPP copy if it is confirmed from official website of issuing authority.

Decision: Registration Board Deferred the case for provision of the following:

i. **Evidence of section approval of required manufacturing facility.**
ii. **Either valid GMP certificate of Source of API or any web link of issuing authority to verify the GMP status of source of API.**
iii. **Either CoPP of finished product manufactured from applied bulk in country of origin or CoPP copy if it is confirmed from official website of issuing authority.**

151.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (Pvt) Ltd.,** **2nd Floor, Plaza 60, Commercial Block K, Phase-1 DHA, Lahore.** **Godown address: House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore**

	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Validity: 08-05-2028 Address of Godown: House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore Status: License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	**M/s Skymap Pharmaceuticals Pvt. Ltd.,** B-2 Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee-247667 Distt. Haridwar Uttarakhand India.
	Name, address of manufacturer(s)	**M/s Skymap Pharmaceuticals Pvt. Ltd.,** B-2 Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee-247667 Distt. Haridwar Uttarakhand India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	CoPP: The firm has submitted copy of CoPP (26/1/Drug/92/2019/19184) issued by Food Safety and Drug Administration Authority, Directorate General of Medical health & Family Welfare Uttarakhand, India. The certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 07-06-2025.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement from manufacturer abroad hereby authorizes M/s AMB HK Enterprises Pvt Ltd, Lahore to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Diary No. 17338, Dated: 11-07-2023
	Details of fee submitted	Rs: 150,000/- Dated: 10-07-2023 Deposit Slip No. 852401390

	The proposed proprietary name / brand name	Heparin Injection 5ml / 5000IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Heparin Sodium……..5000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	BP specifications
	Proposed Pack size	1 × 5 ml vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at a temperature not exceeding 30 °C.
	Reference Regulatory Authorities	Heparin sodium Injection, MHRA Approved.
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd. No. 71, Menglong street, South District of Zhengding High-Tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone P.R. China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches at long term conditions at 25℃ ± 2℃ / 60% RH ± 5% RH for 48 months. The accelerated stability data is
		conducted at 40°C±2℃ / 60%±5%RH for 06 months for accelerated conditions.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A colourless or straw coloured liquid free from turbidity filled from turbidity filled in 5ml light amber colour, tubular glass vials, plugged with 13mm bromo butyl rubber stopper and sealed with 13 mm white flip off.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Heparin Injection at accelerated and real time conditions. The real time stability data conducted at 30°C ± 2°C / 65% RH ± 5%RH for 24 months and accelerated stability data conducted at 40°C ± 2°C/75% RH ± 5%RH for 06 months for 3 batches. A20LV129 A20LV130 A20LV138
	Remarks of Evaluator	• Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin. • *Original, legalized CoPP issued by concerned authority of country of origin is required to be submitted.* • *Original / notarized copy of sole agency agreement is required to be submitted.*

Decision(M-332): Deferred for submission of following:

- *Legalized CoPP issued by concerned authority of country of origin.*
- *Original product specific sole agency agreement / Letter of Authorization.*
- *Legalized GMP certificate of drug substance manufacturer.*

Evaluation by BE&R Division:

Now the firm has submitted following documents:

- *Original Legalized CoPP issued by concerned authority of country of origin.*
- *Original product specific sole agency agreement / Letter of Authorization.*

• *Legalized GMP certificate of drug substance manufacturer.*		
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.		
152.	Name, address of Applicant / Importer	**M/s AMB HK Enterprises (Pvt) Ltd.,** 2nd Floor, Plaza 60, Commercial Block K, Phase-1 DHA, Lahore. Godown address: House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore
	Details of Drug Sale License of importer	License No: 05-352-0058-104514D Validity: 08-05-2028 Address of Godown: House 27, Street 4-A Sanda Bhatian Wala Gulshan Ravi, Lahore Status: License to sell drugs by way of whole sale.
	Name and address of marketing authorization holder (abroad)	**M/s Skymap Pharmaceuticals Pvt. Ltd.,**
		B-2 Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee-247667 Distt. Haridwar Uttarakhand India.
	Name, address of manufacturer(s)	**M/s Skymap Pharmaceuticals Pvt. Ltd.,** B-2 Dev Bhoomi Industrial Estate, Puhana Iqbalpur Road, Roorkee-247667 Distt. Haridwar Uttarakhand India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted copy of CoPP (26/1/Drug/92/2019/19184) issued by Food Safety and Drug Administration Authority, Directorate General of Medical health & Family Welfare Uttarakhand, India. The certificate confirm that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate is valid till 07-06-2025.
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement from manufacturer abroad hereby authorizes M/s AMB HK Enterprises Pvt Ltd, Lahore to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)

	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Diary No. 17339, Dated: 11-07-2023
	Details of fee submitted	Rs: 150,000/- Dated: 10-07-2023 Deposit Slip No. 8120832213
	The proposed proprietary name / brand name	Heparin Plus Injection 5ml / 25,000IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml vial contains: Heparin Sodium……..25000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Finished product specifications	BP specifications
	Proposed Pack size	1 × 5 ml vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at a temperature not exceeding 30 °C.
	Reference Regulatory Authorities	Heparin sodium Injection, USFDA Approved.
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd. No. 71, Menglong street, South District of Zhengding High-Tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone P.R. China.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches at long term conditions at 25℃ ± 2℃ / 60% RH ± 5% RH for 48 months. The accelerated stability data is conducted at 40°C±2℃ / 60%±5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	A colourless or straw coloured liquid free from turbidity filled from turbidity filled in 5ml light amber colour, tubular glass vials, plugged with 13mm bromo butyl rubber stopper and sealed with 13 mm white flip off.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Heparin Injection at accelerated and real time conditions. The real time stability data conducted at 30°C ± 2°C / 65% RH ± 5%RH for 24 months and accelerated stability data conducted at 40°C ± 2°C/75% RH ± 5%RH for 06 months for 3 batches. A20LV141 A20LV142 A21LV032
	Remarks of Evaluator	□ Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin

		Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin. *Original, legalized CoPP issued by concerned authority of country of origin is required to be submitted.* *Original / notarized copy of sole agency agreement are required to be submitted.*

Decision(M-332): Deferred for submission of following:

- *Legalized CoPP issued by concerned authority of country of origin.*
- *Original product specific sole agency agreement / Letter of Authorization.*
- *Legalized GMP certificate of drug substance manufacturer.*

Evaluation by BE&R Division:

Now the firm has submitted following documents:

- *Original Legalized CoPP issued by concerned authority of country of origin.*
- *Original product specific sole agency agreement / Letter of Authorization.*
- *Legalized GMP certificate of drug substance manufacturer.*

Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.

153.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt) Ltd., Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan Lahore.
	Details of Drug Sale License of importer	**License No**: 05-352-0065-016174D **Validity**: 06-02-2024 **Address of Godown:** Ground Floor, 6-Judicial Colony, Phase 1 (Ext.) Shahrah Nazaria e Pakistan Lahore. **Status**: License to sell drugs as a distributor. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited., Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited., Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (DA/6-110/2016/13527) dated 19-07-2023 issued by Ministry of Health & Family welfare, Directorate General of Drug Administration, Dhaka. The CoPP confirms free sale status of the product in exporting country as well as GMP status as recommended by the World Health Organization.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Beacon Pharmaceuticals limited. The letter specifies that Himmel Pharmaceuticals (Pvt) Ltd.,

		Pakistan is an authorized agent of Beacon Pharmaceuticals Limited to register and sell the product in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	(R&I) Dated 00-00-2023
	Details of fee submitted	Rs. 150,000/- Dated 15-08-2023
	The proposed proprietary name / brand name	Eptase Injection 15,00,000 IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Streptokinase BP…..….15,00,000 Units
	Dosage form of applied drug	Lyophilized powder for Injection
	Pharmacotherapeutic Group of (API)	Fibrinolytic agent
	Finished product specifications	BP Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO/DPC
	Shelf life	24 months
	Storage conditions	2 - 8 °C.
	The status in reference regulatory authorities	Icikinase of Abbott, USA Streptase of CSL Behring, Germany
	For generic drugs (me-too status)	Diclair-ST of Gene-Tech pharma
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Levim Biotech LLP, Ticel Biopark Ltd., Phase –II, 501-505, CSIR Road , Taramani Chennai.
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of following 3 batches of drug substance conducted at 5 ± 3°C for 24 months: RSKFB16001 RSKFB16003 RSKFB16005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	• Glass vials • Rubber stopper • Flip off seal
	Stability study data of drug product	Firm has submitted stability study data of 3 batches is conducted at 2 °C to 8 °C for 24 months. 1030001 1030002 1030003
	Non-clinical (Module-IV)	The firm has submitted following: "*The active material of Eptase Injection is Streptokinase which is a Generic product and a well-established existing substance or molecule. Pharmacology, Pharmacokinetics and toxicology profile of Finished Products is pre-set and well defined. That is why this part of the module is not necessary*."
	Clinical (Module-V)	Not applicable.
	Remarks of evaluator	• The submitted copy of DSL was valid till 06.02.2024. • The firm has submitted copy of sole agency agreement. • The firm has not submitted clinical and non-clinical studies for applied product. • The firm has not submitted Bio similarity data as per WHO guidelines.
	Previous Decision(M-336): Registration Board deferred the case for submission of the following: **i. Valid copy of DSL** **ii. Original or notarized copy of sole agency agreement.** **iii. Module IV (safety studies) Module V(Efficacy studies)/Bio similarity data as per WHO guidelines.**	
Evaluation by BE&R Division: Firm has submitted following:		

a. Copy of DSL valid till 06.02.2024
b. Copy of sole agency agreement.
c. Non clinical by Levim Biotech, India.
d. Clinical trial data by Levim Biotech, India with following conclusion:
From the result obtained It can be concluded that Streptokinase A can establish Reperfusion without any unexpected side effects and is equivalent to Stretase in all efficacy and safety parameters analysed. Based on the results and the need for cost effective thromobolytics such as streptokinase in our country where the cost of alternative choices of thromobolysis/reperfusion stretgies is prohibitive, streptokinase-A will be beneficial to our people.

From the data submitted by the firm it is not clear that this data is for the Eptase Injection of M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh.

Decision: Registration board decided to defer the case for clarification as per the remarks of the evaluator that *From the data submitted by the firm it is not clear that this data is for the Eptase Injection of M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh, Bangladesh*

154.	**Name, address of Applicant / Importer**	**M/s Cure Life Pharma (Private) Limited** Address: House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School).
	Details of Drug Sale License of importer	M/s Cure Life Pharma (Private) Limited, House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School).
	Name and address of marketing authorization holder (abroad)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name, address of manufacturer(s)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name of exporting country	INDIA
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Free Sale & GMP: The applicant has attached legalized copy of free sale certificate No. 105946/TS/2023 valid until 13-02-24 and legalized GMP certificate No. 98352/TS/2022 valid till 17-10-2023 issued by the Drug Control Administration of Govt. of Telangana, India
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from the marketing authorizer abroad hereby authorizes M/s Curelife Pharma (Private) Limited to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.889 and date 12-10-2023
	Details of fee submitted	Rs. 150,000/- Dated 03/10/2023 Fee Challan Number 388344972
	The proposed proprietary name / brand name	Stanhep-5
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium…….1000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Heparin Sodium injection comes under the category of anticoagulant which is indicated for both the prevention and treatment of thrombotic events such as deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as atrial fibrillation (AF). Heparin is also used to prevent excess coagulation during procedures such as cardiac surgery, extracorporeal circulation, or dialysis, including continuous renal replacement therapy.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's x 5mL vial
	Proposed unit price	Retail price as per SRO
	Shelf Life	24 months
	Storage Conditions	Store below 30 ^{O}C
	The status in reference regulatory authorities	Heparin Sodium Solution for injection 1000IU/ml is Registered in the country of the origin Spain. Drug Name: HEPARIN SODIUM, API: HEPARIN SODIUM, Strength: 10,000 IU/ml. Dosage Form: INJECTABLE; INJECTION, Company Name: FRESENIUS KABI USAHeparin Injection 5000 IU/5ml of M/s Leo, Heparin Sodium Injection, USFDA approved.
	For generic drugs (me-too status)	Heparin Injection 5000 IU/5ml of M/s Leo/Zam Zam Pharma
	Module-II (Quality Overall Summary)	The applicant has submitted the Quality Overall Summary in accordance with WHO. The information has been summarized related to nomenclature, structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications analytical procedures, batch analysis and justification of specifications, reference standard, container closure system stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	**M/s Gland Chemicals Pvt Limited.** Manufacturing Address: Fact.No,30A, IInd Phase, KIADB Industrial

		Area, Malur-563160, Kolar Dist, Karnataka INDIA
	Module-III Drug Substance:	The applicant has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specifications, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The applicant has submitted stability data of 3 batches at long term conditions at $25^{O}C \pm 2^{O}C$ / 60% RH ±5% for 12 months. The accelerated stability data is conducted at $40^{O}C \pm 2^{O}C$ / 75% RH ±5% for 06 months.
	Module-III Drug Product:	The applicant has submitted the data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	The applicant has submitted the details of analytical method validation.
	Container closure system of the drug product	Standard pack size of Heparin Sodium is 500 MU. Heparin Sodium is packed in the Low-density polythene bag. The sealing is done thermally by a machine. The sealed bag is kept in HDPE drums
	Stability study data of drug product, shelf life and storage conditions	The applicant has submitted study data of 3 batches of heparin injection at accelerated and real time conditions. The real time stability data is conducted at $30^{O}C \pm 2^{O}C$ / 65% RH ±5% for 24 months and accelerated stability data is conducted at $40^{O}C \pm 2^{O}C$ / 75% RH ±5% for 06 months
	Remarks	Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.

Decision (M-324): Keeping in view valid Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized GMP Certificate before issuance of Registration Letter.

Product Specific Inspection for grant of Registration as per letter No. F.No.115/2016-AD (BD)(M-334) dated 9th May 2024 has been carried out by following panel:

i. Dr. Sayed Zia Husnain (Additional Director, CALSD), DRAP, Islamabad.
ii. Ms. Haleema Sharif (Deputy Director, BE&R), DRAP, Islamabad.

The conclusion of the inspection report is as under:

GENERAL REMARKS: *Based on virtual inspection conducted, documents reviewed, virtual interview of the management and technical person conducted, panel of inspectors is of the view to* ***not recommend*** *the facility of M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India for product specific Inspection, due to following reason.*

The building is not completely dedicated and self-contained regarding the manufacturing of biological product as required in section 5.2 of schedule B of Drugs (Licensing, Registration & advertising) rules 1976 as the only one production line exists in the factory and being used for production of biological and non-biological products. Facility also share common ware house for storage of Biological (Heparin) and non-biological Pharmaceutical raw materials.
On other hand firm claimed that in India Biological product like Heparin and Non-Biological products can be manufactured in same non dedicated facility and their products are also being exported to various countries. Hence stance of the firm is also submitted for perusal of Registration Board as per policy and respective provisions of law.

Decision: The registration board on the recommendations of panel as per its inspection report decided to reject the application.

155.	**Name, address of Applicant / Importer**	**M/s Cure Life Pharma (Private) Limited** **Address:** House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School)
	Details of Drug Sale License of importer	M/s Cure Life Pharma (Private) Limited, House No-283-B, Block ,Johar Town Lahore,Ground Floor.(Near Kips School)
	Name and address of marketing authorization holder (abroad)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name, address of manufacturer(s)	M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India.
	Name of exporting country	INDIA
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Free Sale & GMP: The applicant has attached legalized copy of free sale certificate No. 105946/TS/2023 valid until 13-02-24 and legalized GMP certificate No. 98352/TS/2022 valid till **17-10-2023** issued by the Drug Control Administration of Govt. of Telangana, India
	Details of letter of authorization / sole agency agreement	Copy of product specific sole agency agreement from the marketing authorizer abroad hereby authorizes M/s Curelife Pharma (Private) Limited to act as authorized representative to conduct all the formalities related to import, sell, distribute in the territory of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.890 and date 12-10-2023
	Details of fee submitted	Rs. 150,000/- Dated 03/10/2023 Fee Challan Number 9257019722
	The proposed proprietary name / brand name	Stanhep-25
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Heparin Sodium……..5000 IU
	Dosage form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Heparin Sodium injection comes under the category of anticoagulant which is indicated for both the prevention and treatment of thrombotic events such as deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as atrial fibrillation (AF). Heparin is also used to prevent excess coagulation during procedures such as cardiac surgery, extracorporeal circulation, or dialysis, including continuous renal replacement therapy.
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	1's x 5ml vial
	Proposed unit price	Retail price as per SRO
	Shelf Life	24 months
	Storage Conditions	Store below 30 ^{O}C
	The status in reference regulatory authorities	Heparin Sodium Injection, USFDA approved.
	For generic drugs (me-too status)	Heparin-Indar, 5000IU/ml, Reg. No. 107981, Heparin Injection 25000 IU/5ml of M/s Leo/Zam Zam Pharma
	Module-II (Quality Overall Summary)	The applicant has submitted the Quality Overall Summary in accordance with WHO. The information has been summarized related to nomenclature, structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, impurities, specifications analytical procedures, batch analysis and justification of specifications, reference standard, container closure system stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	**M/s Gland Chemicals Pvt Limited.** Manufacturing Address: Fact.No,30A, IInd Phase, KIADB Industrial Area, Malur-563160, Kolar Dist, Karnataka INDIA

	Module-III Drug Substance:	The applicant has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specifications, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The applicant has submitted stability data of 3 batches at long term conditions at $25^{O}C \pm 2^{O}C$ / 60% RH ±5% for 12 months. The accelerated stability data is conducted at $40^{O}C \pm 2^{O}C$ / 75% RH ±5% for 06 months.
	Module-III Drug Product:	The applicant has submitted the data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	The applicant has submitted the details of analytical method validation.
	Container closure system of the drug product	Standard pack size of Heparin Sodium is 500 MU. Heparin Sodium is packed in the Low-density polythene bag. The sealing is done thermally by a machine. The sealed bag is kept in HDPE drums
	Stability study data of drug product, shelf life and storage conditions	The applicant has submitted study data of 3 batches of heparin injection at accelerated and real time conditions. The real time stability data is conducted at $30^{O}C \pm 2^{O}C$ / 65% RH ±5% for 24 months and accelerated stability data is conducted at $40^{O}C \pm 2^{O}C$ / 75% RH ±5% for 06 months
	Remarks	Non- clinical and Clinical trial data are not submitted by the firm. The same is not required as Registration Board in its 271st meeting considered that Heparin Sodium Injection is non-rDNA pharmacopoeial product hence, revised its decision of 260th meeting and granted the approvals on the basis of valid legalized CoPP & availability in country of origin.

Decision(M-334): Keeping in view valid Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized GMP Certificate before issuance of Registration Letter.

Product Specific Inspection for grant of Registration as per letter No .F.No.115/2016-AD (BD)(M-334) dated 9th May 2024 has been carried out by following panel:

iii. Dr. Sayed Zia Husnain (Additional Director, CALSD), DRAP, Islamabad.
iv. Ms. Haleema Sharif (Deputy Director, BE&R), DRAP, Islamabad

The conclusion of the inspection report is as under:

GENERAL REMARKS: *Based on virtual inspection conducted, documents reviewed, virtual interview of the management and technical person conducted, panel of inspectors is of the view to* ***not recommend*** *the facility of M/s Stanex Drugs & Chemicals PVT. LTD Address: 112, IDA, Phase-3, Cherlapally.500051. TS, Cherlapally Village, Kapra Mandal, Medchal- Malkajgiri District, Telangana State, India for product specific Inspection, due to following reason.*

The building is not completely dedicated and self-contained regarding the manufacturing of biological product as required in section 5.2 of schedule B of Drugs (Licensing, Registration & advertising) rules 1976 as the only one production line exists in the factory and being used for production of biological and non-biological products. Facility also share common ware house for storage of Biological (Heparin) and non-biological Pharmaceutical raw materials.
On other hand firm claimed that in India Biological product like Heparin and Non-Biological products can be manufactured in same non dedicated facility and their products are also being exported to various countries. Hence stance of the firm is also submitted for perusal of Registration Board as per policy and respective provisions of law.

Decision: The registration board on the recommendations of panel as per its inspection report decided to reject the application.

Case No. 156: Case for Deregistration of Products Recormon 2000 Injection, Mircera Injection 150mcg PFS, Mircera Injection 200mcg PFS

M/s Roche Pakistan Limited, Karachi has applied for de-registration of their following registered products:

Sr. No.	Reg. No. & Date	Brand Name & Composition	Justification
i.	**019576** Date of Reg. 14-07-1997	**Recormon 2000 Injection** Each vial contains: Epoctin beta (Human erythropientin)….2000IU	• Recormon 2,000IU PFS has been streamlined by our principal, Hoffmann-La Roche Ltd., Basel, Switzerland. As a result, it will no longer be supplied. • There is no market demand for the 2,000IU strength of Recormon, However, the other strengths of Recormon, including 5,000 IU and 10,000IU, are still registered and marketed to cater the demand of patients if needed. • Recormon is indicated for the treatment of anemia associated with chronic renal failure (renal anemia) in patients undergoing dialysis, Epotin Alfa, an alternate product with same therapeutic value, is available in the market for this indication. Therefore, the deregistration of Recormon 2,000IU is not expected to cause a product gap in the market.
ii.	**059049** Date of Reg.	**Mircera Injection 150mcg PFS** Each 0.3ml contains:	• Mircera (Methoxy Polyethylene Glyycol-Epoetin Beta) injections 150mcg and 200mcg PFS have been streamlined by our principal, Hoffmann-La Roche Ltd.,

	02-09-2009	Methoxy polyethylene glycol-epoetin beta ……. 150mcg	Basel, Switzerland. As a result, it will no longer be supplied. • There is no market demand for the 150mcg and 200mcg strengths of Mircera. However, we have alternatives in the form of 100mcg and 50mcg strengths of Mircera, which can be used in combination if required.
iii.	**059048** Date of Reg. 02-09-2009	**Mircera Injection 200mcg PFS** Each 0.3ml contains: Methoxy polyethyleneglycol-epoetin beta ……. 200mcg	• Mircera (Methoxy Polyethylene Glyycol-Epoetin Beta) injections 150mcg and 200mcg PFS have been streamlined by our principal, Hoffmann-La Roche Ltd., Basel, Switzerland. As a result, it will no longer be supplied. There is no market demand for the 150mcg and 200mcg strengths of Mircera. However, we have alternatives in the form of 100mcg and 50mcg strengths of Mircera, which can be used in combination if required.

The firm has enclosed the following documents:

1. Copy of registration letter and last renewal.
2. Justification letter.
3. Undertaking that applied information is correct.
4. Fee deposit slip of Rs.7530/-.

Decision: The Registration Board after detail deliberations decided to call the applicant for personal hearing

156.	**Name, address of Applicant / Importer**	M/s. Immunowell (Pvt) ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Details of Drug Sale License of importer	**License No.**05-352-0066-100098D **Address**: 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan **Validity:**17-Nov-2027
		Status: License to sell, stock & exhibit for sale, distributor registered products on behalf of licensed pharmaceuticals manufacturer as his authorized agent on the premises
	Name and address of marketing authorization holder (abroad)	M/s. Immunowell (Pvt) Ltd, No. 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan
	Name, address of manufacturer(s)	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economic and Technological Development Zone, Heilongjiang Province, China.

	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted original, Legalized CoPP (No. Heilongjiang 20220023) issued on 21-06-2022, valid upto 20-062024, issued by Heilongjiang Medical Products Administration, China. Legalized GMP Inspection Report issued by Heilongjiang Medical Products Administration, China.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific with brand name Globin Well I.V. inj letter of Authorization, from Harbin Pacific Biopharmaceutical Co., Ltd according to the letter, M/s. Harbin Pacific Biopharmaceutical Co., Ltd appoints Immunowell (Pvt) Ltd with address 473, Street No. 7, Block J-2, Johar Town, Lahore, Pakistan It's representative for sole purpose of registration of the said product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. Dated: 02-Jan-2022

	Details of fee submitted	Rs.150, 000/- slip No.029922813 dated: 29-12-2022
	The proposed proprietary name / brand name	**Globin Well I.V. inj.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Immunoglobulin(pH4) for intravenous Injection(IVIG) IgG….. 2.5gm.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Intravenous Immunoglobulin
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	2.5gm/50mL Vial
	Proposed unit price	Rs. 38,398/Vial
	Shelf Life	36 months
	Storage Conditions	$2^{O}C$ - $8^{O}C$
	The status in reference regulatory authorities	Gamimune 5% (Immune Globulin Intravenous) Approved by USFDA.
	For generic drugs (me-too status)	I.V. Globulin SN Injection registered in Pakistan.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to introduction, nomenclature, structure, general properties, solubility, physical form, Manufacture: manufacturers, description of manufacturing process and controls, controls of materials, control of critical steps and intermediates, process validation and /or evaluation, manufacturing process development, Elucidation of structure and other characteristics, impurities, specifications, Analytical procedures and its validation, batch analysis, justification of specification , reference standard or materials, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its Description and composition of the drug product, pharmaceutical development, manufacture, batch formula, description of manufacturing process and process control, control of citical steps and intermediates, process evaluation and/or evaluation, control of excipients, control of drug product, specifications, analytical procedures and its validation, batch analysis, characterization of impurities and justification of specification, reference standard, container closure system and stability studies of drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s. Harbin Pacific Biopharmaceutical Co., Ltd No.77, Siping Road, Limin Economicand Technological Development Zone, Heilongjiang Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and process controls. control of materials, control of critical steps and intermediates, Process Validation and/or evaluation, manufacturing process development, characterization, impurities and Elucidation of structure and other characteristics, control of Drug Substance: specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Bulk solution of human immunoglobulin for intravenous injection is a transitional phase, so the stability studies are inapplicable.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, & composition of the drug product, pharmaceutical development, manufacturer, batch formula, description of manufacturing process and process control, control of critical steps and intermediates, process validation and/or evaluation, control of excipients, control of drug product: specifications, analytical procedures, validation of analytical procedures, batch analysis, characterization of impurities, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical methods as per in House Specs. Validation of analytical procedures, process validation, batch analysis and stability studies have been performed.
	Container closure system of the drug product	Injection vial made of molecule middle borosilicate glass, halogenated butyl rubber stopper for injection (brominated) and aluminum-plastic combination cap.
	Stability study data of drug product, shelf life and storage conditions	The studies are performed according to the current ICH stability guidelines. The studies cover long term storage conditions (2°C - 8°C) for 36 months and accelerated storage conditions (25°C±2°C) 60%±5% RH for 6 months. Based on the results from the long term and accelerated stability studies, the proposed shelf life of 36 months at 2°C ± 8°C
	Module-IV	Not submitted
	Module-V	Not submitted

	Remarks	Firm has not provided stability studies of drug substance with this justification that drug substance stability data is not required in china. Firm has not provided safety and efficacy data with this justification that brands like Gamarrass, HL Globin and our product are being used in china from decades and their safety and efficacy is established for many decades. So Module IV and V are exempted.

Decision in 334th RB meeting:

Registration Board deferred the product for the following:

For submission of Stability studies data of drug substance/evidence of ICH guideline indicating no requirement of stability data for this substance.

For submission of safety and efficacy studies of applied formulation/ evidence of ICH guideline indicating no requirement of safety and efficacy data for applied formulation.

Response of firm:

1. Module IV and Module V have not been submitted.

Answer: As per "Form 5-F" and "Guidance document for submission of application on Form 5F(CTD) for registration of Pharmaceutical Drug for Human Use" Module IV and Module V are optional., please find attached the Page No.39 of same Guidance. As per these guidance:

Module 4: (Non-clinical/ Safety)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 4 is optional.

Module 5: (Clinical/ efficacy)

For all drug products which are approved in the same combination, strength and dosage form by reference regulatory authorities adapted by Registration Board, the submission of documents in module 5 is optional".

Competitors of our product with same combination, strength and dosage form are already registered in all reference countries and with DRAP in many brands.

Therefore, on the basis of above explanations you are requested to include our Product Globin Well I.V. Inj. In upcoming Registration Board Meeting for the approval.

Decision in 336th RB meeting:

Registration Board after detailed deliberations deferred the product for submission of required data as per evaluator remarks.
Response of firm: Firm has submitted following: i. Globin well is registered and available in country of origin. ii. Registered in India from 01-07-2011 to 30-06-2014 as per copy of Registration certificate submitted by the firm.
Decision: The Registration Board deliberated that the matter in detail and decided to ask the firm to submit the following: • **Safety and Efficacy data of the product.** **OR** • **The guidelines from country of origin on the basis of which the product was approved.** • **Periodic Safety Update Report (PSUR) of last 5 years from countries where product has valid market authorization**

Case No 158: Exemption of Inspection of manufacturing facility Abroad.

Firm "M/s. Bristrol Mayer Biotech Pakistan" for exemption of inspection of manufacturer abroad (India) for product approved in 334th RB meeting as the subject manufacturer has GMP certificate issued by Poland and a Weblink that subject products are approved by Authority of Malaysia (PIC/s Participating Authority). Firm has also submitted fee of Rupee 7500/- for each product (slip No. 23404137324, 82866414, 45796706, 97377701030).

In the above context, it is submitted that following products of M/s. Bristrol Mayer Biotech Pakistan for the registration of following Human biological was received in BE&R division as per following details:

Sr. No.	Brand Name & Composition	Name of Manufacturer	Decision of Board (M-334)
1.	Endogen HP 75 IU	M/s. Sanzyme (P) Limited Plot No.8, Sy.No. 542, Koltur (V), Shamirpet (M), MedchalMalkajgiri (D) - 500101, Telangana State, India	Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.
2.	Endogen HP 150 IU		
3.	Pubergen HP 1000 IU		
4.	Pubergen HP 2000 IU		

In the above case, it is submitted that firm has submitted copy of EUDRA GMDP issued to the manufacturer "M/s. Sanzyme (P) Limited" based upon the inspection 28-04-2017 which was valid for the period of three years & "Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024".

However, from the EUDRA GMP it is also observed that certificate is not issued to firm for **Biological Section** rather it is issued for following **pharmaceutical sections** (as mentioned under heading of manufacturing operations) only:

Human Medicinal Products
1 MANUFACTURING OPERATIONS
1.1 Sterile products
1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)* 1.1.2.3 Small volume liquids
1.6 Quality control testing

It is further submitted that firm has also submitted a Weblink:

(https://quest3plus.bpfk.gov.my/pmo2/index.php) that subject products are approved by Authority of Malaysia (PIC/s Participating Authority). The database of authority of Malaysia is assessed by clicking on the above mentioned link and by searching with name of product however approval of above products has not been verifiable.

For the purpose of clarification, a letter was issued on 3rd July, 2023 & a meeting was also held with the Technical person of the firm on 29.07.2024. The technical person of the firm informed following.

Follicle stimulating hormone by M/s. sanzyme is registered in Malaysia as Sanzyme FSH. In Pakistan it will be marketed by the Brand Name Endogen HP.

i. Pubergen HP 1000 IU & Pubergen HP 2000 IU is not registered but other strengths like Pubergen 10000IU, 7500IU, 5000IU.
ii. The representative of the firm further informed that facility of M/s. Sanzyme is completely dedicated for production of Biologicals like Gonadotropins & Hormones etc.

Decision: Registration Board after detailed deliberation decided that Virtual GMP inspection will be conducted as per current import policy of DRAP.

CASES OF DD-IV (Ms. ANUM SAEED)

Imported Human Biologicals from Non-Reference Countries:

159.	Name, address of Applicant / Importer	M//s GENETECH LABORATORIES, 246-B, Block-6, PECHS, Karachi.
	Details of Drug Sale License of importer	License No: 10725 Address:

		246/B, Block-6, PECHS, Karachi Validity: Status: License to sell drugs by way of Whole sale.
	Name and address of marketing authorization holder (abroad)	M/s Hualan Biological Engineering Chongqing Co., Ltd, No.66, Hefang Road, Fuling Chongqing, China.
	Name, address of manufacturer(s)	M/s Hualan Biological Engineering Chongqing Co., Ltd, No.66, Hefang Road, Fuling Chongqing, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**CoPP:** The firm has submitted original, legalized CoPP (Certificate NoChongqin20190019) by Congqing Municipal Drug Administration, No.27 Shipincheng Road Yubei District, Chongqing, China. The certificate confirms that the product is actually on the market in the exporting country and facilities and operations conform to GMP as recommended by WHO. The certificate was valid till 21-12-2020.
	Details of letter of authorization / sole agency agreement	A copy of product specific Contract for International Sales of Goods which was expired in August 2023.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	R&I(DRAP) Dy.No.28710 dated 31-12-2019
	Details of fee submitted	PKR 100000/- dated 26-12-2019 Deposit Slip No.2018041
	The proposed proprietary name / brand name	IVI-GEN
	Strength / concentration of drug of Active	Each 50ml vial contains; Human Immunoglobulin (pH4)…….2.5g (5%)

	Pharmaceutical ingredient (API) per unit	
	Dosage form of applied drug	Human Immunoglobulin (pH4) for Intravenous Injection
	Pharmacotherapeutic Group of (API)	Human Immunoglobulin
	Finished product specifications	Chinese Pharmacopoeia Volume III (2015)
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	Store at 2°C – 8°C
	Reference Regulatory Authorities	
	For generic drugs (me-too status)	• Human Immunoglobulin for IV Injection (Reg.No.033122) of 3A Diagnostics. • Gammaraas (Reg.No.031350) of Raas Pharma. • Higlobin I.V.2.5GM (Hi-Warble Pharmaceuticals pvt. ltd) Mfg. by Shanghai Institute of biological products China • Reg. no 045723 • Intraglobin Inj. (Nabiqasim) Mfg. by Biotest Pharma Germany Reg. no. 028408
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, manufacturers, Characterization, impurities, specifications, and justification of specification. Stability of Drug Substance is not provided rather the manufacturer gave the statement that the bulk produced by the manufacturer is directly put into production of finished product continuously and is not stored. So stability related study is not performed on bulk.
	Name, address of drug substance manufacturer	M/s Hualan Biological Engineering Chongqing Co., Ltd, No.66, Hefang Road, Fuling Chongqing, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, impurities, specification, batch analysis and justification of specification.
	Stability Studies of Drug Substance	Stability of Drug Substance is not provided rather the manufacturer gave the statement that the bulk produced by the manufacturer is directly put into production of finished product continuously and is not stored. So stability related study is not performed on bulk.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, batch analysis, justification of specifications, container closure system and Stability.
	Analytical method Validation / verification of the product	The specifications & analytical procedures are submitted along with validation of Analytical Procedures.
	Container closure system of the drug product	The primary container closure system is neutral borosilicate glass vial and bromobutyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of FPP at accelerated and real time conditions. The real time stability data is conducted at (6±2°C) for 36 months on 3 batches. Accelerated is conducted at (25°C±2°C/60%±10%RH) for 6 months on 3 batches of FPP.
	Module-IV Non-Clinical	The firm has not submitted the Toxicology, genotoxicity, Carcinogenicity data rather gave the justification that in toxicology study, immunoglobulin is a normal component of human body. In animals, single dose toxicity tests are not appropriate because overdose will cause overloading; repeat dose toxicity tests and embryo lethal toxicity studies do not have any practical significance because of the interference of antibodies. The study does not find that the product has effects on the neonatal immune system. Because there is no immunoglobulin, tumorigenesis and mutagenesis in clinical experience, it is not necessary to study the carcinogenesis and mutagenesis in clinical experience, it is not necessary to study the carcinogenesis of the product, especially the study on heterologous organisms.
	Module-V Clinical	The firm has not submitted the clinical data.
	Remarks of Evaluator	COPP was valid till December 2020. Original of notarized LOA is required. Previously copy of LOA was provide with the dossier which was expired on August 2023. Description of manufacturing process of drug substance is not provided under Module 2. The product is available in European pharmacopoeia and USP but the manufacturer has developed the product as per Chinese Pharmacopoeia. Detail of number of plasma donors of human plasma, plasma collection and tests conducted along with specifications followed is required. Protein composition by Zone Electrophoresis is not conducted in method of analysis. B-19 NAT testing in detail required as the product is plasma derived. Virus removal/inactivation procedure is not provided.

		Summary of product Characteristics is not attached in dossier. IgA residue test is not mentioned in method of anlysis. Monograph of standard pharmacopoeia to be followed is required. DSL is not provided. COA not attached. Complete tests are not performed in stability studies as mentioned in method of analysis. Module 5 i.e. Clinical data is not provided.
Decision: Registration board decided to defer the application for clarification of all points mentioned in remarks of Evaluator.		

Imported Human Biologicals from Non-Reference Countries:

160.	Name of Importer	Hilton Pharma (Pvt.) Ltd. Plot 13-14 & 43, Sector 15, Korangi Industrial Area Karachi.
	DSL details	License to sell drug as distributor valid till Jun-2024
	Name of Manufacturer	M/s PT. Medion Farma Jaya
		Address:
		Office : JI. Babakan Ciparay No. 282, Babakan Ciparay, Bandung-Indonesia
		Plant : JI. Raya Batujajar No. 29, Cimareme, Ngamprah , Bandung Barat-Indonesia
	Brand Name+ Dosage Form+ Strength	Medivac ND G7-EDS-IB Emulsion
		Inactivated emulsion vaccine for poultry
	Composition	Each dose contains:
		Inactivated Newcastle Disease virus MD15 strain, at least $10^{7.0}$ EID_{50},
		Inactivated Adenovirus 127 virus, Mc Ferran strain at least 1000 HA unit,
		Inactivated Infectious Bronchitis virus, Massachusetts 41 strain, at least $10^{4.5}$ EID_{50}
	Finished product specifications	Innovator's Specifications
	Pharmacological Group	Inactivated emulsion vaccine
	Shelf life	18 Months (2-8°C)

International availability	Not provided
Products already registered in Pakistan	The combination of all these strains is not registered before.
Type of Form	Form 5-A
Dy. No. Date of	Dy No. 29017 Dated: 25-10-2021
Application, Fee submitted	Fee Submitted: Rs. 75,000/- dated 12-10-2021 (Slip#67788045)
Demanded Price / Pack size	De-controlled 500ml
General Documentation	Scanned copy of Legalized Certificate of Pharmaceutical Product (CoPP) No 30281/PI.500/F/12/2020 dated December 30,2020 issued by: Ministry of Agriculture Directorate General of Livestock and Animal Health Services Indonesia.
Stability Study	Firm has submitted the stability data of Batch No. 31L05, 31L06, 31L07 at 0,3,6,9,12,18 and 21 months when stored at 2-8 °C.
Evaluation by DBE&R	• Original legalized COPP is not provided. Scanned copy is attached in dossier. • Product specific Letter of Authorization is not provided. • Fee paid is Rs.75000/- under the head of new drug molecule while the applied product is not a new drug. Remaining fee is not submitted yet. • Pack size and Batch size are not mentioned in stability data. • Mc Ferran strain of Adenovirus is not registered before as per data available.

Decision: Registration board decided to defer the application for clarification of all points mentioned in remarks of Evaluator.

ADDITIONAL AGENDA OF DBER FOR 339TH MEETING OF REGISTRATION BOARD

Sr. No.	Deputy Director	Designated No.	No. of Cases
1.	Dr. Muhammad Kashif Mehsud	DD-I	09
2.	Dr. H.M Jawad Ali	DD-II	04
3.	Ms. Haleema Sharif	DD-III	03

CASES OF DD-II (DR. H.M JAWAD ALI)

Imported Veterinary Biologicals from Non-Reference Countries:

01	Name and address of Importer	M/s. Jovac Global-PAK, Plot No. 17, Block D, EME, DHA Phase 12, Lahore
	Detail of DSL	M/s. Jovac Global-PAK; Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore. Valid up to:15.06.2023
	Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Exporting country	Jordan
	Brand Name +Dosage Form + Strength	Jova Zeit H5N8 vaccine, Injectable water in oil emulsion
	Diary No. Date of R& I & fee	Dy. No. 503 R&I Dated 31-01-2024 Rs. 150,000/- (Slip No. 3016579226)
	Composition	Each 0.25ml of vaccine contains: At least 10^8 EID_{50} inactivated Avian Influenza subtype H5N8.
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	2 years (store below 2-8^{0}C)
	Document Details	• Valid legalized free sale certificate is submitted by the firm. • Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020. • Firm has submitted notarized distribution agreement & Authorization letter
	Pack size	500ml bottle
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Otto FLU Plus Vac of Ottoman Pharma. Inactivated Avian Influenza H5 Virus Oil based vaccine.
	Remarks of Evaluator	Firm has submitted safety studies on 120 Birds and efficacy studies on 20 Birds.
	Previous Decision: Registration Board deferred the case for submission of Field Trial Data OR Efficacy studies on larger number of Birds.	
	Firm's Submission: Now, the firm has submitted Field Trial Data as follows: - Number of Birds: 44000 vaccinated and 200 given challenge test, i.e., concluded as follows: Conclusion: - The serological tests and the challenge infection results showed a significant increase in the hem-agglutination inhibiting antibodies level beyond the minimum protective titer which was a key predictor to the satisfactory clinical signs prevention and survival rates observed after the challenge; Hence the Jova Zcit H5N8 vaccine dosed through the recommended routes to the minimum recommended age of layer chickens is satisfactorily protective. Submitted for consideration of the Board.	
	Decision: The Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs.	

Deferred Case of M-317 of Registration Board.

02	Name and address of Importer	M/s Niraav Pharma (Pvt). Ltd Horizon Tower, Office 204, Block 3 Clifton, Karachi.
	Detail of DSL	M/s Niraav Pharma (Pvt). Ltd authorized agent of M/s. Vet Pharma Trading Company. Address: Plot No. A-81, Eastern Industrial Zone, Port Qasim Authority, Karachi. Validity: 23-09-2020, 22-09-2022.
	Name and address of Manufacturer	M/s. Shangqiu Meilan Biological Engineering Co., Ltd. Address: No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	Meilan L.V IB H120 Live
	Diary No. Date of R& I & fee	Dy. No. 2778 Dated 25-01-2021 Rs. 100,000/- Dated 18-01-2021
	Composition	Each dose contains: Infectious Bronchitis live virus strain H120 (CVCC AV 1514)≥ $10^{3.5}$ EID_{50}
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	12months (2^0C-8^0C)
	Document Details	Following documents are submitted: a. Original legalized CoPP dated 12-01-2022. b. Original legalized Sole agency agreement (validity was five years it is not valid now).
	Pack size	1000 doses vial
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	(Reg No. 91374) JOVAC IB H120 Vaccine Each dose of vaccine contains: Infectious Bronchitis Disease Virus strain (Live attenuated) H120……at least $10^{3.0}EID_{50}$

	Remarks of Evaluator	In response to this division's letter dated 2nd November 2021 firm has submitted following: i. Clarification regarding difference in address on sole agency agreement DSL that sole agency agreement address of head office is mentioned. ii. Finished product Specifications; As per Innovator's. iii. Safety and efficacy data. Following documents are still required: i. Sole agency agreement is not valid now. ii. Clarification regarding this number with the strain name "CVCC AV 1514" is required.
Decision of M-317: Registration Board deferred the product for submission of following by the firm: **i.** Immunological relevance of CVCC AV 1514 strain with circulating strains of Pakistan. **ii.** Valid Sole Agency Agreement.		
Now Firm has submitted the followings: - i. Notarized Copy of sole agency agreement; ii. Valid DSL copy. (validity date till 14-04-2029)		
Dr. Qurban has informed that the applied product is the same as already approved by DRAP		
Decision: The Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs		
03.	Name and address of Importer	M/s Niraav Pharma (Pvt). Ltd Horizon Tower, Office 204, Block 3 Clifton, karachi.
	Detail of DSL	M/s Niraav Pharma (Pvt). Ltd authorized agent of M/s. Vet Pharma Trading Company. Address: Plot No. A-81, Eastern Industrial Zone, Port Qasim Authority, Karachi. Validity: 23-09-2020, 22-09-2022.
	Name and address of Manufacturer	M/s. Shangqiu Meilan Biological Engineering Co., Ltd. Address: No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	Meilan L.V ND+IB Live
	Diary No. Date of R& I & fee	Dy. No. 2778 Dated 25-01-2021 Rs. 100,000/- Dated 18-01-2021
	Composition	Each dose contains: New castle disease live virus strain Lasota (CVCC AV1615)$\geq 10^6$ EID50 Infectious Bronchitis live virus strain H120 (CVCC

		AV1514)≥$10^{3.5}$ EID_{50}
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per innovator's specifications
	Shelf Life	18months (2^0C-8^0C)
	Document Details	Following documents are submitted: a. Original legalized CoPP dated 12-01-2022. b. Original legalized Sole agency agreement (validity was five years it is not valid now).
	Pack size	1000 doses vial
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	(Reg No. 077560) BIO-VAC LS-H120 Live attenuated virus of New Castle Disease, LaSota strain Titer: Not less than $10^{6.5}$ EID_{50} Live avian infectious brochitis virus, strain Massachusetts H120: Not less than $10^{3.5}$ EID_{50}
	Remarks of Evaluator	In response to this division's letter dated 2nd November 2021 firm has submitted following: i. Clarification regarding difference in address on sole agency agreement DSL that sole agency agreement address of head office is mentioned. ii. Finished product Specifications; As per Innovator's. iii. Safety and efficacy data. Following documents are still required: i. Sole agency agreement is not valid now.
Decision of M-317: Registration Board deferred the product for submission of valid Sole Agency Agreement, by the firm.		
Now Firm has submitted the followings: - iii. Notarized Copy of sole agency agreement; iv. Valid DSL copy. (validity date till 14-04-2029)		
Decision: The Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs.		
04.	Name and address of Importer	M/s Niraav Pharma (Pvt). Ltd Horizon Tower, Office 204, Block 3 Clifton, karachi.

	Detail of DSL	M/s Niraav Pharma (Pvt). Ltd authorized agent of M/s. Vet Pharma Trading Company. Address: Plot No. A-81, Eastern Industrial Zone, Port Qasim Authority, Karachi. Validity: 23-09-2020, 22-09-2022.
	Name and address of Manufacturer	M/s. Shangqiu Meilan Biological Engineering Co., Ltd. Address: No.9 Zhuzhou Road, High Tech Development Zone, Zhecheng Shangqiu, Henan, China.
	Name of exporting country	China
	Brand Name+Dosage Form + Strength	Meilan L.V IBD Live
	Diary No. Date of R& I & fee	Dy. No. 2778 Dated 25-01-2021 Rs. 100,000/- Dated 18-01-2021
	Composition	Each dose contains: Infectious Bursal Disease Vaccine, Live virus strain B87 (CVCC AV 140)…….. ≥103 ELD50
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per innovator's specifications
	Shelf Life	12months (20C-80C)
	Document Details	Following documents are submitted: a. Original legalized CoPP dated 12-01-2022. b. Original legalized Sole agency agreement (validity was five years it is not valid now).
	Pack size	1000 doses vial
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Not verifiable
	Remarks of Evaluator	In response to this division's letter dated 2nd November 2021 firm has submitted following: i. Clarification regarding difference in address on sole agency agreement DSL that sole agency agreement address of head office is mentioned. ii. Finished product Specifications; As per Innovator's. iii. Safety and efficacy data. Following documents are still required: i. Evidence of locally registered product for applied product is

		required. ii. Sole agency agreement is not valid now
Decision of M-317: Registration Board deferred the product for submission of following by the firm: **i.** Immunological relevance of B87 (CVCC AV 140) strain with circulating strains of Pakistan. **ii.** Valid Sole Agency Agreement.		
Now Firm has submitted the followings: - v. Notarized Copy of sole agency agreement; vi. Valid DSL copy. (validity date till 14-04-2029)		
Dr. Qurban has informed that the applied product is the same as already approved by DRAP		
Decision: The Registration Board after detailed deliberation approved the product subject to compliance to current Import Policy for finished drugs		

Additional Agenda of BE&R, Division
(Dr. Muhammad Kashif)

Application of registration on priority basis /out of queue on the basis of export facilitation.
Case.No.1. Locally manufactured Human Biological applied by M/**s** Macter International Limited.

1.	Name, address of Applicant / Marketing Authorization Holder	Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan. Tel: 021- 32591000 Ext.2007: FAX: 2564263, 2565854 & 2566894
	Name, address of Manufacturing site.	NAME: Macter International Limited. DML NO: 000141 ADDRESS: F- 216, S.I.T.E, Karachi 75700, Pakistan. Tel: 021- 32591000 Ext.2007 FAX: 2564263, 2565854 & 2566894
	GMP status of the firm	GMP certificate issued to M/s Macter International Limited. based on inspection conducted on 04.08.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 19-07-2012 which specifies liquid and lyophilized recombinant DNA technology products (biological) section.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Application number; dated 05-JAN-2024, tracking ID 15D-SEB-NB2X
	Details of fee submitted	PKR 300,000/- dated 23-FEB-2024
	proposed proprietary name/brand	ADIMAC
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8 ml single dose vial contains 40 mg of adalimumab.
	Pharmaceutical form of applied drug	Liquid solution for injection
	Pharmacotherapeutic Group of (API)	(a) Disease-modifying Antirheumatic Drugs – DMARDs (b) ATC code: L04AB04
	Reference to Finished product specifications	As per innovator's specification
	Proposed Pack size	1's Vial
	Proposed unit price	As per Drug pricing committee

	The status in reference regulatory authorities	-Humira 40mg/0.8ml Solution for Injection, AbbVie Inc. North Chicago, IL 60064, U.S.A, USFDA Approved. -Humira 40mg/0.8ml Solution for Injection, AbbVie Deutschland GmbH & Co. KGKnollstrasse 67061 Ludwigshafen Germany, EMA Approved.
	For generic drugs (me-too status)	Rumab adalimumab 40mg/0.8ml Solution for Injection,by Nextar pharma Pvt. limited Pamera 40 adalimumab 40mg/0.8ml Solution for Injection by Altimi biosciences Adalimab by adalimumab 40mg/0.8ml Solution for Injection M/s Getz Pharma (Pvt.) Ltd Adalib adalimumab 40mg/0.8ml Solution for Injection by M/s the Searle Company Limited.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product
	Name, address of drug substance manufacturer	**M/s. Hetero Biopharma Limited** **Address: Sy. No. 458 (Part), TSIIC - Formulation SEZ, Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509301, Telangana State, India**
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 9 batches (i.e. preclinical, clinical and commercial batches) of FDS at accelerated and real time conditions. The real time stability data is conducted at (-20°C±5°C) for 36 months on preclinical, clinical and commercial batches. Accelerated study is conducted at (5±3°C) for 6 months on same preclinical, clinical and commercial batches of FDS.
	Module-III Drug Product:	-Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and Stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Summary of Comparative Analysis of our product ADIMAC (Adalimumab) Macter international ltd. against the innovator product HUMIRA (AbbVie Inc.); 1. Identification by SDS PAGE, CBB Stain 2. Purity by Weak Cation Exchange Chromatography 3. Protein Content by UV-Method @ 280 nm: 4. Determination of High Molecular Weight Impurities by Size Exclusion HPLC
	Analytical method validation/verification of product	The specifications & analytical procedures are submitted along with validation of Analytical Procedures
	Container closure system of the drug product	3 ml USP type 1 clear glass vials accompanied with 13 mm slit less grey butyl rubber stopper and aluminum flip off seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability study data of 3 batches at 5±3°C for 06 months. The accelerated stability study data is conducted at 25±2°C & 60±5%RH for 6 months. Shelf life: The intended shelf life for adimac injection in vial at 5°C ± 3°C is therefore designated to be two (02) years.
	Storage Conditions	Store in a refrigerator (2°C to 8°C).
	Module 4	Firm has submitted following data: **i. In-vitro Studies** **Primary Pharmacodynamics** 1. Fab-mediated activities 2. Neutralization of TNF-α by L929 cytotoxic assay 3. Inhibition of soluble TNF- α induced IL-8 Secretion in HUVEC 4. tmTNF-α binding assay by using CHOK1 cells 5. TNF-α binding assay by ELISA 6. FcɣR Binding 7. CDC (Complement dependent cytotoxicity) assay 8. Antibody dependent cell mediated cytotoxicity (ADCC) assay **Secondary Phamacodynamics** **Safety Pharmacology** **Pharmacodynamic Drug Interaction.** **ii. In-vivo Studies** 1. Single Dose Toxicity Study of Adalimumab in Wistar Rats Following Intravenous Administration. 2. Single Dose Toxicity Study of Adalimumab in Wistar Rats Following Subcutaneous Administration. 3. Single Dose Toxicity Study of Adalimumab in Swiss Albino Mice Following Intravenous Administration. 4. Single Dose Toxicity Study of Adalimumab in Swiss Albino Mice Following Subcutaneous Administration. 5. 28-Day Repeated Dose Toxicity Study of Adalimumab in Wistar Rats with 14 Days Recovery Period Following Weekly Subcutaneous Administration. 6. 28-Day Repeated Dose Toxicity Study of Adalimumab in New Zealand White Rabbits with 14 Days Recovery Period Following Weekly Subcutaneous Administration

	Module 5	Firm has submitted following data: PHASE I: Prospective, Randomized, Multi Center, Comparative, Parallel, single dose; To compare the pharmacokinetic and pharmacodynamic characteristics of Hetero Adalimumab with Reference-Adalimumab (Adalimumab, AbbVie Inc.) PHASE III: A Prospective, Randomized, Multiple-Dose, Multi-Center, Comparative, Parallel group Clinical Study to Evaluate the Efficacy, Safety, Immunogenicity, and Pharmacokinetics of Subcutaneous Injection of Adalimumab (Test Product, Hetero) and Reference Medicinal Product (Reference product, AbbVie) Concomitantly Administered with Methotrexate in Patients with Rheumatoid Arthritis A Phase IV: Multi-Centric Post Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero – Adalimumab Study Indication(s): Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), Axial Spondyloarthritis (AS), Psoriatic Arthritis (PsA), Psoriasis, Paediatric Plaque Psoriasis, Hidradenitis Suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative Colitis and Uveitis

Data as per guidelines of 278th meeting of Registration Board;
For Bulk Concentrate Import, Local formulation Filling:

The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Date: June-13-2022 GMP Valid Date : June-11-2025 Firm has submitted the legalized GMP issued by Drug Control Administration Government Of Telangana India
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority	Firm has submitted legalized COPP (3049930/TS/2022) & FSC Valid till June-11-2025 issued by Drug Control Administration Government Of Telangana India
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable)	Not Applicable
The firm shall provide the 6 months accelerated and real time stability studies for drug substance	Submitted
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents	Submitted

Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm has submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm has submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to	Firm has submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative Analysis study of applied product ADIMAC (Adalimumab) Macter international ltd. against the innovator product HUMIRA (AbbVie Inc.) has been submitted by firm
Analytical method validation/verification of product	The specifications & analytical procedures are submitted along with validation of Analytical Procedures
Container closure system of the drug product	3 ml USP type 1 clear glass vials accompanied with 13 mm slit less grey butyl rubber stopper and aluminum flip off seal.
Documents for the procurement of API with approval from DRAP	Submitted
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability study data of 3 batches at 5±3°C for 06 months. The accelerated stability study data is conducted at 25±2°C & 60±5%RH for 6 months. Shelf life: The intended shelf life for adimac injection in vial at 5°C ± 3°C is therefore designated to be two years.
Module IV	Submitted, Detail given above
Module V	Submitted, Detail given above

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.

WHO Bio-similarity guidelines	**Data submitted by the firm**

Quality Comparison Physicochemical characterization	**Primary structure by;** • Amino acid sequencing by LCMS/MS • Intact Mass spectrometry • Reduced Mass spectrometry • Peptide mapping **High-level structure by:** • Far UV CD spectroscopy • Near UV CD spectroscopy • Intrinsic fluorescence spectroscopy. • Extrinsic fluorescence spectroscopy. • Free thiol estimation
Biological Activity	• Neutralization of soluble TNF-α induced cell death in L929 cells • ADCC assay • CDC assay • C1q binding assay • Soluble TNF-α binding assay (ELISA) / SPR / tmTNF-α binding assay • Inhibition of soluble TNF-α induced IL-8 in HUVEC • Specificity against TNF-β
Immunochemical properties	• FcγRIIIa (V158) Receptor Binding Assay • FcγRIIIa (F158) Receptor Binding Assay • FcγRIa Receptor Binding Assay • FcγRIIa (131H) Receptor Binding Assay • FcRn Receptor Binding Assay • Immuno blotting
Impurities	Purity and impurity were detected by: • SE-UPLC • CE-SDS (Reducing) • CE-SDS (Non-reducing) • CEX
Non-clinical Studies i. In-vitro Studies ii. In-vivo Studies	Firm has submitted following data: **i. In-vitro Studies** **Primary Pharmacodynamics** 1. Fab-mediated activities 2. Neutralization of TNF-α by L929 cytotoxic assay 3. Inhibition of soluble TNF- α induced IL-8 Secretion in HUVEC 4. tmTNF-α binding assay by using CHOK1 cells 5. TNF-α binding assay by ELISA 6. FcɣR Binding 7. CDC (Complement dependent cytotoxicity) assay 8. Antibody dependent cell mediated cytotoxicity (ADCC) assay **Secondary Phamacodynamics** Safety Pharmacology Pharmacodynamic Drug Interaction. **ii. In-vivo Studies**

	1. Single Dose Toxicity Study of Adalimumab in Wistar Rats Following Intravenous Administration. 2. Single Dose Toxicity Study of Adalimumab in Wistar Rats Following Subcutaneous Administration. 3. Single Dose Toxicity Study of Adalimumab in Swiss Albino Mice Following Intravenous Administration. 4. Single Dose Toxicity Study of Adalimumab in Swiss Albino Mice Following Subcutaneous Administration. 5. 28-Day Repeated Dose Toxicity Study of Adalimumab in Wistar Rats with 14 Days Recovery Period Following Weekly Subcutaneous Administration. 6. 28-Day Repeated Dose Toxicity Study of Adalimumab in New Zealand White Rabbits with 14 Days Recovery Period Following Weekly Subcutaneous Administration 7. Skin sensitization study (GMPT) of Adalimumab in Guinea Pigs
Clinical Studies	Firm has submitted following data: PHASE I: Prospective, Randomized, Multi Center, Comparative, Parallel, single dose; To compare the pharmacokinetic and pharmacodynamic characteristics of Hetero Adalimumab with Reference-Adalimumab (Adalimumab, AbbVie Inc.) PHASE III: A Prospective, Randomized, Multiple-Dose, Multi-Center, Comparative, Parallel group Clinical Study to Evaluate the Efficacy, Safety, Immunogenicity, and Pharmacokinetics of Subcutaneous Injection of Adalimumab (Test Product, Hetero) and Reference Medicinal Product (Reference product, AbbVie) Concomitantly Administered with Methotrexate in Patients with Rheumatoid Arthritis A Phase IV: Multi-Centric Post Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero – Adalimumab Study Indication(s): Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), Axial Spondyloarthritis (AS), Psoriatic Arthritis (PsA), Psoriasis, Paediatric Plaque Psoriasis, Hidradenitis Suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative Colitis and Uveitis
Decision: The Board after detailed deliberation approved the product.	

Cases deferred of 336th R.B Meeting:

Cases.No.2. Locally manufactured Human Biological applied by M/s SAMI Pharmaceuticals (Pvt.) Ltd., Karachi

2.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Details of Drug Manufacturing License	DML No:000072 Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.**

		Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 715/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. Dated 13-06-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN R 100 IU/ml Injection (rDNA origin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ……..……100IU (rDNA origin) Ph. Eur. Specs
	Pharmaceutical form of applied drug	Colorless liquid, free from turbidity and foreign matter
	Pharmacotherapeutic Group of (API)	Insulin and analogues for injection, fast acting ATC: A10AB01
	Reference to Finished product specifications	Ph. Eur. Specs
	Proposed Pack size	As per SRO

	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	HUMULIN S (Soluble) 100IU/ml solution for injection in cartridge by Eli Lilly UK, MHRA approved
	For generic drugs (me-too status)	Actrapid – HM Penfills by M/s Novo Nordisk, Reg. No. 010344
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20˚C ± 5˚C for 60 months Accelerated: 5˚C ± 3˚C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G).
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary Packaging is 3mL glass cartridge Type I with rubber disc seal and Bromobutyl rubber plunger head with secondary packaging unit carton

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C/ 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest European Pharmacopoeia of three trial batches of Finished Pharmaceutical Product.** • **In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.**
Decision of 336th R.B Meeting: Registration Board deferred the case for submission of the following. • ***Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).*** • ***Bio-similarity data as per WHO Bio similarity guidelines.***		

Now the firm has submitted Bio similarity data as under.

<table>
<tr><th>WHO Biosimilarity Guidelines</th><th>Data Submitted by M/s SAMI Pharmaceutical (Pvt) Ltd.</th></tr>
<tr><td>Quality Comparison
Physicochemical Characterization</td><td>Regular Human Insulin produced by Bioton S.A. has been compared with and the reference drug, Humulin® R, produced by Eli Lilly and Company
<table>
<tr><th>Category</th><th>Quality Attributes</th><th>Analytical methods</th></tr>
<tr><td rowspan="2">Primary structure</td><td rowspan="2">Amino acid sequence</td><td>Peptide mapping</td></tr>
<tr><td>Edman method of the peptide N-terminal sequencing</td></tr>
<tr><td>Higher order structure</td><td>Secondary, tertiary and quaternary structures</td><td>Far UV Circular Dichroism spectra (far UV CD)
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<tr><td></td><td></td><td>Nuclear Magnetic Resonance analysis (NMR)</td></tr>
<tr><td>Hydrophobicity</td><td>Hydrophobic variants</td><td>Near UV Circular Dichroism (near UV CD)
Nuclear Magnetic Resonance analysis (NMR)</td></tr>
<tr><td>Size heterogeneity</td><td>HMW impurities</td><td>Size exclusion chromatography</td></tr>
<tr><td>In-solution particle size homogeneity</td><td>Average size</td><td>Laser diffraction</td></tr>
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<tr><td>Biological Activity</td><td>Cell based Bioactivity Assay – Surface Plasmon Resonance (SPR)
Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors.
The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake.</td></tr>
<tr><td>Immunochemical properties</td><td>For determination of HCP a specific ELISA method was developed using antibodies obtained by the immunogenization of rabbits by E. coli strain used during the drug substance manufacturing process. The application of specific antibodies ensured the selectivity of the method. During the validation process, the LOQ and LOD were set to 1.25 ppm and 0.625 ppm respectively. Analysis of samples revealed that HCP levels in the final drug substance were, in most cases, bellow the limit of detection. In 9 out of 101 cases, results were higher than 1.0 ppm and the highest value equals 1.7 ppm. We have set an upper limit for HCP at 10 ppm for dry substance.</td></tr>
<tr><td>Impurities</td><td>Process-related impurities/Product-related impurities:

• E. coli proteins (HCP) from the host cells
• Residual DNA from the host cells
• Carboxypeptidase B (specific enzyme used for insulin precursor digestion)
• Zinc (used in the insulin precipitation step)
• Inorganic residues determined by Sulphated ash method
• Related proteins – insulin derivatives formed as side-products or degradation products during manufacture, determined by HPLC according to Ph. Eur.
• HMWP include insulin oligomers and protein impurities with molecular masses greater than that of insulin determined by HPLC in accordance with Ph. Eur.</td></tr>
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	• A21-desamido insulin – product-related substance identified in the chromatogram in the system for related proteins and human insulin assay based on the Ph. Eur. • Single chain precursor – residual protein that has not undergone the enzymatic digestion, specific to the particular step
Stability Studies	The firm has submitted stability studies.
Non-clinical Comparison I. *In-vitro* Studies II. *In-vivo* Studies a) Biological / Pharmacodynamic activity b) Non- clinical Studies	The principles of pharmacodynamic in vitro studies on insulin products are set out in ICH guidelines2,3. Considering these guidelines, the following set of in vitro pharmacodynamic studies was adopted for comparison of Biological Product with Comparator: • Binding to IR-A and IR-B (SPR) • Tyrosine phosphorylation/dephosphorylation of IR-A and IR-B • Glycogen formation in adipocytes • Lipolysis rate • Glucose uptake An indirect evaluation of Biological Product vs. Comparator was performed including the recommended in vitro studies. Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors. The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake. Evaluation of Biological Product and Comparator biological attributes was indirect in such a way that instead of the composite products, their particular components were used for comparison. Both Biological Product and Comparator are biphasic isophane insulin injections including human insulin and protamine sulphate complex suspended in a solution of insulin of the same species. Reasoning on the Biological Product and Comparator similarity of the kinetics of binding to IR-A and IR-B is based on the comparison of their components represented by Gensulin N and Humulin N (isophane insulin) and Gensulin R and Humulin R (soluble insulin). The same set of products represented Biological Product and Comparator in the tyrosine phosphorylation and dephosphorylation.
Clinical Studies	A double blind, randomized crossover clinical trial with administration of a single subcutaneous dose to compare the pharmacokinetics (PK) and pharmacodynamics (PD) of two recombinant regular human insulins, the test drug being the Regular Human Insulin produced by Bioton S.A. and the reference drug, Humulin® R, produced by Eli Lilly and Company, packaged and registered by Eli Lilly do Brasil Ltda, using euglycemic and hyperinsulinemic CLAMP technique in patients with Type 1Diabetes
Decision: The Board after detailed deliberation approved the product.	

3.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi**
	Details of Drug Manufacturing License	DML No:000072

		Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 713/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy.No. Dated 13-06-2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN-NPH 100 IU/ml Injection Isophane Suspension (rDNA origin)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ……100IU (rDNA origin) Ph. Eur. Specs
	Pharmaceutical form of applied drug	White or almost white suspension which on standing deposits a white or almost white sediment and leaves a

		colorless or almost colorless supernatant; the sediment is readily suspended by gently shaking
	Pharmacotherapeutic Group of (API)	Insulins and analogues for injection, Intermmediate-acting ATC: A10AC01
	Reference to Finished product specifications	Ph. Eur. Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin I 100 IU/ml Suspension for Injection in Cartridge, MHRA approved
	For generic drugs (me-too status)	Insulatard-HM Penfills by M/s Novo Nordisk, Reg. No. 010341
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20˚C ± 5˚C for 60 months Accelerated: 5˚C ± 3˚C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product..
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary packaging is 3mL clear glass vial, bromo-butyl rubber stopper and aluminum seal with secondary packaging of unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C/ 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest Ph.Eur Pharmacopoeia of three trial batches of Finished Pharmaceutical Product.** • **In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.**

Decision of 336th R.B Meeting: Registration Board deferred the case for submission of the following.

- ***Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).***
- ***Bio-similarity data as per WHO Bio similarity guidelines.***

Now the firm has submitted Bio similarity data as under.

WHO Biosimilarity Guidelines	**Data Submitted by M/s SAMI Pharmaceutical (Pvt) Ltd.**
Quality Comparison Physicochemical Characterization	Rrecombinant NPH human insulins from BIOTON S.A. has been compared with Humulin® N, produced by Eli Lilly and Company, packaged and registered by Eli Lilly do Brasil Ltda.– Reference Listed Drug (RLD)

Category	**Quality Attributes**	**Analytical methods**
		Peptide mapping

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<tr><td>Impurities</td><td>Process-related impurities/Product-related impurities:

• E. coli proteins (HCP) from the host cells
• Residual DNA from the host cells</td></tr>
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	• Carboxypeptidase B (specific enzyme used for insulin precursor digestion) • Zinc (used in the insulin precipitation step) • Inorganic residues determined by Sulphated ash method • Related proteins – insulin derivatives formed as side-products or degradation products during manufacture, determined by HPLC according to Ph. Eur. • HMWP include insulin oligomers and protein impurities with molecular masses greater than that of insulin determined by HPLC in accordance with Ph. Eur. • A21-desamido insulin – product-related substance identified in the chromatogram in the system for related proteins and human insulin assay based on the Ph. Eur. - Single chain precursor – residual protein that has not undergone the enzymatic digestion, specific to the particular step
Stability Studies	The firm has submitted stability studies.
Non-clinical Comparison III. *In-vitro* Studies IV. *In-vivo* Studies c) Biological / Pharmacodynamic activity d) Non- clinical Studies	The principles of pharmacodynamic in vitro studies on insulin products are set out in ICH guidelines2,3. Considering these guidelines, the following set of in vitro pharmacodynamic studies was adopted for comparison of Biological Product with Comparator: • Binding to IR-A and IR-B (SPR) • Tyrosine phosphorylation/dephosphorylation of IR-A and IR-B • Glycogen formation in adipocytes • Lipolysis rate • Glucose uptake An indirect evaluation of Biological Product vs. Comparator was performed including the recommended in vitro studies. Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors. The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake. Evaluation of Biological Product and Comparator biological attributes was indirect in such a way that instead of the composite products, their particular components were used for comparison. Both Biological Product and Comparator are biphasic isophane insulin injections including human insulin and protamine sulphate complex suspended in a solution of insulin of the same species. Reasoning on the Biological Product and Comparator similarity of the kinetics of binding to IR-A and IR-B is based on the comparison of their components represented by Gensulin N and Humulin N (isophane insulin) and Gensulin R and Humulin R (soluble insulin). The same set of products represented Biological Product and Comparator in the tyrosine phosphorylation and dephosphorylation.

Clinical Studies		A double blind, randomized crossover clinical trial with administration of a single subcutaneous dose to compare the pharmacokinetics (PK) and pharmacodynamics (PD) of two recombinant NPH human insulins, the test drug being the NPH Human Insulin produced by Bioton S.A. and the reference drug, Humulin® N, produced by Eli Lilly and Company, packaged and registered by Eli Lilly do Brasil Ltda., using euglycemic and hyperinsulinemic CLAMP technique in patients with Type 1 Diabetes.
Decision: The Board after detailed deliberation approved the product.		
4.	Name, address of Applicant / Importer	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Details of Drug Manufacturing License	DML No:000072 Expiry: 20-08-2020 (Renewal applied)
	Name, address of Bulk manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Name of exporting country	Poland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 711/22) issued by Ewa Krajewska, Chief Pharmaceutical Inspector, 12 Senatorska street, 00-082 Warsaw, Poland. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 3 year.
		GMP: Firm has submitted Copy of legalized GMP certificate issued by Chief Pharmaceutical Inspector, competent authority of Poland, valid till 06.12.2026
	Details of letter of authorization / sole agency agreement	N/A.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only

	Dy. No. and Date of submission	Dy.No. Dated 13/06/2023
	Details of fee submitted	PKR 30,000/- Dated 24-02-2023
	The proposed proprietary name / brand name	**SAMULIN 70/30 *(Human Insulin rDNA origin)* Biphasic 100IU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Human Insulin Ph. Eur. ….100 IU [70% Human Insulin Isophane Suspension, 30% Human Insulin Injection (rDNA Origin)] Ph. Eur. Specs
	Pharmaceutical form of applied drug	A white or almost white suspension which on standing deposits a white or almost white sediment and leaves a colorless or almost colorless supernatant; the sediment is readily suspended by gently shaking
	Pharmacotherapeutic Group of (API)	Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting ATC: A10A D01
	Reference to Finished product specifications	Ph. Eur. Specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per DPC
	Shelf Life	3 years
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin M3 100 IU/ml suspension for injection in cartridge, MHRA Approved
	For generic drugs (me-too status)	Mixtard 30 HM by M/s Novo Nordisk, Reg. No. 010346
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted..
	Name, address of drug substance manufacturer	**BIOTON S.A.** Macierzysz, 12 Poznańska Street 05-850 Ożarów Mazowiecki, Poland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its complete verification studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: -20°C ± 5°C for 60 months Accelerated: 5°C ± 3°C for 6 months Batches: (12-07-022G, 12-07-023G, 12-07-024G, 14-07-086G, 14-07-087G, 14-07-088G, 19-07-014G, 19-07-015G, 19-07-016G)
	Module-III Drug Product:	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, intermediate precision, solution stability, specificity.
	Container closure system of the drug product	The primary packaging is 3mL clear glass vial, bromo-butyl rubber stopper and aluminum seal with secondary packaging of unit carton.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 6 months. Lab-01 Lab-02 Lab-03
	Module IV	Not provided
	Module V	Not provided
	Evaluation by DBE&R	• **Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form) is required including the tests as per latest Ph.Eur Pharmacopoeia of three trial batches of Finished Pharmaceutical Product.** • **In Biosimilarity data submitted by the firm, Gensulin M30 (30/70) is compared with Humulin M3 (mixture 3) in all three products and data is also incomplete. Separate biosimilarity data of all three products as per WHO Biosimilarity guidelines are required.**
Decision of 336th R.B Meeting: Registration Board deferred the case for submission of the following. • ***Complete data as per guidelines approved in 297th meeting of Registration Board for Biological Products (Concentrated Form/Ready to Fill Form).*** • ***Bio-similarity data as per WHO Bio similarity guidelines.***		

Now the firm has submitted Bio similarity data as under.

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<tr><th>WHO Biosimilarity Guidelines</th><th>Data Submitted by M/s SAMI Pharmaceuticals (Pvt.) Ltd.</th></tr>
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	than 1.0 ppm and the highest value equals 1.7 ppm. We have set an upper limit for HCP at 10 ppm for dry substance.
Impurities	Process-related impurities/Product-related impurities: • E. coli proteins (HCP) from the host cells • Residual DNA from the host cells • Carboxypeptidase B (specific enzyme used for insulin precursor digestion) • Zinc (used in the insulin precipitation step) • Inorganic residues determined by Sulphated ash method • Related proteins – insulin derivatives formed as side-products or degradation products during manufacture, determined by HPLC according to Ph. Eur. • HMWP include insulin oligomers and protein impurities with molecular masses greater than that of insulin determined by HPLC in accordance with Ph. Eur. • A21-desamido insulin – product-related substance identified in the chromatogram in the system for related proteins and human insulin assay based on the Ph. Eur. • Single chain precursor – residual protein that has not undergone the enzymatic digestion, specific to the particular step
Stability Studies	The firm has submitted stability studies.
Non-clinical Comparison V. *In-vitro* Studies VI. *In-vivo* Studies e) Biological / Pharmacodynamic activity f) Non- clinical Studies	The principles of pharmacodynamic in vitro studies on insulin products are set out in ICH guidelines2,3. Considering these guidelines, the following set of in vitro pharmacodynamic studies was adopted for comparison of Biological Product with Comparator: • Binding to IR-A and IR-B (SPR) • Tyrosine phosphorylation/dephosphorylation of IR-A and IR-B • Glycogen formation in adipocytes • Lipolysis rate • Glucose uptake An indirect evaluation of Biological Product vs. Comparator was performed including the recommended in vitro studies. Receptor binding studies were carried out on IR-A and IR-B insulin receptors with the use of SPR method. First level of biological activity studies was executed by the assessment of tyrosine phosphorylation and dephosphorylation of IR-A and IR-B insulin receptors. The second level of biological activity studies was achieved in three studies on metabolic activity in mouse 3T3-L1 cells: measuring of glycogen formation in adipocytes, measuring of lipolysis rate and pharmacodynamic evaluation of glucose uptake. Evaluation of Biological Product and Comparator biological attributes was indirect in such a way that instead of the composite products, their particular components were used for comparison. Both Biological Product and Comparator are biphasic isophane insulin injections including human insulin and protamine sulphate complex suspended in a solution of insulin of the same species. Reasoning on the Biological Product and Comparator similarity of the kinetics of binding to IR-A and IR-B is based on the comparison of their components represented by Gensulin N and Humulin N (isophane insulin) and Gensulin R and Humulin R (soluble insulin). The same

	set of products represented Biological Product and Comparator in the tyrosine phosphorylation and dephosphorylation.
Clinical Studies	Study Title: BIOAVAILABILITY STUDY OF GENSULIN M30 VERSUS A SDE AFTER SUBCUTANEOUS ADMINISTRATION Investigator/Performer: Internal Diseases and Diabetes Department of Medical Academy in Warsaw, Brodno Hospital, Kondratowicza Objective: To compare the Bioavailability of a new recombinant insulin GENSULIN M30 by IBATECH with a reference drug by Eli Lilly after subcutaneous administration Planned number of volunteers: 24 Trial Participants: Healthy males aged 18-45 Trial medication, dose and mode: Gensulin M30 0.1 U/kg of body weight, subcutaneously (sc) Reference drug: Humulin M3 by Eli Lilly Duration of treatment: 24-hour monitoring after subcutaneous administration in two treatment periods, with 7-day washout between Safety Criteria: Essential physiological parameters, glycaemia
Decision: The Board after detailed deliberation approved the product.	

Case deferred of 334th R.B Meeting
Case No.3. Imported Heparin Injection from non-Reference countries:
Molecule: Heparin Sodium

5.	Name, address of Applicant/ Importer	**M/s Safemed Technologies**, APT, 3, 2nd Floor, Retoon Plaza, Mini Market, Sector G-15/1, Islamabad.
	Details of Drug Sale License of importer	License No:DHO-ISB-333 Address: APT, 3, 2nd Floor, Retoon Plaza, Mini Market, Sector G-15/1, Islamabad. Validity: 24-08-2024 Status: Distribution License
	Name and address of marketing authorization holder (abroad)	M/s Hebei Changshan Biochemical Pharmaceutical Co. Ltd., No.71MenglongStreet,SouthDistrictofZhengdingHigh-tech Industrial Development Zone, Zhengding AreaofChina(Hebei) Pilot Free Trade Zone (050800), China
	Name, address of manufacturer(s)	M/s Hebei Changshan Biochemical Pharmaceutical Co. Ltd.,
		No.71MenglongStreet,SouthDistrictofZhengdingHigh-tech Industrial Development Zone, Zhengding Area of China(Hebei) Pilot Free Trade Zone (050800), China
	Name of exporting country	China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP(No.Hebei20210440)dated 15-10-2021validtill14-10-2023issuedbyHebeiProvinceDrug Administration. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization/ sole agency agreement	Firm has submitted product specific Letter of Authorization from Enterprise Legal Person of M/s Hebei Changshan Biochemical Pharmaceutical Co., Ltd., According to the letter, the firm *M/s Hebei Changshan* exclusively authorizes "Safemed Technologies" to register, sale and quote the product. The letter was issued on 06-04-2022 and valid till 30-03-2025.
	Status of the applicant	☐ Manufacturer ☒Importer ☐ Is involved in one of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product(GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purposeonly
	Dy. No. and date of submission	Dy.No.14234(R&I)Dated13-06-2022
	Details of fee submitted	Rs.150,000/-dated02-06-2022
	The proposed proprietary name/ brand name	Metaparin Injection
	Strength/concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial(5mL) contains: Heparin Sodium..... 25000IU
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of(API)	Anticoagulant
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	5'sVials
	Proposed unit price	Rs.1600/Vial
	Shelf life	03 Years
	Storage Conditions	25±2°C/60±5%RH
	The status in reference regulatory authorities	Heparin Panpharma of M/s Panpharma, France.

	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers(Reg. No. 088528).
	Module-II(Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and
		justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Hebei Changshan Biochemical Pharmaceutical Co. Ltd., No.71MenglongStreet,SouthDistrictofZhengdingHigh-tech Industrial Development Zone, Zhengding Area of China(Hebei) Pilot Free Trade Zone (050800), China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Drug Substance at real time conditions for 36 months and accelerated conditions for 06 months. The real time stability data conducted at $25^0C\pm2^0C/60\pm5\%RH$.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verificationofproduct	Firm has submitted validation of Analytical methods of Anti-factor IIa Activity, Anti-factor Xa activity, Benzyl Alcohol determination & Sterility test. Firm has submitted verification of Analytical methods of Related substances & Bacterial Endotoxin test.
	Container closure system of the drug product	EP Type-I Colorless Glass vial, Grey Halogenated Butyl Rubber stopper, Aluminum & Plastic combined caps.
	Stability study data of drug product	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40±2°C/75%RH±5%for6months.Therealtimestabilitystudy data is conducted at 25±2°C/60%±5RH for 36 months.

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

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

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

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

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

Decision of 332nd DRB Meeting:

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

Remarks:

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

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

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

Decision of 334th Registration Board Meeting: Registration Board deferred the case for evidence of availability of product in the country of origin or in RRA or in any three eastern European countries from same manufacturer."

Now the firm has submitted following clarification from the manufacturer Heibei Changshan Biochemical Pharmaceutical Co. Ltd.:

"We Hebei Changshan Biochemical Pharmaceutical Co. Ltd have applied for the registration of Heparin Sodium Injection 5ML;25000IU through agent in Pakistan M/s Safemed Technologies located at APT. 3, 2nd Floor Retoon Palaza, Sector G 15/1, Islamabad.

In P.R China, Heparin Sodium Injection is registered in 5000IU/1ML, THE STRENGTH IS SAME.As per requirement of various countries including Pakistan, We have also been manufacturing Heparin Sodium Injection 5ml:25000IU, and exporting to various countries 01)Bolivia, 02)Uzbekistan, 03)Philippines, 04)Yemen.

We certify that HEPARIN SODIUM INJECTION 5ML:25000IU IS BEING MANUFACTURED IN THE SAME SECTION AND ALSO MEETS THE SAME GMP COMPLIANCE AND WITH SAME MANUFACTURING LICENSE."

Decision: The Board accepted the clarification submitted by the firm and approved the product with direction to BE&R Division for issuance of registration letter as the panel has already conducted the virtual GMP inspection.

Deferred case of 5th PRV Meeting.

Case No.4. M/s Novartis Pharma (Pakistan) Limited, Karachi has applied for the change of Manufacturing Site and Marketing Authorization Holder of their already registered biological product as per following details:

Sr. No.	Reg. No. and date	Brand Name and Composition	Existing Marketing Authorization Holder & Manufacturer	Demanded New Manufacturing Site
6.	025218 Dated 23-11-1999	**Simulect 20 mg injection** Each vial contains: Basiliximab 20 mg	**Manufacturer:** M/s Novartis Pharma Stein AG, Schaffhauserstrasse 4332, Stein, Switzerland.	**Marketing Authorization Holder:** M/s Novartis Europharm Limited, Vista Building Elm Park, Merrion Road, Dublin 4 Ireland. **Manufacturer.** M/s Patheon Italia S.P.A., Viale G.B. Stucchi, 110 – 20900 Monza (MB), Italy.

The case has been evaluated as per approved Guidelines: Post Registration Variation Guidelines of Pharmaceutical and Biological and tabulated below:

Documents required as per Guidelines	Documents submitted by the firm	Remarks
Application	Submitted	
Required fee as per relevant SRO.	**Simulect 20mg Injection:** Fee Challan of Rs. 150,000/- Online Slip Number: 5968537970 dated 20-03-2023	
Copy of registration letter and last renewal status	Copy of Registration letter, dated 23-11-1999 Copy of last renewal submission dated 21-Oct-2019	

Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	• Firm has submitted Valid copy of EMA CoPP for **Simulect 20mg Injection** (Certificate # 02/23/178577) with issue date: 24.01.2023 issued by EMA. Authenticity verification for electronic certificates | European Medicines Agency (europa.eu) • The CoPP specifies free sale status of applied product in exporting country. • The CoPP also confirms GMP compliant status of the manufacturer.	
Manufacturing Process and Batch Analysis Data of both Manufacturing Sites	Submitted	
Revised Sole Agency Agreement when there is change in MAH	Submitted	
Undertaking that provided information/ documents are true & correct.	Submitted	

Registration Board in its 307th and 316th meetings delegated its power/Functions for Change of Manufacturing Site and Marketing Authorization Holder of imported drugs to the Chairman Registration Board.

Decision of 5th PRVC Meeting: **After detailed deliberation, on the recommendation of the Committee, the Chairman Registration Board decided to defer the application for seeking the clarification of the following:**

a. **Provide any evidence for the existing Manufacturer and Marketing Authorization Holder address.**

b. **Marketing Authorization Holder in CoPP is different from the existing approved Marketing Authorization Holder.**

Now the firm has submitted old CoPP and the detail of the product is as under:

Reg. No. and date	Brand Name and Composition	Existing Marketing Authorization Holder(MAH) & Manufacturer	Demanded New Manufacturing Site and(MAH)
025218 Dated 23-11-1999	**Simulect 20 mg injection** Each vial contains: Basiliximab 20 mg	**Manufacturer:** M/s Novartis Pharma Stein AG, Schaffhauserstrasse 4332, Stein, Switzerland. **MAH (As per old CoPP):** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland	**MAH:** M/s Novartis Europharm Limited, Vista Building Elm Park, Merrion Road, Dublin 4 Ireland. **Manufacturer.** M/s Patheon Italia S.P.A., Viale G.B. Stucchi, 110 – 20900 Monza (MB), Italy.

Decision: The Board after detailed deliberation approved the change of Manufacturing Site and Marketing Authorization Holder as per following details:

Reg. No.	Brand Name and Composition	Previous Marketing Authorization Holder(MAH) & Manufacturer	New Approved Manufacturing Site and Marketing Authorization Holder (MAH)
025218	**Simulect 20 mg injection** Each vial contains: Basiliximab 20 mg	**Manufacturer:** M/s Novartis Pharma Stein AG, Schaffhauserstrasse 4332, Stein, Switzerland. **MAH (As per old CoPP):** M/s Novartis Pharma Schweiz AG 6343 Risch Switzerland	**MAH:** M/s Novartis Europharm Limited, Vista Building Elm Park, Merrion Road, Dublin 4 Ireland. **Manufacturer.** M/s Patheon Italia S.P.A., Viale G.B. Stucchi, 110 – 20900 Monza (MB), Italy.

Case No.5. Registration of Drug (s) of M/s Nextar Pharma Pvt Ltd, Plot No, E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel Inspection Report dated 22-03-2023
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 20-05-2021. GMP Receiving date: 17-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
7.	Sematide Solution for Injection 0.5mg/0.375ml Pre-filled Syringe Each 0.375mL contains: Semaglutide…….0.5mg	Ozempic Injection Novo Nordisk Pharma (Private) Limited Karachi	XD4-62N-E6QM 30,000/(09-07-2024)
8.	Sematide Solution for Injection 0.25mg/0.188ml Pre- filled Syringe Each 0.188mL contains: Semaglutide…….0.25mg	Ozempic Injection Novo Nordisk Pharma (Private) Limited Karachi	QAE-359-3R2M 30,000/(09-07-2024)
9.	Sematide Solution for Injection 1mg/0.75ml Pre- filled Syringe Each 0.75mL contains: Semaglutide…….1mg	Ozempic Injection Novo Nordisk Pharma (Private) Limited	1YE-A37-QVQX 30,000/(09-07-2024)

		Karachi	
Source of Bulk: M/s Zhejiang Peptites Biotech Co.,Ltd. **Manufacturing Address;** No.8, Hengyizhi Road, Sanjie Town, Shengzhou City, 312452, Zhejiang China			

Remarks:

The firm has submitted following documents:

i. Copy of GMP Certificate is issued by Zhejiang Medical Products Administration, 27Wenbei Lane Mogansan Road Hangzhou 310012 P.R.China.

ii. Copy of Export Order from M/s World Health Pharmaceutical Co.,Ltd ,Cambodia is submitted.

Decision: The Board after detailed deliberation approved the products Sematide Solution for Injection 0.5mg/0.375ml Pre-Filled Syringe, Sematide Solution for Injection 0.25mg/0.188ml Pre- Filled Syringe and Sematide Solution for Injection 1mg/0.75ml Pre- Filled Syringe for export purpose only.

Case No.6. Registration of Drug (s) of M/s The Searle Company Limited F-319, S.I.T.E Karachi contract manufactured by Nextar Pharma Pvt Ltd, Plot No, E-58, North Western Industrial Zone, Port Qasim, Karachi, Pakistan for export purposes only.

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

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel Inspection Report dated 22-03-2023
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate dated 20-05-2021.GMP Receiving date: 17-05-2023
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy. No. (EFD)/Fee with date
I	**II**	**III**	**IV**
10.	Clotenox 40mg Pre-filled Syringe Each 0.4ml Pre-filled Syringe Contains: Enoxaparin Sodium…….40mg	Clexane 40mg PFS Hoechst Pakistan Limited (Formerly Sanofi Aventis)	LT8-MRL-ABBN 30,000/(16-05-2024)
11.	Clotenox 60mg Pre-filled Syringe Each 0.6ml Pre-filled Syringe Contains: Enoxaparin Sodium…….60mg	Clexane 60mg PFS Hoechst Pakistan Limited (Formerly Sanofi Aventis)	DMH-U6U-JAMM 30,000/(16-05-2024)
12.	Clotenox 80mg Pre-Filled Syringe Each 0.8ml Pre-Filled Syringe contains: Enoxaparin Sodium…….80mg	Clexane 80mg PFS Hoechst Pakistan Limited (Formerly Sanofi Aventis)	TZT-GZQ-58RS 30,000/(16-05-2024)
Source of Bulk: Dongying Tiandong Pharmaceutical Co., Ltd			

Manufacturing Address;
No.1236,Nan-er Road, Dongying City

Remarks:

The firm has submitted following documents:

i. Copy of GMP Certificate is issued by Shandong Food & Drug Administration

ii. Copy of Export Order from M/s World Health Pharmaceutical Co.,Ltd ,Cambodia is submitted.

Decision: The Board after detailed deliberation approved the products Clotenox 40mg Pre-filled Syringe, Clotenox 60mg Pre-filled Syringe and Clotenox 80mg Pre-Filled Syringe to M/s The Searle Company Limited F-319, S.I.T.E Karachi contract manufactured by Nextar Pharma Pvt Ltd, for export purpose only.

CASES OF DD-III (Ms. HALEEMA SHARIF)

WHO PQ Vaccine

13.	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd.** **Plot 36-A, PSIC SIE, Taxila Rawalpindi**
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A,PSIC,SIE,Taxila Rawalpindi Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	Name: Sinovac Biotech Co., Ltd. Address: No.15 Zhitong Road, Changping District, Beijing, P.R China.
	Name, address of manufacturer(s)	Name: Sinovac Biotech Co., Ltd. Address: No.15 Zhitong Road, Changping District, Beijing, P.R China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of COPP issued by NMPA China. The COPP specifies that the product is licensed for sale in country of origin. This COPP can be verified from National Medicine Product Administration Database
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of Sole Agency Letter from **M/s Sinovac Biotech Co., Ltd.** According to the letter, the firm **M/s Sinovac Biotech Co., Ltd** exclusively authorizes "**M/s Lab Diagnostic Systems (SMC) Pvt. Ltd.** for the purpose of registration, distribution and marketing of the product."

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form -5F Dy. No.: Dated: 31/5/2024
	Details of fee submitted	Rs: 3,00,000 Dated: 23/05/2024 Deposit Slip No. 284391799406
	The proposed proprietary name / brand name	Poliomyelitis Vaccine (Vero Cell), Inactivated Sabin Strains
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	1 dose (0.5ml) contains: 15 DU of inactivated Poliovirus Type 1, 45 DU of inactivated Poliovirus Type 2, 45 DU of inactivated Poliovirus Type 3
	Dosage form of applied drug	Suspension for Intramuscular Injection.
	Pharmacotherapeutic Group of (API)	Polio Vaccine
	Reference to Finished product specifications	Chinese Pharmacopeia
	Proposed Pack size	1 vial/ box
	Proposed unit price	As per SRO
	Shelf Life	24 Months
	Storage Conditions	Store between +2 and +8 °C. Protect from light. Do not freeze. Keep out of children.
	The status in reference regulatory authorities	Product Name: Sabin 株脊髓灰质炎灭活疫苗（ Vero 细胞） English Name: Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains Authorization Number: GYZZ S20170006

		Marketing Authorization Holder: Name: Beijing Institute of Biological Products Co., Ltd. Address: Room 205, Second Floor, Building 4, No.9 Bo'xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China Manufacturer: Name: Beijing Institute of Biological Products Co., Ltd. Address: No. 6&9 Bo' xing 2nd Road, Economic-Technological Development Area, Beijing, P.R. China **WHO-PQ Product**
	For generic drugs (me-too status)	Product Name: **Imovax Polio Vaccine MD** Reg. No. **077526** MAH: **Sanofi aventis Pakistan Limited** Manufacturer: **Sanofi Pasteur S.A. Lyon France**
	Module-II (Quality Overall Summary	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Manufacturer: Sinovac Biotech Co., Ltd. Registration address: No. 39, Shangdi Xi Road, Haidian District, Beijing, P. R. China Site Address: No.15, Zhi Tong Road, Changping Science Park, Changping District, Beijing, P. R. China Qc Test Address: No.15, Zhi Tong Road, Changping Science Park, Changping District, Beijing, P. R. China No. 39 Shangdi Xi Road, Haidian District, Beijing, P. R. China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of Type I Bulk (3 Batches), Type II Bulk (3 Batches) , Type III Bulk (3 Batches) at at 2℃ to 8 ℃ for 42 months. And the firm has also submitted stability data conducted at commercial scale for Type I Bulk (3 Batches) Type II Bulk (3 Batches) Type III Bulk (3 Batches) at 37℃ ℃ for 28 days.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	The container closure system consists of primary packaging materials and secondary packaging materials. The primary packaging consist of Injection vial (2ml tubing made of neutral borosilicate glass) Stopper for injection (Halogenated butyl rubber stopper for 2ml vial) ;secondary packaging materials include labels, package inserts, boxes.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches conducted at 2 °C -8°C for 24 months and also at 37 ± 2 °C for 7 days. The accelerated stability data provided of 03 batches and is conducted at 25°C for 6 months.
	Module-IV Non-Clinical	Firm has provided Module IV
	Module-V Clinical	Firm has provided Module V
	Remarks of Evaluator	
	Decision: Keeping in view the WHO PQ status of product Registration Board approved the product.	

Rabies Vaccine:

Out of que consideration of Rabies vaccine owing to shortage of Rabies vaccine.
So following application of Rabies vaccine is evaluated & placed before Board for its consideration:

14.	**Name, address of Applicant / Importer**	**Lab Diagnostic Systems (SMC) Pvt. Ltd.**

		Plot 36-A, PSIC SIE, Taxila Rawalpindi
	Details of Drug Sale License of importer	License No: 01-374-0006-96845D **Address:** 36-A,PSIC,SIE,Taxila Rawalpindi Validity: 04/08/2024
	Name and address of marketing authorization holder (abroad)	Name: Changchun Zhuoyi Biological Co. Ltd. Address: No. 2 Yongxin Road, Economic Development Zone, Shuangyang District, Changchun, Jillin Province, China.
	Name, address of manufacturer(s)	Name: Changchun Zhuoyi Biological Co. Ltd. Address: No. 2 Yongxin Road, Economic Development Zone, Shuangyang District, Changchun, Jillin Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted copy of CoPP issued by NMPA China. The COPP specifies that the product is licensed for sale in country of origin. The COPP also specifies the GMP status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted Pakistan notarized copy of Sole Agency Letter from **M/s** Changchun Zhuoyi Biological Co. Ltd. According to the letter, the firm **M/s** Changchun Zhuoyi Biological Co. Ltd. exclusively authorizes "M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. for the purpose of registration, distribution and marketing of the product."
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Form -5F Dy. No.: Dated: 25/03/2024
	Details of fee submitted	Rs: 3,00,000 Dated: 25/03/2024 Deposit Slip No. 838472375473
	The proposed proprietary name / brand name	BioShoot Rabies Vaccine (Vero Cell) for Human use, Freeze dried.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	After Reconstitution, 1 dose (0.5ml) contains: Protective activity of Rabies antigen …….. ≥2.5IU.
	Dosage form of applied drug	Freeze dried powder for injection
	Pharmacotherapeutic Group of (API)	Rabies Vaccine
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack size	5 vials/ box. 5 vials/person with 5 sterile water for injection
	Proposed unit price	As per SRO
	Shelf Life	36 Months
	Storage Conditions	2–8 °C
	The status in reference regulatory authorities	Imovax® Manufacturer: Sanofi Pasteur, SA USFDA Approved
	For generic drugs (me-too status)	Rabies vaccine (vero cell) Human use Reg No. 091880 Bulk Manufacturer: Liaoning cheng da Biotechnology Co., Ltd. No.1, Xinfang Street, Hunnan New District, Shengyang, China Pakistan;
	Module-II (Quality Overall Summary	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies

		of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Manufacturer: Changchun Zhuoyi Biological Co., Ltd. Address: No.2 Yongxin Road, Economic Development Zone, Shuangyang District, Changchun, Jilin Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions. The real time stability data is conducted at 5℃ ±3 ℃ and 25 ± 2 ℃ for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	The container closure system consists of primary packaging materials and secondary packaging materials. The primary packaging consist of neutral borosilicate glass vial for injection and chlorobutyl rubber stoppers for freeze-dried sterile powder for injection. ;secondary packaging materials include labels, package inserts, boxes.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted accelerated stability data of 3 batches conducted at 25 ± 2 °C and 60%±10% for 6 months. The long term stability data provided is of 03 batches and is conducted at 4°C ± 2 °C for 42 months.
	Module-IV Non-Clinical	Firm has provided Module IV as per CTD format
	Module-V Clinical	Provided

	Remarks of Evaluator	
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin. Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Heparin Sodium 25,000IU

15.	Name, address of Applicant / Importer	**M/s Sultan Health Care** Khaiwat No 47,khatooni No 170,khasra No 35,saddat plaza, Main shahpur syedan Road,near Radio Colony Gate, Adyala Gate,Adyala Road,Rawalpindi
	Details of Drug Sale License of importer	License No: 01-374-0176-108203D Address: Khaiwat No 47,khatooni No 170,khasra No 35,saddat plaza, Main shahpur syedan Road, near Radio Colony Gate, Adyala Gate,Adyala Road, Rawalpindi Validity: 05-09-2028 Status: Distribution License
	Name and address of marketing authorization holder (abroad)	M/s Tianjin Biochemical Pharmaceutical Co. Ltd., No. 269,Huanhenan Road, Tianjin pilot free trade zone (Airport Economic Area) Tianjin China
	Name, address of manufacturer(s)	M/s Tianjin Biochemical Pharmaceutical Co. Ltd.,
		No. 269,Huanhenan Road, Tianjin pilot free trade zone (Airport Economic Area) Tianjin China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. Tianjin) valid till (14-02-2025) issued by Tianjin Province Drug Administration. The certificate specifies the GMP status of the manufacturer. The certificate specifies the Free Sale status of the product in country of origin.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Letter of Authorization from Enterprise Legal Person of M/s Tianjin Biochemical Pharmaceutical Co., Ltd., According to the letter, the firm *M/s Tianjin* exclusively authorizes "Sultan Health Care" to register, sale and quote the product. The letter was issued on 21-02-2023 and valid till 08-02-2028.
	Status of the applicant	• Manufacturer ☒ Importer • Is involved in none of the above (contract giver)
	Status of application	• New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dated 05-01-2024
	Details of fee submitted	Rs. 300,000/- dated 07-06-2024
	The proposed proprietary name / brand name	Seltaparin Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial (5mL) contains: Heparin Sodium..... 25000IU
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anticoagulant
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10 Vials\Box
	Proposed unit price	As per SRO
	Shelf Life	03 Years
	Storage Conditions	25±2°C/60±5% RH
	The status in reference regulatory authorities	Heparin Panpharma of M/s Panpharma, France.
	For generic drugs (me-too status)	Vaxcel Heparin Sodium Injection of M/s Ghazali Brothers (Reg. No. 088528).
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and
		justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Tianjin Biochemical Pharmaceutical Co. Ltd., No. 269,Huanhenan Road, Tianjin pilot free trade zone (Airport Economic Area) Tianjin China

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Drug Substance at real time conditions for 36 months and accelerated conditions for 06 months. The real time stability data conducted at $25^0C \pm 2^0C/60 \pm 5\%RH$.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Anti-factor IIa Activity, Anti-factor Xa activity, Benzyl Alcohol determination & Sterility test. Firm has submitted verification of Analytical methods of Related substances & Bacterial Endotoxin test.
	Container closure system of the drug product	Low Borosilicate Glass Tube Injection Bottle, Halogenated Butyl Rubber Stopper for injection, Aluminum plastic combined cover
	Stability study data of drug product	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 40±2°C/75%RH±5% for 6 months. The real time stability study data is conducted at 25±2°C/60%±5RH for 36 months.
	Remarks of Evaluator	The product is not on free sale in china as per CoPP.
	Decision: Registration Board deferred the product for clarification/evidence whether this API is used in manufacturing of finished product registered in any other strength in the country of origin	

Division of Quality Assurance & Laboratory Testing

Agenda Item No. 01	**Complaint of M/s Brookes Pharma (Pvt.)Ltd , Karachi for manufacturing and sale of Alleged counterfeit of their Product "Pyodine solution" by various manufacturer throughout the country.**

BACK GROUND:

1. M/s Brookes Pharma (Pvt.) Ltd has launched complaints for manufacturing and sale of Alleged counterfeit of their Product "Pyodine solution" by various manufacturer throughout the country. Further M/s Brookes Pharma filed writ petition No.2073/2024 before the honorable Islamabad High Court. Honorable High Court passed disposed of the petition with following orders and also requested for personal appearance before Director QA/LT

- ***"The petitioner is aggrieved by inaction of the respondents in taking action against the sale and distribution of counterfeit products.***
- ***The learned counsel for the petitioner states that the petitioner is a licensed producer of pyodine solution. He states that centerfield versions of the said products are being sold and in such regard complaints have been made by the petitioner on 24-05-2024 and 29-05-2024 to the respondents to take action pursuant to section 30 of the Drugs Regulatory Authority of Pakistan Act ,2023. but no action has been taken by the respondents.***
- ***Let a copy of this petition along with the annexures be sent to the respondents, who will treat as a part of already filed and decide the same in accordance with law through a reasoned order within period of two weeks.***
- ***The petition is disposed of in the above terms."***

PROCEEDS AND DECSION OF 242ND Meeting of DRB:

(Item No. X Change of brand name of registered drugs.)

- Drugs are registered with brand names. Due to various reasons names are changed after grant of registration due to any of following reasons:
  a. Due to resemblance with already registered drug, manufacturer applies for change of name. No fee is charged for this purpose.
  b. Due to any business / commercial reason. Fee is charged.
  c. One manufacturer / registration holder grants No Objection Certificate to another for change of brand name. Fee is charged for such cases but in some cases one manufacturer apply for change of name but another did not apply for same for much time and thus product remain without name till that time.

- **Decision**: Registration Board discussed scenarios for change of brand name and decided as follows:
  Brand names of already registered drugs will be changed due to resemblance with another brand name.
- In future, change of brand names of both manufacturers / importers due to grant of No Objection Certificate will be processed simultaneously. However, for those cases in which brand name for

one manufacturer / importer has already been changed then brand name of another registration holder will be decided on priority.

- Registration Board decided that if brand names of two products resemble, then later registration holder is bound to propose alternate names for approval as one of condition of registration. But in some cases, later registration holder do not propose alternate names. The Board decided that in such cases DRAP will issue one reminder with 15 days time period and then manufacturing of the product will be stopped after approval of Chairman, Registration Board. Stoppage of manufacturing will be till approval of new brand name.
- Registration Board also decided that if packing material of two products resemble, then later registration holder is bound to change packing material / design as one of condition of registration. But in some cases, later registration holder avoids to change packing design. Thus Board decided that in such cases DRAP will advise the manufacturer / importer to change the pack design with one reminder with 15 days' time period and then manufacturing of the product will be stopped after approval of Chairman, Registration Board. Stoppage of manufacturing will be till approval of new pack design.

Proceeds of QA/LT:

2. In compliance to orders of honorable Islamabad High Court passed in writ petition No 2073/2024, received in DRAP on 12-07-2024, DRAP has initiated the response and directions were passed on to all DRAP field offices for taking the necessary action under the law to address the complaints of the applicant regarding manufacturing and sales of allegedly counterfeit products of "Pyodine Solution".

3. Upon request of the firm, QA/LT division of DRAP has also provided an opportunity vide letter No.Dy.162-2024-DDLT dated 22-07-2024 to the applicant, M/s Brooks Pharma (Pvt.) Ltd. Karachi through their authorized representative to personally appear and submit their stance along with the proofs and evidences. Mr. Arif Hussain Siddique along with Council appeared before Director QA/LT and presented physical samples of many manufacturers and claimed that they have close resemblance with their product and immediate action / cognizance along with manufacturing stoppage and sale restriction, seizure of marketed stock be taken immediately.

4. DRAP field offices have already started market surveillance and also issued explanation letter to all alleged manufacturers of counterfeit products. Reports along with explanation letter of eight manufacturers have been received from DRAP, Lahore office one from DRAP, Karachi and three from DRAP, Islamabad.

5. Director QA/LT appraised representative of firm that market surveillance has been started, once the reports from all field offices along with explanation of alleged counterfeit product will be received, then the matter will be placed before the upcoming meeting of competent forum, i-e Drug Registration Board to be held on 6,7 and 8 August 2024 under Drug Act 1976, DRAP Act 2012 and rules made thereunder. It was also observed from the provided evidenced that all the alleged counterfeit Products were found registered by Drug Registration Board and any complain of registered product would be presented before Drug registration board after conduct of thorough investigation by DRAP field offices/ Federal Inspector of Drugs for consideration and decision.

6. Representative of Brookes Pharma also requested for opportunity of personal hearing before Drug Registration Board in forthcoming meeting to be held on 6 -8 August 2024. Director QA/LT agreed to provide applicant with personal hearing on 08-08-2024, before Drug Registration Board.

7. The details of Alleged countrified products of "Pyodine Solution" of M/s Brookes Pharma, Karachi, as provided by firm is as under,

Resemblance Status of Pyodine Solution

S#	Brand Name	Reg. No	Strength	Pack size	Manufactured by	Picture
OUR PRODUCT						
01.	Pyodine Solution	009528	10%	60ml, 450ml	Brookes Pharma Private Limited, Plot no 58-59, Sector 15, KIA, Karachi	Attached
COUNTERFEIT/ LOOK ALIKE PRODUCTS						
1.	Zyodine Solution	045451	7.5%	50ml, 400ml	Zanctok Pharmaceutical Laboratories, F/5 site Hyderabad Sindh	Attached
2.	Prodine Solution	037440	10%	500ml 50ml	M/s. Kohinoor Industries 159-160/B Small Industrial Estate, Sahiwal Pakistan	Attached
3.	Pyidine Solution	080824	7.5%	50ml, 60ml	Cortex Pharmaceuticals Plot No 16-A, St No. SS 4, Rawat Industrial Estate, Rawalpindi	Attached
4.	Povine Solution	037527	10%	50ml, 450ml	PharmaWise Labs. (Pvt), 5-M, Green Belt Rd, Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore, Punjab	Attached
5.	Pyogon Solution	0020062	10%	50ml	Glorious Laboratories Plot no. 136 Industrial Triangle, Kahuta Road, Islamabad	Attached
6.	Poviderm Solution	094559	5%	75ml	Hoover Pharmaceuticals (Pvt.) J745+598, Varat, Lahore, Punjab	Attached
7.	Povidone-I	026935	7.5%	60ml	N.B.S Pharma 8th -Km. Thokar Rawid Road, Lahore	Attached
8.	Septodine Antiseptic Solution	049925	10%	60ml	Oval Pharmaceuticals 112/11, Quaid-e-Azam Industrial Estate Township, Lahore	Attached
9.	Japodon Solution	096512	10%	60ml	JAWA Pharmaceuticals (Pvt). Ltd, 11/10 Quaid-e-Azam Kot Lakhpat, Lahore	Attached

10.	Plasodine	014228	7.5%	50ml	Lahore Pharma 9 Km Lahore-Sheikhupura-Faisalabad Rd, near Al Ghazi Tractors, Kot Abdul Malik Lahore, Sheikhupura Punjab	Attached
11.	Povidone Iodine	071551	7.5%	60ml	Paradise Pharma 23-KM, Sheikhupura Road, Lahore	Attached
12.	ISIS Povidone Iodine Solution	110071	10%	450ml	ISIS Pharmaceuticals & Chemical Works 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi, Pakistan	Attached
13.	Povid Solution	036463	-	60ml	Eros Pharmaceuticals (Pvt.) Ltd. 94-95-Korangi Industrial Area, Karachi-Pakistan	Attached
14.	Payodine Solution	-	10%	60ml	A.Mannan Lab. Plot # 125, Korangi No. 04 Industrial Area Karachi	Attached
15.	Pyoline Solution	-	7.5%	50ml	Zaiman Pharma Nutraceuticals &CAM Division 4-B Industrial Estate Multan Road, Lahore	Attached
16.	Septiwel Solution	073137	-	60ml, 450ml	Medwell Pharmaceuticals 1 KM Tarbela Rd, Attock, Punjab	N/A
17.	Pyrodent Scrub	038201	-	50ml	Rehmat Pharma X3GM+V4P, Sector 11-F Sector 11 F North Karachi Twp, Karachi, Karachi City, Sindh	N/A
18.	Povidone Solution	059806	-	-	Festel Laboratories Plot # 9 Street 1, Block 5 model colony, Karachi, Karachi City, Sindh	N/A
19.	Wonderseptic Solution	030073	-	-	Izra Pharma J6CV+B55, Kot Abdul Malik, Sheikhupura, Punjab	N/A
20.	Halodine Solution	057302	7.5%	60ml	Trigon Pharmaceuticals 8-km Thokar, Raiwind Rd, Bhobtian, Lahore, Punjab 54000	N/A

21.	Pyosept Solution	036090	-	-	Medisearch Pharmacal (Pvt) Ltd 5-KM Raiwind Manga Road Lahore	N/A
22.	Povidone Iodine	026935	7.5%	60ml	Perfect Pharma (Pvt.) Ltd. 5-K.M Manga Road Raiwind Lahore, Pakistan.	N/A
23.	Pyrodine Solution	062748	7.5%	-	A'raf (Pvt) Ltd 23 KM Raiwind Road Lahore	N/A
24.	Pyosep Solution	-	-	60ml	Sapient Pharma 123/S, Quaid-e-Azam Industrial Estate Quaid e Azam Industrial Estate, Lahore, Punjab	N/A
25.	Povidone Iodine Solution	-	10%	60ml	Nawab Sons Laboratories 7/A Friends Colony, Bastami Road, Multan Road,Lahore	N/A
26.	Paydeen Solution	-	-	50ml	Aleeq Chemicals B, 15Km Bhimber Road Gujrat Pakistan	N/A

8. The replies/explanation letters as submitted by different alleged manufacturer submitted to F.I. Ds which are forwarded to QA/LT division, are as under;

irza
"Health First" is "Health Always"
Irza Pharma (Pvt) Limited.

REGISTERED

Ref. No. IP/17/2024
Dated: 18.07.2024

To,
Federal Inspector of Drugs
Lahore.

Subject: **Reply of The Letter "Counterfeit" Product, Pyodine Solution(Reg No 009528)**

Dear Sir,

In the Context of the subject caption above vide **letter No. 1860/2024-DRAP(L-IV) dated 11.07.2024** regarding the manufacturing of counterfeit Pyodine Solution.

We M/s Irza Pharma (Pvt) Limited is law abiding unit and never ever involved in any kind of illcit activity as mentioned in the subject.The proof is attached as comparison of the label of our Product (WONDSEPTIC Solution 7.5% Both 50ml as well as 450ml).

The color scheme is different to the **Brooks Product.** Therefore we M/s Irza Pharma (Pvt) Ltd. is not involved in any violation of DRAP rules and Regulation.

We do belive in the independent and isolated color scheme which should not match to the color schem of any product available in the market. Moreover some highlighted differences are.

Difference		
Sr. No	**WONDSEPTIC Solution**	**PYODINE Solution**
1.	Irza Pharma (Pvt) Ltd.	Brooks Pharma (Pvt) Ltd.
2.	50 ml/450ml	60 ml/450ml
3.	7.5 %	10 %
Color Difference		
4.	Blue/ White & Red	White /Redaish brown
5.	White Dominated	Redash brown Dominated
6.	Brand Name in yellow ink	Brand Name in white ink

Contd. Page No.02

19 JUL 2024

10.2 km. Lahore Sheikhupura Road, Lahore, Pakistan.Tel: (+92-42) 37924842 - 37921141 E-mail: irzapharma@gmail.com URL: http:\www.irzapharma.com

ISO Certified

irza

"Health First" is "Health Always"

Irza Pharma (Pvt) Limited.

Therefore kindly drop the issue and oblige. We shall be very thankful to you in this favour.

THANKS IN ANTICIPATION

Attachment:

i) Colored copies of labels attached
(As available in market)

Sincerely Yours

***for* IRZA PHARMA (PVT) LTD.**

Iftikhar Masud
(Plant Manager)

Akbar Ali
Deputy Director (Lab Testing)
Monday, 29 July, 2024, 11:45:12 AM

10.2 km, Lahore Sheikhupura Road, Lahore, Pakistan Tel: (+92-42) 37924842 - 37921141 E-mail: irzapharma@gmail.com URL: http:/www.irzapharma.com

Annex-2

PharmaWise Labs.

(Pvt.) Ltd.
(Formerly Fakma Pharma)

Dated: 19-07-2024

To

Mohtaram,
Abdul Rashid Shaikh,
Federal Inspector of Drugs,
Government of Pakistan,
Drug Regulatory Authority of Pakistan,
06-A.R., Chugtai Road, **Lahore.**

Dear Sir,

Subject: - **COUNTERFEITS PRODUCT PYODINE SOLUTION (REG.NO.009528).**

Immense thanks for your letter No.1863/2024/DRAP(L-IV) dated 11-07-2024, on the said subject, received by us via WHATSAPP on 12-07-2024, the original yet not received.

The matter of manufacture and sale (MARKETING) of COUNTERFEIT DRUGS is frequent and it seems the market is FLOODED with such drugs (Medicine), which indeed needs remedial measures to be adopted by the learned DRAP.

So as to precisely reply your above esteemed letter dated 11-07-2024, you are requested to supply to us an attested photocopy of letter No.BPL/RA/2024/360 dated 29-05-2024 of our friends M/S Brooks Pharma (Pvt) Limited, Karachi, mentioned in first line of your above refered letter dated 11-07-2024.

It is also requested to extend the time to reply to your above letter up to fifteen days beyond the date we receive an attested copy of the letter requested as above, from your good person.

Yours Truly

(Ch. Nadir Khan) B.Pharm.
Chief Executive.
Age: 82-Years
Ph: 0333-4241632

22 JUL 2024

Headquarters: 25-M,Q.A. Industrial Estate, Lahore-Pakistan. Tel:(+92-42)-35120719 to 721, 35153067, 35215618, 35215620, Fax:(+92-42)-35116574, Mobile: 0333-4244632, 0300-8417025, E-mail: pharmawise@yahoo.com
Sale office : 213 - Zulqarnain Chamber, Ganpat Road, Lahore-Pakistan. Tel:(+92-42)-37311594, 37221103, 37353323
Exporters/ N.Tax NO. 0452894-8, S.TAX NO. 03-02-3000-017-37, E-mail: pharmawise@hotmail.com

OVAL PHARMACEUTICALS

Annex-3

Ref: OV/786/24-010

Dated: 13-07-2024

Abdul Rashid Shaikh
Federal Inspector of Drugs
Lahore

Subject:- RE: Counterfeit Product Pyodine Solution Reg.No. 009528

Respected Sir,

In reference to your letter No. 1864/2024 DRAP(L-iV) dated 11-07-2024 regarding counterfeit Product Pyodine Solution, It is stated that our Product Septodine 10% was registered in 17th July,2008. It was applied for registration in 2004. It is stated that we are given a legal brand name from DRAP. We have not changed the name after registration. The first four alphabets do not resemble with Pyodine, brand name, as per requirement of DRAP. So it cannot claimed that our brand name resemble with Pyodine.

It is further stated that our packing design do not resemble with the brand Pyodine. It is therefore requested that kindly accept our explanation and obliged.

Regards,
For Oval Pharmaceuticals

OVAL PHARMACEUTICAL * LAHORE. *

Muhammad Tahir Mehmood
Managing Partner.

15 JUL 2024

Annex-4

Please examine and process as per the Drugs (T&E) Rules 1976

Ref: JPPL /QCM/24-16
Date: 20-07-2024

JAWA PHARMACEUTICALS (PVT.) LTD.

To,

Abdul Rasheed Sheikh,
Federal Inspector of Drugs,
Lahore.

Subject: -**Purported Counterfeit Japodon.**

Dear Sir,

Reference to your office letter no. 1866/2024-DRAP (L-IV) dated 11-07-2024, we want to submit as follows.

1- Sir, we got registration of our product Japodon 10% Solution with Reg. No. 096512 on 31st May 2019 via DRAP Letter No. F.15-2/2016-Reg-V (M-257).
2- Sir, we are manufacturing the said drug strictly in accordance with the design/pattern/Style of label on submitted along with our registration letter/application.
3- Sir, now vide your above said letter we have come to know that our design resembles to some extent to a product manufactured by M/S Brookes Pharma, Karachi.
4- Sir, our Product's label is not resembling with product manufactured by M/S Brookes Pharma, Karachi (Label of our Product Japodon 10% Solution is attached for your kind review).
5- In Sha Allah, you will always find us inclined to cooperate with DRAP and his officers when and where some mistake will be highlighted in future as well.

Thanking You

For
JAWA
PHARMACEUTICALS (PVT.) LTD

Government of Pakistan
Diary No. 123
22 JUL 2024
Drug Regulatory Authority of Pakistan, Islamabad
Ministry of National Health Services Regulation & Coordination

Quality Control Incharge

QUALITY CONTROL INCHARGE
JAWA PHARMACEUTICALS (PVT) LTD.

112/10
QUAID-E-AZAM
INDUSTRIAL AREA
KOT LAKHPAT LAHORE PAKISTAN

Label of Japodon 10% Solution

JAWA PHARMACEUTICALS
(PVT.) LTD.

Annex-5

LAHORE PHARMA
SIGN OF QUALITY & NATIONAL SERVICE
ISO 9001:2008 Certified

DATED:18/07/2024

TO

Government of Pakistan,
Ministry of national Services, Regulation and Coordination,
Drug Regulatory Authority of Pakistan,
6, A.R Chughtai Road, Lahore-54000.

Subject: *Counterfeits Product Plasodine Liquid (Reg. No 014228)*

Respected Sir,

As this is with reference the letter no.1867 / 2024- DRAP (L-IV) Dated11/07/2024 received on 12/07/2024 regarding complaint received from M/S Brooks (pvt) .Ltd. Karachi with letter no BPL/RA/2024/ DATED29-05-2024. It Here by to inform you that M/S.LAHORE PHARMA product registered as brand name Plasodine liquid 7.5% with under the Drug act 1976 PLASODINE LIQUID, registered with the Registration no 014228.

But M/S Brooks. PVT. Ltd Karachi registered product with brand name Pyodine solution 10 %.

In the respect sir kindly accept my letter if any query about for the registration of registered product plasodine liquid 7.5% we have fulfilled all requirement of the registration of Plasodine liquid 7.5% according to Drug Act 1976. In this letter for your kind perusal.

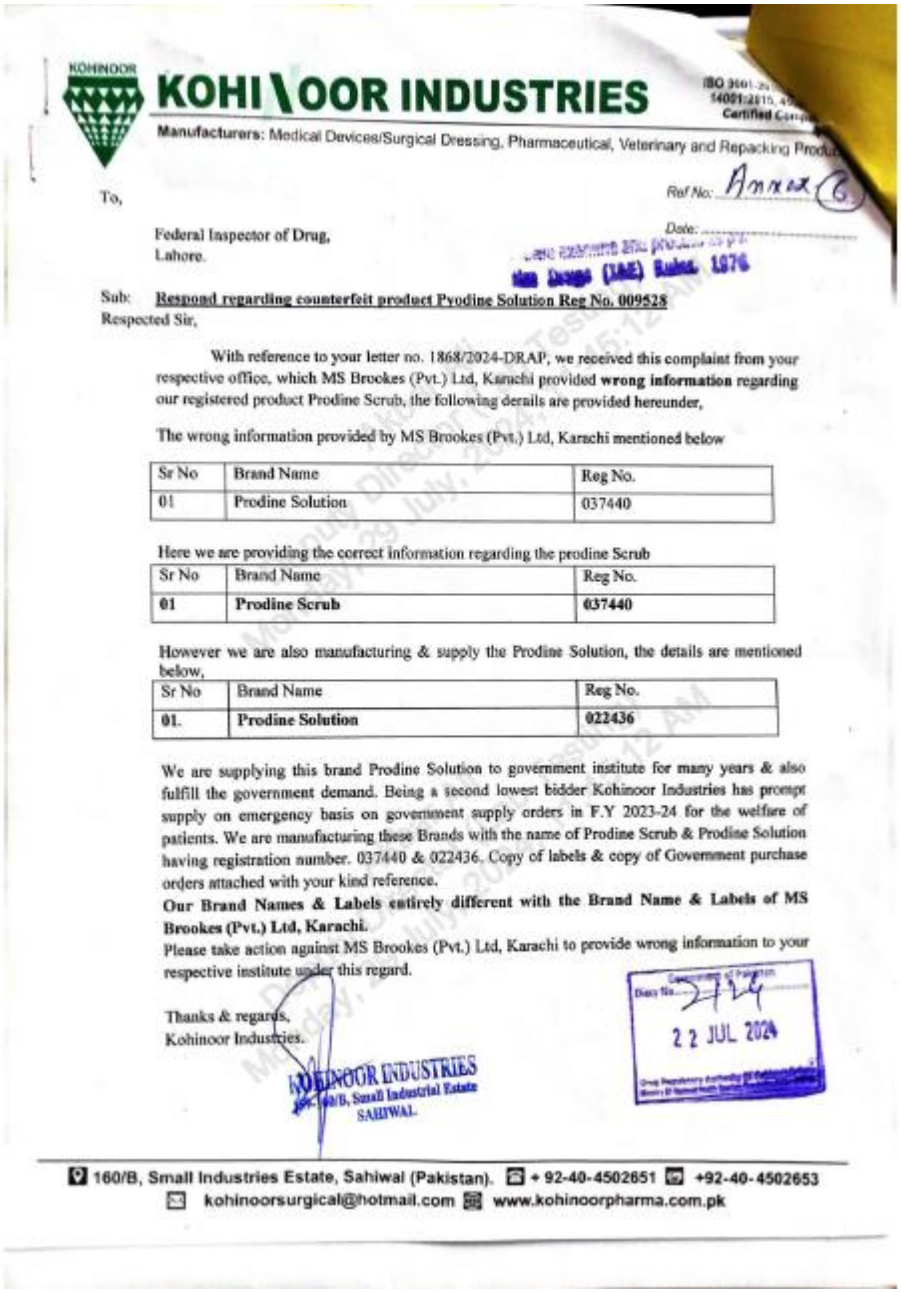
19 JUL 2024

Thanking you we remain.

Managing Director
(Mr. Yasir Saeed)

LAHORE PHARMA
9 KM Sheikhupura Road Dist. Sheikhupura

9 Km, Sheikhupura Road, Lahore
T: +92 42 37306848
E: info@lahorepharma.com



KOHINOOR INDUSTRIES

Manufacturers: Medical Devices/Surgical Dressing, Pharmaceutical, Veterinary and Repacking Prod

Ref No: Annex 6

Date:

To,

Federal Inspector of Drug,
Lahore.

Sub: **Respond regarding counterfeit product Pyodine Solution Reg No. 009528**

Respected Sir,

With reference to your letter no. 1868/2024-DRAP, we received this complaint from your respective office, which MS Brookes (Pvt.) Ltd, Karachi provided **wrong information** regarding our registered product Prodine Scrub, the following details are provided hereunder,

The wrong information provided by MS Brookes (Pvt.) Ltd, Karachi mentioned below

Sr No	Brand Name	Reg No.
01	Prodine Solution	037440

Here we are providing the correct information regarding the prodine Scrub

Sr No	Brand Name	Reg No.
01	**Prodine Scrub**	**037440**

However we are also manufacturing & supply the Prodine Solution, the details are mentioned below,

Sr No	Brand Name	Reg No.
01.	**Prodine Solution**	**022436**

We are supplying this brand Prodine Solution to government institute for many years & also fulfill the government demand. Being a second lowest bidder Kohinoor Industries has prompt supply on emergency basis on government supply orders in F.Y 2023-24 for the welfare of patients. We are manufacturing these Brands with the name of Prodine Scrub & Prodine Solution having registration number. 037440 & 022436. Copy of labels & copy of Government purchase orders attached with your kind reference.

Our Brand Names & Labels entirely different with the Brand Name & Labels of MS Brookes (Pvt.) Ltd, Karachi.

Please take action against MS Brookes (Pvt.) Ltd, Karachi to provide wrong information to your respective institute under this regard.

Thanks & regards,
Kohinoor Industries.

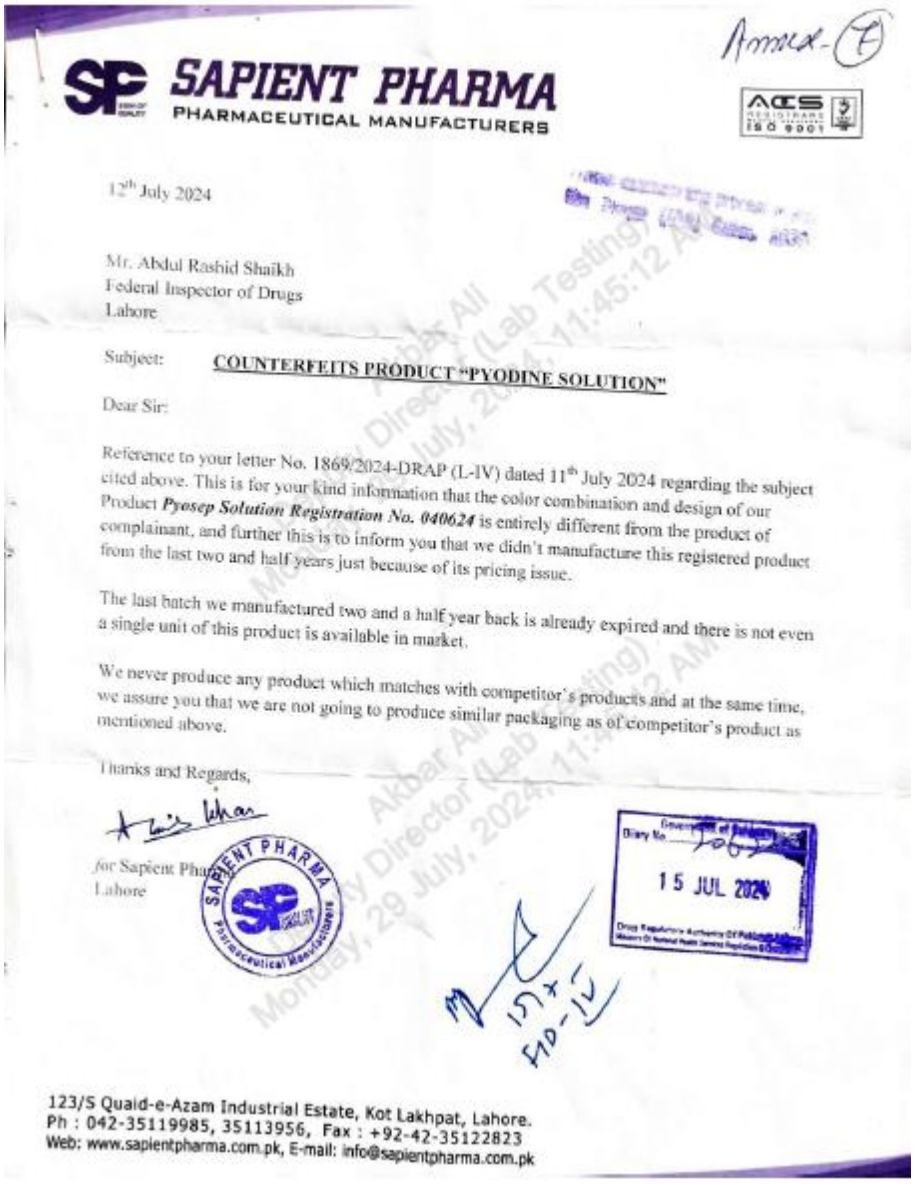
KOHINOOR INDUSTRIES
160/B, Small Industrial Estate
SAHIWAL

Dairy No. 2716
22 JUL 2024

160/B, Small Industries Estate, Sahiwal (Pakistan). + 92-40-4502651 +92-40-4502653
kohinoorsurgical@hotmail.com www.kohinoorpharma.com.pk

KOHINOOR
PRODINE®
SCRUB (USP)
POVIDONE-IODINE 7.5% W/V USP
EQUIVALENT TO 0.75% AVAILABLE IODINE
450 ml (Approx)
FOR EXTERNAL USE ONLY
IDEAL TOPICAL ANTISEPTIC
GERMICIDE BACTERICIDAL
FUNGICIDAL VIRUCIDAL
M.Lic. No : 000197
Reg. NO : 037440
Batch No.
Mfg. Date.
Exp. Date.
M.R.P. Rs.
Directions:
As Antiseptic Germicidal virucidal skin
cleanser forper and post operative
scrubbing or washing.
Cautions:
1. Discontinue treatment if irritation
or sensitivity develops.
2. Keep away from the reach of children.
3. Protect from sun light and heat.
COMPOSITION:
Each 100 ml contains:
Povidone-Iodine USP 7.5 g
equivalent to 0.75g available Iodine(0.75% W/V)
Manufactured By:
KOHINOOR
INDUSTRIES

IDEAL TOPICAL ANTISEPTIC
GERMICIDE BACTERICIDAL
FUNGICIDAL VIRUCIDAL
M.Lic. No: 000197
Reg. NO: 022436
FOR EXTERNAL USE ONLY
Batch No.:
Mfg. Date.
Exp. Date.
M.R.P. Rs.
450 ml
KOHINOOR
PRODINE®
SOLUTION (USP)
POVIDONE-IODINE 10% W/V USP
EQUIVALENT TO 1% AVAILABLE IODINE
COMPOSITION:
Each 100 ml contains:
Povidone-Iodine USP 10.0 g
equivalent to 1.0 g available Iodine (1% W/V)
Manufactured by
KOHINOOR INDUSTRIES
Directions:
1. For pre-operative cleansing apply directly.
2. For Cuts and wounds wash the area with prodine Solution and apply dressing if necessary.
Cautions:
1. Discontinue treatment if irritation or sensitivity develops.
2. Keep away from the reach of children.
3. Protect from sun light and heat.



Annex-(F)

SAPIENT PHARMA
PHARMACEUTICAL MANUFACTURERS

12th July 2024

Mr. Abdul Rashid Shaikh
Federal Inspector of Drugs
Lahore

Subject: **COUNTERFEITS PRODUCT "PYODINE SOLUTION"**

Dear Sir:

Reference to your letter No. 1869/2024-DRAP (L-IV) dated 11th July 2024 regarding the subject cited above. This is for your kind information that the color combination and design of our Product ***Pyosep Solution Registration No. 040624*** is entirely different from the product of complainant, and further this is to inform you that we didn't manufacture this registered product from the last two and half years just because of its pricing issue.

The last batch we manufactured two and a half year back is already expired and there is not even a single unit of this product is available in market.

We never produce any product which matches with competitor's products and at the same time, we assure you that we are not going to produce similar packaging as of competitor's product as mentioned above.

Thanks and Regards,

for Sapient Pharma
Lahore

SAPIENT PHARMA
Pharmaceutical Manufacturers

Diary No. 1869
15 JUL 2024

FD-IV

123/S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.
Ph : 042-35119985, 35113956, Fax : +92-42-35122823
Web: www.sapientpharma.com.pk, E-mail: info@sapientpharma.com.pk

N.B.S. PHARMA

R.T.M. No. 71114

Annex-(B)

Ref No: <784>

Dated: 20-07-2024

To

Please examine and process as per the Drugs (T&E) Rules, 1979

Abdul Rashid Shaikh

Federal Inspector of Drugs, Lahore.

Subject: **Explanation regarding my product Povidone-I Solution, Registeration number: 025552**

Dear Sir,

Respectfully, it is stated that I have received this letter **No. 1861/2024-DRAP(L-IV)** on 18-07-2024 in which my product Povidone Iodine has been rendered counterfeit.

Sir this is a baseless allegation from such Big company, which is also the brand leader of the market.

Sir we are a small factory, with very limited products on the list and we have no malafide intentions to copy or make any counterfeit drug products.

Sir I would like to state some differences among the products, which are visible to the naked eye,

	M/s Brookes (Pvt.) Ltd.	NBS Pharma
REG. Name	Pyodine with ® logo	Povidone-I Solution with no ® logo
REG. No.	009528	025552
LABEL	Not overlapped	Overlapped label
LABEL	Background pictures	No Background picture
LABEL	No 'SOL' stated	Clearly visible 'SOL' with distinguished picture
LABEL	Brooke's logo	NBS Logo with Yellow sun
LABEL	No Barcode	Visible 2D Barcode, opening to company profile.
CAP	Nothing is printed	NBS printed on top
BOTTLE	HDPE printed with some groove in bottom	ARR printed with no groove

22 JUL 2024

Sir, I hope above mentioned difference between both products are enough to clarify our position in this regard.

Thanking you & I remain,

N.B.S. PHARMA
8th-Km Thokar Raiwind Road
Lahore
Ph: 35321444

Sh.Shahzad Nabi,C.E.O (NBS Pharma)

Factory Address:- 8th-Km. Thokar Raiwind Road Lahore.
Postal address:- 328-Block (B) M.A. Johar Town Lahore.
Tel.Factory:
Cell: 0321-9453166
E-mail:nbspharma@hotmail.com

467

No. F. SHM/NTF-43-45/2024-(FID)(K-IV)
Government of Pakistan
Drug Regulatory Authority of Pakistan
2nd Floor, Building No. IV, Block-B
S.M.C.H.S.
"SAY NO TO CORRUPTION"

Karachi dated the 24th June, 2024

The Director (QA &LT),
Drug Regulatory Authority of Pakistan,
Islamabad.

Subject: Complaint of Ms. Brookes Pharma (Pvt.) Ltd., Korangi Industrial Area, Karachi, regarding Counterfeit/ Falsified Product - Inspection Thereof.

Dear Sir,

In compliance to the directions on the complaint of Ms. Brookes Pharma letter dated 3rd April' 2024 (Annexure-A), undersigned inspected the Ms. Zanctok Pharmaceutical Laboratories, F/5, S.I.T.E., Hyderabad on 24th April 2024 (Annexure-B) and draw samples on prescribed Form-3 (Annexure-C) and also visited Authorized distributor of Ms Brookes Pharma namely Ms. Abdullah Brothers & Co. situated at H. No. 115-A, Unit No. 03, Latifabad, Hyderbad (Annexure-D), and draw samples on Presribed Form-3 (Annexure-E). The sealed samples were sent to the Federal Government Analyst vide Memorandum Nos. SHM/NTF-43-44/2024-FID-(K-IV) dated 25th April' 2024 (Annexure-F) along with the Ms. Zanctok Statement (Annexure-G) and SHM/NTF-45/2024-FID(K-IV) dated 25th April' 2024 (Annexure-H) along with the copy of complaint (Annexure-A).

2. The **Federal Government Analyst**, Central Drugs Laboratory issued Form 6 i.e. Certificate of Test/ Analysis vide no.F.5-3(K)/2024-CD/S-1211 dated 9th May 2024 (Annexure-G) with remarks **"The sample cannot be declared as Imitation Product"**.

3. This is submitted in compliance to the DRAP, Islamabad letter no. F.03-23/2024-QC dated 4th June' 2024 referring similar complaint dated 15th May' 2024 by Ms. Brookes Pharma, K.I.A., Karachi.

4. The complete case is submitted for your perusal and further necessary action/ direction if deem appropriate in the matter please.

Yours sincerely,

(Encl. As above)

(Syed Hakim Masood)
Federal Inspector of Drugs-IV
Karachi

Copy to:
1. The Additional Director (QA& LT), DRAP, Islamabad.
2. The Additional Director, DRAP, Karachi.

Federal Inspector of Drugs-IV

ZANCTOK
Pharmaceutical Laboratories
Drug Manufacturing License #: 000251

Date:_____ Ref No.:_____

Finished Product Comparison Chart of Zyodine 7.5% Solution (ZPL) and Pyodine 10% Solution (Brooks)

S/No.	Description	Zanctok Pharma	Brooks Pharma
A	General Description		
1.	Brand Name	Zyodine Solution	Pyodine Solution
2.	Registration No.	045451	009528
3.	Strength	7.5%	10%
4.	Company Address	Zanctok Pharmaceutical Laboratories, F/5, SITE, Hyderabad.	Brooks Parma Private Limited Plot No. 58-59, Sector 15, Kia Karachi.
B	Pack Description		
01	Pack Material	Pet Bottle	Pet Bottle
02	Pack Size	50ml/400ml	60ml/450ml
03	Empty Bottle weightage	28.30 Gram (aprox)	43.18 Gram (aprox)
04	Different Cap weightage	3.18 Gram (aprox)	3.82 Gram (aprox)
05	Bottle Dimension	Different	Different
C	Label Description		
01	Colour	Brick red Pink Art Work with Dull Design	Mustard Off-White brown Art Work with Prominent Design
02	Text and Colour	Black, White & Red Colour	Black & White Colour
03	Font Type	Ariel Bold	Different
04	Style for Text at Bottle is different	Urdu nomenclature at bottle is written in normal style	Urdu nomenclature at bottle is written in stylish style
05	Different Company Logo	Oval Shaped with ZPL written in the Middle of Logo	Round Bottle Flask Merge in Black Colour Capital Alphabet B
06	Company Logo Colour	Red, Blue & White	Black
07	Certification Logo	IAS, BQSR Logos	No Logo of Certification
08	Stamp Space Colour and Text	White space square window for specifying following. Retail Price: B. No. Mfg. Date: Exp. Date:	Mustard, Brown off-white Colour art work merged window for mentioning following B. No. Mfg. Date: Exp. Date: MRP:
09	Price Difference	678.00	1600.00

From all above-mentioned comparison chart data facts, it is clearly justified that Zyodine 7.5% Solution is not a counterfeit product. It is an original DRAP Registration and Approved formulation of Zanctok Pharmaceutical Laboratories Hyderabad.

F/5, S.I.T.E, Area Hyderabad, Sindh - Pakistan

Government of Pakistan
Drug Regulatory Authority of Pakistan
CENTRAL DRUGS LABORATORY

Karachi the 09th May 2024

Test Report No.KQ-4-24-000092.

FORM 6
(See Rule 16)

CERTIFICATE OF TEST OR ANALYSIS
BY THE CENTRAL DRUGS LABORATORY/GOVERNMENT ANALYST

Certified that the samples, bearing number (SHM/NTF-44/24) purporting to be a sample of ZYODINE 7.5% w/v Solution received on 26-04-2024 with memorandum No.SHM/NTF-43-44/2024-FID-(K-IV). Dated 25-04-2024 from Federal Inspector of Drugs, Karachi has been tested / analyzed and that the result of such test / analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows: Intact.

~~3. In the opinion of undersigned the sample is not adulterated / sub standard / misbranded / spurious, as defined in the Drugs Act, 1976 for the reason given below:~~

DETAILS OF RESULTS OF TEST OR ANALYSIS **(with protocols of tests applied).**

ZYODINE 7.5% w/v Solution. Mfg. Lic.No.000251. Reg. No. 045451

Batch No. 835. Date/ Mfg. 03-24. Date/Exp. 02-26

Claimed to be manufactured by M/S. ZANCTOK Pharmaceutical Laboratories, HYDERABAD.

[Reproduced from Form-4 /label]

REMARKS: - 1) The sample has been referred to Central Drugs Laboratory by the Federal Inspector of Drugs, Karachi with note on Form-4 "sample drawn on a complaint of M/s. Brookes Pharma".

2) The sample (ZYODINE 7.5% w/v Solution) has been compared with brand leader i.e. "Pyodine Solution", registration number 009528, manufactured by M/S. Brookes Pharma (Private) Limited, Karachi. The colour scheme of the label and outer packing, font size, font style and graphics of the sample are different as compared with the brand leader, therefore the sample can not be declared as "Imitation product".

Test report is forwarded to: -

1. Concerned Federal Inspector of Drugs, Karachi.
2. The Additional Director QA & LT/ Chairman Quality Control for Registration Board, DRAP, Islamabad.

(Dr. Saif-ur-Rehman Khattak)
FEDERAL GOVERNMENT ANALYST

GLORIOUS LABORATORIES

TO

AREA FID

Subject: **Complaint Regarding Pyogon (Povidone-Iodine) Manufactured By Glorious Laboratories**

With reference to your telephonic direction, we are pleased to inform you that we are using this color scheme and design since 2016 and do not imitated any product label available in the market. However we are justifiable to inform that certain people are imitating our Pyogon label color scheme and design. It is pertinent to mention that certain manufacturer changes their labeling to disgrace our leading products and some are instituting fake complaints. Glorious Laboratories has its own ethical standard and does not believe in such activities

2. We are enclosing herewith the labels of Pyodine manufactured by Brooks Laboratories whose product Pyodine is available in different color scheme Label and design as per their web side information. We have downloaded label with different color scheme and design for one registered. Product We do not know that why the complained and what is there latest color scheme and label design in question. Our brand name address manufacturing and expiry date are all readable in chocolate color scheme with our own design, which we are using since 2016. Whereas Pyodine is available in Brown Red and other different color scheme each scheme is entirely different from the other for our product. However, if they have changed their color scheme in the recent past which is similar to our product we are unaware of it.

3. in the light above submission and documentary evidence, it is evident that the compliant does not hold any legal or ethical grounds, and there for requested that the same may be ignored.

Thanks and Regard

Plant Manager Glorious laboratories

Islamabad

GLITZ

R&I
24 JUL 2024

Ref. No.: GP/FID/07/2024-01 (Islamabad)
Date: July 23, 2024

Madam Saadia Mahwish
Federal Inspector of Drugs-1,
QALT DRAP, Islamabad

Subject: **GOVID SOLUTION (M/s Glitz Pharma) RESEMBLANCE CASE WITH PYODINE SOLUTION (M/s Brooks Pharma)**

Respected Madam,

I am writing to bring into your attention a concerning issue regarding a discrepancy in the Packaging and labeling resemblance of *Govid Solution* manufactured by Glitz Pharma with *Pyodine Solution* manufactured by Brooks Pharma. Govid is registered with the DRAP under Glitz Pharma registration Number 038607, while Pyodine is registered with DRAP by Brooks Pharma with registration number 009528, indicating compliance with regulatory authorities. We have not been manufacturing Govid Solution since 2021 because of Cost Impact.

Upon careful observation and comparison, it has come to attention that there exists a significant dissimilarity in the packaging, labeling, and even in the appearance of both medicines.

On review, it is evident that there are several notable differences between these two products:

1- The registered product name from DRAP of povidone iodine solution is Govid solution of Glitz Pharma whereas the trade name of Brooks Pharma is Pyodine.
2- Govid solution label is in dark brown in color whereas Brooks Pyodine are in light brown orange in color.
3- Govid solution labels is in simple text whereas Brooks Pyodine label with some different type of germicidal sketches.
4- Design of labels are clearly different with each other.
5- Text and font sizes are not match.
6- Govid solution bottle embossed with Glitz Pharma on the bottom of bottle and brooks Pyodine have no such company name.
7- Design and size of bottle also do not match with each other.
8- The Glitz Pharma product, Govid, features an embossed design with the Glitz Pharma name prominently displayed on the bottle.

Head Office: 205, Muhammadia Plaza, College Road, Rawalpindi, Pakistan.
Tel: + 92-51-5542849, 5552613Fax: 5552487
E-mail: info@glitzpharma.net
Web: www.glitzpharma.net

Plant: Plot No. 265, Industrial Triangle
Kahuta Road, Islamabad, Pakistan.
Tel:92-51-4491310
Fax: 92-51-4491268

GLITZ

9- In contrast, the Brooks Pharma product, Pyodine, does not have any such embossing or distinctive branding elements.
10-The design of the bottles varies significantly, which may affect consumer recognition and preference.
11-The color schemes and printing styles used for labeling are also different, contributing to a unique market presence for each product.

Given these differences in branding, design, and regulatory registration, it is clear that the two products are not similar in the context of their presentation and market identity.

Thanks & Regards
Muhammad Ashfaq
Manager Regulatory Affair

Date: 23/07/2024

GOVID SOLUTION MANUFACTURED BY GLITZ PHARMA

450mL Label

60mL Label

MEDWELL
PHARMACEUTICALS

ISO 9001:2008

Head Office:
Flat No 1, 3rd Floor, Al-Ihsan Plaza,
Villa No 53, Service Road, Spring North
Bahria Town, Rawalpindi
Ph. 051-5400319-20
Fax. 051-5400318

Plant:
1 KM Terbela Road,
Lawrencepur, Distt. Atock
Web.www.medwell.com.pk

The FID IV,

DRAP, Islamabad,

Pakistan.

Subject: **Resemblance of SEPTIWEL SOLUTION LABLE color scheme.**

Respected Madam.

Kindly refer to our telephonic conversation over the matter of resemblance of color scheme of our product label

SEPTIWEL 10% SOLUTION W/V (POVIDONE IODIDE).

With M/S BROOKS PHARMA product brand name

PYODINE 10% SOLUTION W/V (POVIDONE IODIDE).

We hereby declare;

a. That that product is not being Manufactured for 03 years due to construction work in factory.
b. That The management has already decided to change the color scheme of our product packaging after Manufacturing is re-started. And
c. That new Packaging scheme will be intimated to your office as finalized.

We do acknowledge your kind coordination over the matter.

Regards'

23/07/2024.

Ahmad Usman,
P.M. MEDWELL

Cortex Pharmaceutical

Date: 27/07/24

Ref. # CP/RCC/24

To,

M/S KHALID MEHMOOD

Federal Inspector of Drugs-II

DRAP ISLAMABAD.

Respected Sir,

Reference to Letter No. F.01-01/2024-FID-II DATED 23-07-2024 regarding the purported counterfeit Pyidine solution manufactured by M/S CORTEX PHARMACEUTICAL in resemblance with the Pyodine Solution manufactured by M/S Brookes Pharmaceuticals(Pvt) Ltd, Karachi.

It is to mention here that we are manufacturer licensed by Central Licensing Board of Drug Regulatory Authority of Pakistan (DRAP) and our product with brand name Pyidine is a registered product from Drug Registration Board. Therefore, if Registration Board considers it as purported counterfeit product then we will immediately apply for change of name of our product as per requirement of rules & laws.

COPY TO:
DIRECTOR(QA&LT),DRAP.

May kindly be placed before R.B. in view upcoming meeting of R.B. decision taken before 242nd meeting of R.B. under section 19(7) of Drugs Act 1976. Please submitted for directions to Quality concerned DC

Director QA&LT
Add. Director QA&LT.
Director R.B.
Chairman

1/8/2024

REGARDS
MANAGING DIRECTOR
Cortex Pharmaceuticals

SS4 Plot No.16-A NATIONAL INDUSTRIAL ZONE Rawat. Cell: 0349-5703233

HOOVER PHARMACEUTICALS (PVT) LTD.

HO-FIDL/07/24-001
Dated: 26th July, 2024

To,
Abdul Rashid Shaikh
Federal Inspector of Drugs,
Lahore.

Subject: **Counterfeits Product Pyodine Solution (Reg.No.009528)**

Respected Sir,

Kindly refer to the Letter.No.1929/2024-DRAP (L-IV) dated 11.07.2024

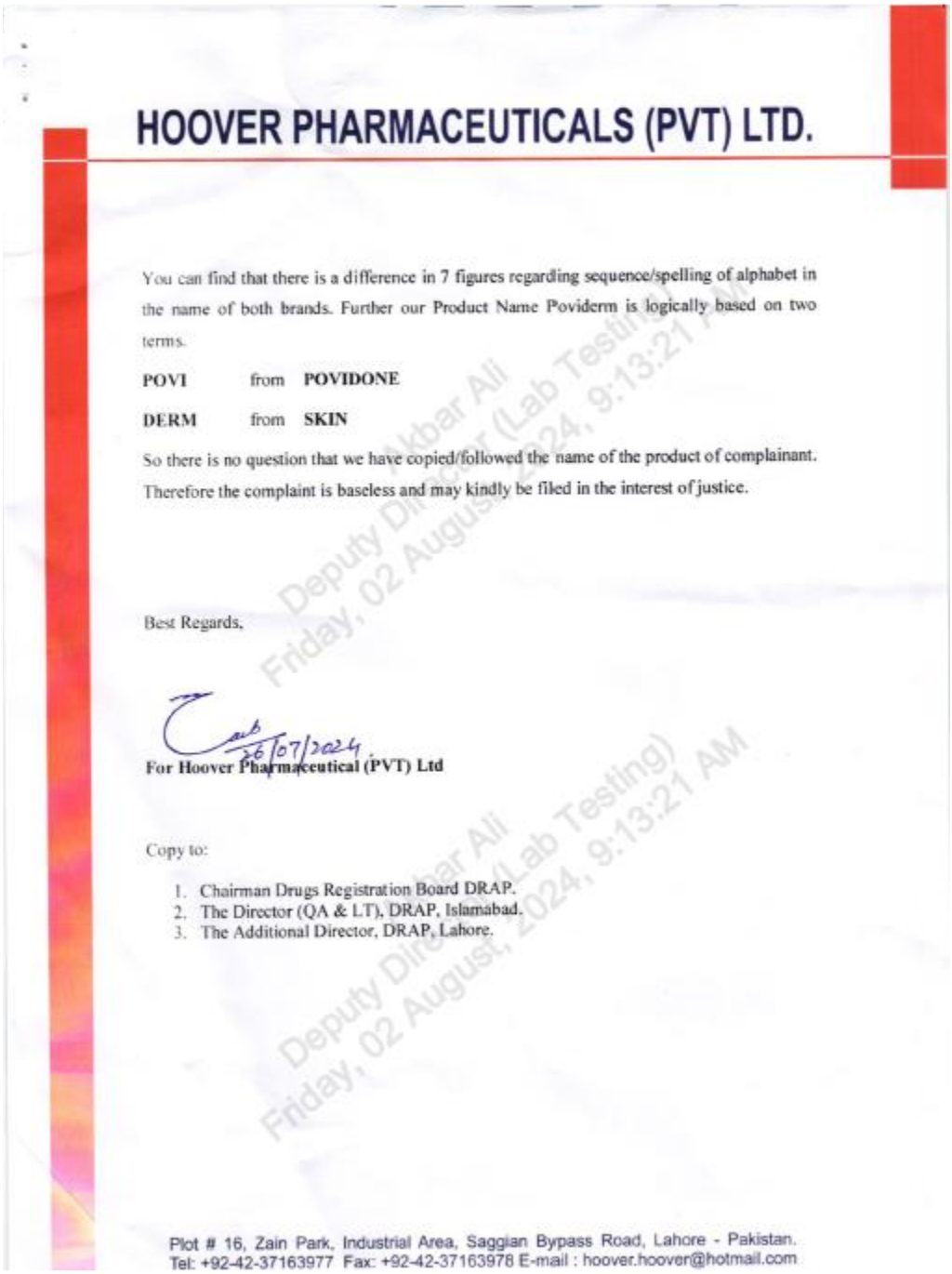
(Received on 25/07/2024), it is submitted that we have not received your letter. No. 1865/2024-DRAP (L-IV) dated 11.07.2024(Surprisingly the date mentioned on both referred letters is 11.07.2024).

It is incorrect to say that Hoover Pharmaceuticals (Pvt.) Ltd is involved to manufacture any counterfeit product in particular to the alleged drug Poviderm Solution. The product Poviderm having registration no.094559 has been properly registered with the DRAP and the concerned department of DRAP has given us the name of product after thorough and careful consideration.

Kindly note the difference of phonic effect and the spelling in our product and the product of complainant.

Complainant Product	PYODINE	پایوڈین
Our Product	POVIDERM 1234567	پووِیڈرم

Plot # 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore - Pakistan.
Tel: +92-42-37163977 Fax: +92-42-37163978 E-mail : hoover.hoover@hotmail.com
Website : www.hooverpharmaceuticals.com



HOOVER PHARMACEUTICALS (PVT) LTD.

You can find that there is a difference in 7 figures regarding sequence/spelling of alphabet in the name of both brands. Further our Product Name Poviderm is logically based on two terms.

POVI from **POVIDONE**

DERM from **SKIN**

So there is no question that we have copied/followed the name of the product of complainant. Therefore the complaint is baseless and may kindly be filed in the interest of justice.

Best Regards,

26/07/2024

For Hoover Pharmaceutical (PVT) Ltd

Copy to:

1. Chairman Drugs Registration Board DRAP.
2. The Director (QA & LT), DRAP, Islamabad.
3. The Additional Director, DRAP, Lahore.

Plot # 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore - Pakistan.
Tel: +92-42-37163977 Fax: +92-42-37163978 E-mail : hoover.hoover@hotmail.com

Proceedings and decision of 339th meeting of Registration Board:

M/s Brooks Pharma (Pvt.) Ltd. Karachi (Complainant) through representative Dr. Arif Hussain Siddique along with Council Mr. Umar Hameed Advocate appeared before Board for personal hearing/representation and presented physical samples /Bottles of allegedly counterfeit Pyodine manufacturers along with list of 26 alleged counterfeit Pyodine Products and urged their claim that these products have close resemblance and imitation with their product Pyodine.

Board after hearing the arguments of the firm in details and after thorough discussing and deliberation decided and nominated Director QA/LT to review each individual claimed counterfeit product in comparison with Pyodine for resemblance of packs for lookalike imitation of label which may deceive the patients. The Shortlisted reviewed imitation product cases on individual basis would be presented by QA/LT division before next Board meeting for consideration and further decision of the Board.

Agenda Item No. 02	**Adulterated & substandard paracet 1g infusion by M/S Standpharm (Pvt). Ltd, Lahore**

BACK GROUND:

FID DRAP Quetta informed that he has done sampling of product Paracet 1g/100ml Infusion from M/S usman Traders Yet Road Quetta on 16-11-2022.

Sr.No	Name of Product	Batch No.	Mfg. date	Expiry Date	Manufacturer
1	Paracet IV 1 G/100 ml Infusion.R.No.(083853)	CIJ170	20-09-2022	20-09-2024	M/s StandPharm (Pvt) Ltd,Lahore

CDL vide report No. KQ11-22-000234 dated has declared the above said sample to be **ADULTERATED AND SUBSTANDARD** based on the presence of visible black particles. Accordingly, FID issued copy of report to firm and also issued letter for recall and explanation.

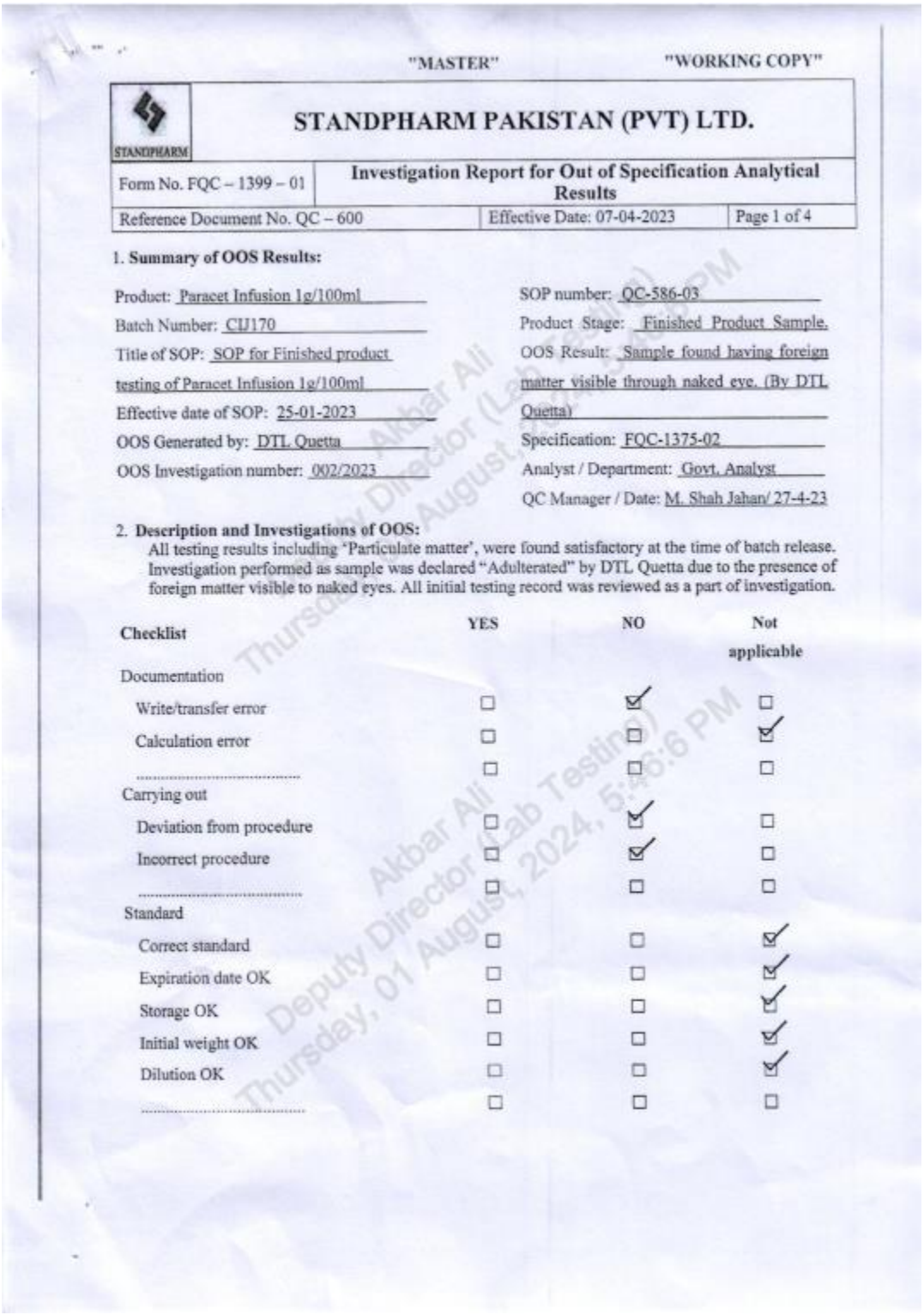
2. The Product Recall Alert of Paracet 1g/100mL Infusion was also uploaded on DRAP website.

3. Firm Submitted their reply to FID vide letter Nil dated 03-01-2023 wherein the firm challenged the test result of the CDL section 22, sub-section 5 of Drug Act 1976 and requested for appellate test. Firm also stated that they did not received manufacture sample portion and also stated that they have check retained sample and do not found any bottle with black particles.

4. Letters were issued to manufacturer and FGA, dated 18-04-2023 for provision of OOS investigation as per the decision of 313th meeting of DRB

5. Reply has been received from M/s Standpharm, Lahore, dated 02-05-2023 wherein firm has submitted OOS investigation, stating that they have checked retained samples as well as recalled stock and did not find any quality contravention, moreover they have performed OOS investigation and

declared that no OOS deviation was found, it is pertained to mention that the submitted OOS investigation was conducted in response to PQCB Quetta.



"MASTER" "WORKING COPY"

STANDPHARM PAKISTAN (PVT) LTD.

Form No. FQC – 1399 – 01	**Investigation Report for Out of Specification Analytical Results**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 1 of 4

1. Summary of OOS Results:

Product: Paracet Infusion 1g/100ml
Batch Number: CIJ170
Title of SOP: SOP for Finished product testing of Paracet Infusion 1g/100ml
Effective date of SOP: 25-01-2023
OOS Generated by: DTL Quetta
OOS Investigation number: 002/2023

SOP number: QC-586-03
Product Stage: Finished Product Sample.
OOS Result: Sample found having foreign matter visible through naked eye. (By DTL Quetta)
Specification: FQC-1375-02
Analyst / Department: Govt. Analyst
QC Manager / Date: M. Shah Jahan/ 27-4-23

2. Description and Investigations of OOS:

All testing results including 'Particulate matter', were found satisfactory at the time of batch release. Investigation performed as sample was declared "Adulterated" by DTL Quetta due to the presence of foreign matter visible to naked eyes. All initial testing record was reviewed as a part of investigation.

Checklist	YES	NO	Not applicable
Documentation			
Write/transfer error	☐	☑	☐
Calculation error	☐	☐	☑
.....	☐	☐	☐
Carrying out			
Deviation from procedure	☐	☑	☐
Incorrect procedure	☐	☑	☐
.....	☐	☐	☐
Standard			
Correct standard	☐	☐	☑
Expiration date OK	☐	☐	☑
Storage OK	☐	☐	☑
Initial weight OK	☐	☐	☑
Dilution OK	☐	☐	☑
.....	☐	☐	☐

STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	**Investigation Report for Out of Specification Analytical Results**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 2 of 4

Samples			
Correct sample	☑	☐	☐
Storage OK	☑	☐	☐
Initial weight OK	☐	☐	☑
Dilution OK	☐	☐	☑
.....	☐	☐	☐
.....	☐	☐	☐
Instrument *(Liquid Particle Counter)*			
Calibration OK	☐	☑	☐
Parameter set correctly	☐	☑	☐
Injector correct	☐	☐	☑
Detector correct	☐	☐	☑
.....	☐	☐	☐
.....	☐	☐	☐
.....	☐	☐	☐
System Suitability Test carried out	☐	☐	☑
.....Not Applicable.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑

Comments: No documentation, instrument, performance or sample related problem found. All testing result, including 'Particulate matter', were found satisfactory & valid.

3. Determinate Error ☐ Indeterminate Error ☐ Clerical Error ☐

QC Analyst: _____ Supervisor / QC Manager: _____

"MASTER" "WORKING COPY"

STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	Investigation Report for Out of Specification Analytical Results	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 3 of 4

4. Investigation

4.1 Result of investigation:

No error found during initial investigation.

4.2 Corrective Action: (only if it is Determinate or Clerical Error)

As there is no OOS hence not applicable

4.3 Remarks:

Description / Appearance of solution, Particulate matter and all other results found satisfactory. Complete testing record is attached.

5. Retest

5.1 Retest by Analyst 'A' Result: NA Pass ☐ Fail ☐
(In case of Determinate Error)

5.1.1 If failed, determine the cause (s) of failure

Determinate Error ☐ Indeterminate Error ☐ Clerical Error ☐

5.1.2 If the result is Pass, Accept the results and release the sample.

5.1.3 Remarks: _____

5.2 Indeterminate Error

Retest Result: Analyst 'A': _____ Pass ☐ Fail ☐

Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

Resample Result: Analyst 'A': _____ Pass ☐ Fail ☐

Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

"MASTER" "WORKING COPY"

STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	Investigation Report for Out of Specification Analytical Results	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 4 of 4

6. **Discussion & Conclusion:**

Testing results at the time of batch release were satisfactory and valid. Retained sample of this batch was tested on 26-12-2022 and found the sample clear and having no sign of particulate matter. Result of other tests were also satisfactory and submitted to PQCB, Quetta on 26-12-2022 & Drug Inspector Zone-N, Quetta Baluchistan on 03-01-2023.

Analyst / Date: 27/4/2023 QC Manager / Date: 27/4/2023

7. **Remarks by QA:**

Batch recall has already been done. We have recalled 731 packs from market. We have also checked recalled pack and no sign of particulate matter visible to naked eye found in recalled packs.

QA Manager Signature / Date: 27/04/2023

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STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1400 – 01	**Formal Investigation for Un-Assignable Cause**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 1 of 2

Section I

Date of test: 26-12-2022	SOP #: QC-586-03
Title of SOP: : SOP for Finished product testing of Paracet Infusion 1g/100ml	Sample description: Paracet Infusion 1g/100ml, batch # CIJ170.
Observed value: No foreign matter found visible	Reason for investigation: Declared "Adulterated" by DTL Quetta
Specification: FQC-1375-02	Analyst name: Asad Nawaz
OOS Investigation number: 002/2023	

Section II

Impact on Process and Product Quality:

Determine whether or not Un-assignable OOS has impacted process or Product Quality

Yes ☐ The quality of product (s) impacted due to:

1-
2-
3-

No ☐ The quality of product (s) impacted due to:

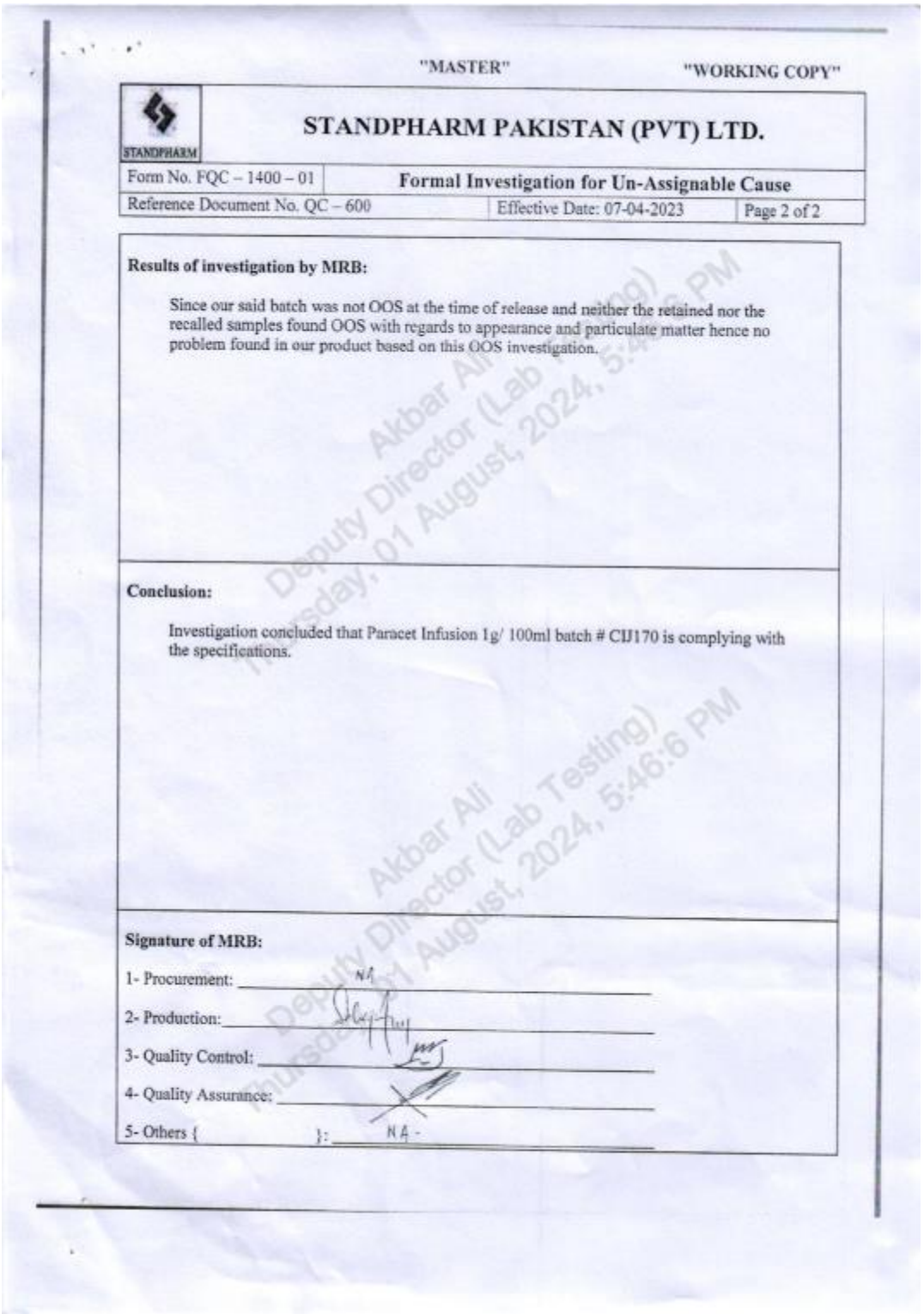
1-
2-
3-

NA ☑

Analyst Signature: AA

Identify batches / Lots / materials that are impacted:
NOT APPLICABLE

Material Review Board (MRB) Investigations:
From the review of Batch Processing record of Paracet infusion batch no. CIJ170, it was noted that batch was manufactured and filled on 21-09-2022. Vials washing, manufacturing, filtration & filling in closed loop were performed after proper line clearance and area clearance according to SOPs. Bags of pre-autoclaved Bromobutyle Rubber stoppers were opened under LFH and instilled in respective hopper to minimize the chance of contamination. Environmental condition during batch processing were satisfactory.
Non-viable count monitoring has been performed on 13-09-2022 with satisfactory results.
Filter integrity tests of HEPA filters has been performed on 08-09-2022 with satisfactory results.
Visual inspection was performed by 8 trained staff in 2 stages, i.e. first by 5 trained staff & then the passed vials were rechecked by 3 other trained staff.



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STANDPHARM PAKISTAN (PVT) LTD.

Form No. FQC – 1400 – 01	**Formal Investigation for Un-Assignable Cause**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 2 of 2

Results of investigation by MRB:

Since our said batch was not OOS at the time of release and neither the retained nor the recalled samples found OOS with regards to appearance and particulate matter hence no problem found in our product based on this OOS investigation.

Conclusion:

Investigation concluded that Paracet Infusion 1g/ 100ml batch # CIJ170 is complying with the specifications.

Signature of MRB:

1- Procurement: NA

2- Production:

3- Quality Control:

4- Quality Assurance:

5- Others { }: NA

6. It is further submitted that the Board Sample portion was received in broken form, and letter was issued to area FID Quetta to investigate this matter and fix the responsible person for packing and delivering broken sample, the reply of which is still pending.

7. PQCB Quetta was also requested vide letter No.F.No.13-09/2023-QC dated 10-07-2023 and reminder dated 12-08-2023 to provide details of proceeding and results of DTL Quetta / NIH (if any) regarding this Batch of Paracet Infusion 100 ml batch No. CIJ170. No reply has been received from PQCB Quetta.

Proceedings and decision of Registration Board:

Board deliberated the case in detail and decided not to accede firm's request of appellant testing and decided to issue showcase notice to firm for suspension /cancelation of subject cited drug to M/s Standpharm Pakistan (Pvt) Ltd, Lahore and personal hearing before Registration Board.

Agenda Item No. 03	**REQUEST FOR APPROVAL TO DISPOSE OF EXPIRED DRUGS/SAMPLES OF BOARD PORTION OF PRODUCTS PRESENT IN SAMPLE STORAGE ROOM.**

Background:

The sample room for the storage of Board portion of samples sent by the relevant Federal Inspectors of Drugs was shifted from second floor, TF Complex, G9/4 building to current DRAP building in the month of March 2024. The sample room in the new DRAP building has reached its maximum capacity limit. The sample room at TF complex had samples that date back decades and since the establishment of the said room, no samples have ever been disposed of. A significant number of samples have expired and need to be disposed of to free up space for new samples. For the said purpose, a proper disposal mechanism for disposal of expired samples and samples whose fate have been decided by the Board is necessary to maintain compliance with current regulatory guidelines and ensure effective use of already scarce resources.

Proposed Disposal Plan:

It is proposed that the Registration Board may constitute a committee having representation from the divisions of QA&LT, PE&R and Admin & HR. The division of QA&LT will provide the record of expired samples to the committee and the committee will devise a mechanism for the disposal of said samples.

Proceedings and decision of the Board:

The Board after thorough deliberations decided to constitute a committee that will decide the mechanism for destruction of expired samples present in the sample storage room and will also devise an SOP for the same purpose. Moreover, the committee will apprise the Board regarding its proceedings and progress on regular basis. The said committee will constitute of following members:

i. Add. Director QA&LT (Convener of the committee) or nominee of the director QA/LT.
ii. Mr. Muhammad Asad Abrar, Director, DTL Bahawalpur.
iii. Mr. Shahid Nawaz, Assistant Director, PE&R Division.
iv. Deputy Director, Admin, HR & Logistics.

Agenda Item 3	**MANUFACTURE AND SALE OF SUBSTANDARD MANADOL SUSPENSION (PARACETAMOL) BATCH NO. 4MD-005 MANUFACTURED BY M/S MASFA INDUSTRIES (PVT.) LTD LAHORE**

1. FID-III, DRAP, Lahore dated 10-09-2014 took the sample from M/s Masfa Industries (Pvt.) Ltd Lahore. CDL vide report No. LHR230/214 dated 02-10-2014 declared the sample as substandard on the basis of assay test i.e. 70.15% (Limit 955 – 105%). Thereafter, the firm challenged the test/analysis report and requested for appellate testing. Appellate laboratory vide their test report No. 020MNHSR/2014 declared the sample as of substandard for assay (54.7%) and description, as the glass bottle was having undissolved masses which do not disperse even on shaking.
2. Accordingly, a show-cause notice was issued dated 24-11-2015. Registration Board in its 257th meeting dated 24-25/03/2016 decided to suspend the registration of Manadol suspension (Paracetamol) for 6 months and to conduct the PSI from the following panel;
    a. Director DTL Punjab, Lahore.
    b. Area FID.
    c. ADC, Lahore.
3. The report from DRAP office Lahore dated 27-12-2016 was received and the case was presented before the Registration Board in its 266th meeting held on 07-02-2017 and board decided as under;
    a. QA Division should consider the GMP issues of the firm M/s Masfa Industries (Pvt.) Ltd, Lahore, like use of old bottles in syrup manufacturing instead of new ones as it is violation of GMP.
    b. The firm M/s Masfa Industries (Pvt.) Ltd, Lahore, shall submit accelerated and real time stability studies of 03 batches for 06 months of the product Manadol suspension.
    c. The registration of the product Manadol Suspension, Reg. No. 071558 will remain suspended till the submission of stability studies by firm M/s Masfa Industries (Pvt.) Ltd, Lahore, for consideration of Registration Board.
4. The above decision of the Registration board was issued on 2-05-2017 and in response the firm submitted a reply which was presented before registration Board in its 274th meeting. The Registration Board after detailed discussion, deliberation and necessary evaluation of stability studies submitted by the firm decided that firm M/s Masfa Industries (Pvt.) Ltd., Lahore will resubmit the stability studies as per decision of the Registration Board in its 266th meeting dated 07th February, 2017. The registration of the product Manadol Suspension, Reg. No. 071558 will remain suspended till the submission of stability studies by firm M/s Masfa Industries (Pvt.) Ltd, Lahore, as per decision of the Registration Board.
5. The firm on 06-09-2018 submitted their reply wherein they have enclosed the accelerated and real time stability studies of 03 batches for 06 months, Purchase invoice of raw material, HPLC chromatograms for assay determination, Stability chamber study data, Storage condition for long term and accelerated condition. Provided data was evaluated by QC section and was not accepted and accordingly, letter was issued to the firm dated 26-10-2018.

6. The case is now placed before Registration Board for guidance on the matter as the product is suspended since March 2016.

Decision: Registration Board decided to conduct the product specific inspection for verification of manufacturing and testing facilities of the said product and submit report within 15 working days for consideration of the board.

ADDITIONAL AGENDA

Agenda of Mr. Ammar Ashraf

Deferred cases:

1.	**Name and address of manufacturer/ Applicant**	**Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.**
	Brand Name + Dosage Form + Strength	**TAMIZOLE Suspension**
	Composition	Each 10ml contains: Benzoyl metronidazole……320mg Diloxanide furoate……250mg
	Diary No. Date of R & I & fee	Dy.No. 928 Dated: 01-06-2011, Fee Rs: 8,000/-, Dated 01-06-2011 (photo copy) Dy.No. 80 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antiamoebic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 90ml, Rs: 34.00/90ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Zolt suspension (Metronidazole benzoate eq to metronidazole: 200mg; Diloxanide Furoate: 250mg) per 10ml of M/s Stanley Pharmaceuticals, Peshawar. Registration No. 076851
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • The generic/me-too has Metronidazole (as metronidazole benzoate) ….200mg Benzoyl metronidazole is the synonym for metronidazole benzoate. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide recent/last GMP inspection report. • Differential fee for two products Peptic-C suspension and Tamizole suspension submitted vide same challan No.0515191 dated 23-12-2015. Amount submitted is 24000/- for two products.

	Decision of 323rd meeting: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Submission of most recent GMP audit report conducted within last 03 years. • Evidence of approval of requisite manufacturing facilities/ section by Licensig Division, DRAP Islamabad.	
	Evaluation by PEC: • Firm has approval of "oral liquid section" granted vide letter no. F.1-16/2003-Lic issued by Secretary CLB dated 15-06-2011 • Me-too reference of applied formulation is available as "Dizole suspension of M/s Fynk Pharmaceuticals, 19 K.M. G.T. Road, Kala Shah Kaku, Lahore"vide Reg.# 065878" • Evidence of approval of applied formulation from reference regulatory authorities could not be verified.	
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. **The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.** **1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
2.	Name and address of manufacturer/ Applicant	Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	ECEPHYL cough syrup
	Composition	Each 5ml contains: Acefylline piperazine……...45mg Diphenhydramine HCl……8mg
	Diary No. Date of R & I & fee	Dy.No. 930 Dated: 01-06-2011, Fee Rs: 8,000/-, Dated 01-06-2011 (photo copy) Dy.No. 81 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Cough and anti-histamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 60ml, Rs: 35.00/60ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Acelyf syrup of M/s Hicon Pharmaceuticals, Peshawar. Registration No. 077431
	GMP status	Not provided

	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • The firm has claimed manufacturer specifications. While the product is non-pharmacopoeial. • Provide evidence of relevant section approval. • Provide recent/last GMP inspection report conducted within last 03 years. • Differential fee of Rs: 24,000/- for two products Ecephyl cough syrup and Otillion suspension submitted vide same challan No.0515190 dated 23-12-2015.
	Decision of 323rd meeting: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Submission of most recent GMP audit report conducted within last 03 years. • Evidence of approval of requisite manufacturing facilities/ section by Licensig Division, DRAP Islamabad.	
	Evaluation by PEC: • Firm has approval of "oral liquid section" granted vide letter no. F.1-16/2003-Lic issued by Secretary CLB dated 15-06-2011 • Me-too reference of applied formulation is available as "Acefin plus syrup of M/s Hamaz pharma" Reg.# 054278 • Evidence of approval of applied formulation from reference regulatory authorities could not be verified.	
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. **The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate.** **1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	

3.	Name and address of manufacturer/ Applicant	Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	PEPTIC-C suspension
	Composition	Each 5ml contains: Famotidine…….10mg
	Diary No. Date of R & I & fee	Dy. No. 4042 Dated: 02-04-2011, Fee Rs: 8,000/-, Dated 01-04-2011 (photo copy) Dy. No. 80 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy), "Duplicate dossier, R & I verified"
	Pharmacological Group	H_2 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 60ml, Rs: 68.64.00/60ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Dinex suspension of M/s Gulf Pharmaceuticals, National Industrial Zone, Rawat. Registration No. 075050
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • The firm has claimed manufacturer specifications. While the product is non-pharmacopoeial. • Provide evidence of relevant section approval. • Provide recent/last GMP inspection report conducted within last three years. • Differential fee of Rs: 24,000/- for two products Peptic-C suspension and Tamizole suspension submitted vide same challan No.0515191 dated 23-12-2015.
	Decision of 323rd meeting: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Submission of most recent GMP audit report conducted within last 03 years. • Submission of approval of requisite manufacturing facilities/ section by Licensing Division, DRAP Islamabad.	
	Evaluation by PEC: • Firm has approval of "oral liquid section" granted vide letter no. F.1-16/2003-Lic issued by Secretary CLB dated 15-06-2011	

	• Evidence of approval of applied formulation from reference regulatory authorities is available as per following composition: **Dosage form:** Dry powder suspension **Strength:** 40mg/5ml of reconstituted suspension **Reference Regulatory Authority:** Approved by US FDA	
	Decision: Deferred for confirmation whether firm has previously registered drug product of Famotidine dry powder suspension (40mg/5ml)	
4.	**Name and address of manufacturer / Applicant**	**M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore**
	Brand Name +Dosage Form + Strength	Mazomax capsule 500mg
	Diary No. Date of R& I & fee	Dy. No. 9570 dated: 01-03-2019 Rs.20,000/
	Composition	Each capsule contain Azithromycin(as dihydrate).. 500mg
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1 x 6'S & 1 x 10'S /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	**Not Confirmed**
	Me-too Status	AZOTINE of M/s Nimral Pharma, Islamabad
	GMP Status	New Section
	Remarks of the Evaluator.	RRA is not confirmed
	Decision of 290th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Evaluation by PEC: Me-too reference of applied formulation is available as "Clozip 500mg (Azithromycin) capsule of Medisynth"	
	Decision: Approved as per decision of the 179th meeting of the Authority as the formulation is already registered / available in Pakistan. Registration letter shall be issued with following conditions as narrated in the said decision of the Authority. The Firm shall submit commitment, before issuance of Registration Certificate, for provision of following documents / information within 6 months of the issuance of Registration Certificate. **1. Evidence that the product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.** **2. Evidence that the manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.** **3. Evidence that the international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.** **4. Evidence that the product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.**	
5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker (Pvt.) Ltd. 45-KM, Dina Nath, Multan road, Lahore.**
	Name, address of Manufacturing site.	M/s May & Baker (Pvt.) Ltd. 45-KM, Dina Nath, Multan road, Lahore. (DML No. 000953)
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Copy of approval letter of capsule section (General) vide No. 1-10/2019-Lic dated 29.04.2022 is submitted.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 18305 dated 20.07.2023
	Details of fee submitted	PKR 30,000/- Slip No. 08374729 dated 20.07.2023
	The proposed proprietary name / brand name	**MAYTAM 0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains; Tamsulosin HCl……0.4mg (SR pellets 0.2%)
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists ATC Code: G04CA02
	Pharmaceutical form of applied drug	White/red hard gelatin capsule in Alu-Alu blister packed in unit carton along with leaflet.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	4's, 5', 6's, 10's, 14's, 20's, 28's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TAMSULOSIN HYDROCHLORIDE 400 MICROGRAMS MR CAPSULES MHRA Approved.
	For generic drugs (me-too status)	Tamsolin 0.4mg Capsule (Reg. No. 050392) M/s Getz Pharma Karachi.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.). Ltd, Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. TMS365
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. TMS205T, TMS206, TMS208.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Test product:** Maytam 0.4mg capsule **Reference product:** Tamsolin Capsule, Batch No. 011H. mfg.: 12.22, Exp. 11.24 **manufactured** by M/s Getz Pharma Pictorial evidence is not submitted. **Tests done:** physical characteristics, Identification, weight variation, assay. **CDP:** **pH 1.2:** **pH 4.5:** **pH 6.8:**
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.). Ltd, Plot No. 22-23, Industrial triangle, Kahuta Road, Islamabad.
API Lot No.	202109103A
Description of Pack (Container closure system)	Off-white granules filled in hard gel caps size 3, body: white, cap: re. Packedin Alu-Alu blister and UC with leaflet.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 1	Trial 2	Trial 2
Batch Size	1500 caps	1500 caps	1500 caps
Manufacturing Date	11.05.2022	11.05.2022	11.05.2022
Date of Initiation	13.05.2022	13.05.2022	13.05.2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of certificate No. 3-26/2019-Addl Dir (QA&LT-I)-56 dated 22.08.2022 issued by DRAP Islamabad is submitted valid till 13.04.2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Tamsulosin HCl SR pellets 0.2%** Batch No.: TMS365 Mfg date: 01.04.2022 Exp date: 01.2025 Quantity: 15Kg Invoice No.: 60009 Invoice date: 09.05.2022 Local purchase
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has stated that their HPLC system is not CFR 21 compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply
1.	3.2.P.2.2.1	In CDP, Analytical raw data sheets are submitted. The data is not understandable. Time intervals are mentioned as 5 10 15 20 30 minutes; pharmacopoeia gives different time intervals. Data of only Maytam is mentioned in sheets. Details of CDP are required clearly describing the comparison of results in 3 pH media at different time intervals.	The firm vide letter No. nil dated 18.10.2023 has stated that CDP was performed using USP Apparatus II and they are submitting updated data. Firm has submitted revised summary sheets of comparative dissolution profile done at 3 different physiological pH. The results are comparable to comparator product.

			Supporting data is not submitted, only summary sheets are submitted.
2.	3.2.P.5	It is not mentioned which dissolution test of USP will be used for your applied product. (test 1 or test 2 or test 3…. or test 10)	The firm has submitted that USP Test 2 will be used.
3.	3.2.P.5.2	In analytical procedures Dissolution is not mentioned. Clarify.	The firm has stated that it was a typographic mistake.
4.	3.2.P.5.4	In batch analysis, results of dissolution are provided at 8h time point only. Why sampling intervals as per USP are not followed?	The firm has stated that it was a typographic mistake and they have followed USP test 2 for their product.
5.	3.2.P.8	In chromatograms provided, sample name in all is "UNKNOWN001" it is not possible to identify which chromatogram is of RS and which is of drug product. Further in every chromatogram there are 2 to 3 major peaks. Which one is of the drug substance? Justify. In calculations values are mentioned around 0.9 under heading AUC, how does this value correspond to the area of curve in each chromatogram? If test is done on UV, then why pharmacopoeial method is not followed for test and analysis? (value of 0.9 corresponds to UV absorption)	• The firm has stated that sample name UNKNOWN001 is by default in system and cannot be changed. In sample description details of sample are given, the firm has submitted a copy of chromatogram with description Tamsulosin HCl 0.4mg capsule std 1 0 month. It has 2 major peaks of almost equal height even though chromatogram appears of std. The peak marked as of drug substance has less area than preceding peak. • Justification for peaks, firm has stated that peak of interest is recognized by considering retention time. • Retention time is determined by comparison for peaks obtained of working standard and also peak having maximum AUC, rest of the peaks are minor and ignored. • Calculations 0.9 show ratio between peaks of API and internal standard. • Test done on HPLC not on UV.

Decision of 331st meeting: Registration Board deferred the case for submission of clarification regarding unidentified peak in submitted chromatograms of assay having area more than the peak identified as drug substance.

Firm's Response: Each chromatogram will have two major peaks as per USP method wherein each peak is of the Tamsulosin.

Decision of 336th meeting: The Board after detail deliberation and keeping in view the reply submitted by the firm, deferred for submission of clarification in detail and also for the submission of complete analytical record for identification of the peaks exhibited in chromatograms of Assay analysis to be reviewed by the board.
Remarks of Evaluator: Firm has submitted analytical chromatograms with following declaration: • 1st peak at retention time 3.850 is of Methyl paraben that was used along with Propyl paraben as an internal working standard just on trial basis. • 2nd peak at retention time of 7.240 is of Propyl paraben which was used as internal working standard. • 3rd peak at retention time of 7.840 is of Tamsulosin. Firm has submitted that result was found satisfactory by using propyl paraben as internal working standard so you are requested to ignore peak of Methyl paraben because it has no effect on our stability data
Decision: Approved.

Applications submitted on Form 5F by way of contract manufacturing

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s GT Pharma (Pvt) Ltd. 713-Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s DeMont Research Laboratories (Pvt) Ltd. 20-km, Lahore-Sharikpur Road, Shekhupura.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.18242: 19-07-2023
	Details of fee submitted	PKR 75,000/- : 23-06-2023
	The proposed proprietary name / brand name	**Pyrenol 37.5/325 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Tramadol HCl…37.5mg Paracetamol……375mg
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP specification
	The status in reference regulatory authorities	Trapadex film coated tablet, MHRA Approved.
	For generic drugs (me-too status)	Tonoflex-P Tablet of Sami Pharma, Karachi
	Proposed Pack size	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Section#	Observation	Response of the Firm
1.	**1.6.5**	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	

2.	**3.2.S.4**	Submit drug substance specifications and analytical procedures of drug substances from drug substance manufacturers.	
3.	**3.2.S.7**	• Drug substance specification for Assay test of Tramadol HCl declared in the stability sheets is different for that declared in the drug substance specifications. • Long term stability studies data of Tramadol HCl shall be submitted till claimed shelf life. • Readable copies of drug substance stability data shall be submitted for Paracetamol.	
4.	**3.2.P.2.2.1**	Justification shall be submitted for not including sampling time point of "15 minutes" in the performance of CDP studies, as recommended by the relevant guidelines.	
5.	**3.2.P.5.2**	Submitted analytical procedure of Assay test is not as per USP monograph for applied formulation.	
6.	**3.2.P.5.3**	Analytical method verification studies of drug product Assay method have not been performed as per the chromatographic conditions recommended by US monograph. Justification shall be submitted in this regard.	
7.	**3.2.P.8**	• Justification shall be submitted for the significant change reported in the Assay results of Paracetamol during accelerated stability studies of batch no. T20063. • Documents confirming procurement for Tramadol HCl issued by DRAP I&E office, shall be submitted.	

		• Justification shall be submitted for not performing Assay test as per the test method declared n USP monograph. • The dilutions applied for the performance of dissolution test shall be justified against the method recommended by USP monograph.	

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

7.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries Private Limited, 17/24, E128, Korangi Industrial Area, Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13946: 05-06-2023
	Details of fee submitted	PKR 75,000/- :19-05-2023
	The proposed proprietary name / brand name	Gramotive 2 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to Colistin Base…2 MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Colistimethate Sodium 2MIU Injection, MHRA Approved.
	For generic drugs (me-too status)	Colstizon 2MIU Injection of M/s Valor Pharma.
	Proposed Pack size	As per SRO

Evaluation by PEC^{II}:

Decision: Approved.

8.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Nabi Qasim Industries Private Limited, 17/24, E128, Korangi Industrial Area, Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 14903: 13-06-2023
	Details of fee submitted	PKR 75,000/- :18-04-2023
	The proposed proprietary name / brand name	Gramotive 1 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to Colistin Base…1 MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Colistimethate Sodium 1MIU Injection, MHRA Approved.
	For generic drugs (me-too status)	Colstizon 1MIU Injection of M/s Valor Pharma.
	Proposed Pack size	As per SRO
Evaluation by PEC[II]:		
Decision: Approved.		
9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Labs Pvt Ltd.** **Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18737 dated 25-07-2023
	Details of fee submitted	Rs.75,000/- dated 03-05-2023
	The proposed proprietary name / brand name	**Monest 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast Sodium Eq. to Montelukast…4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Montika sachet of M/s Sami
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP specifications

Evaluation by PEC[II]:

1.	**3.2.P.8.3**	• Commercial invoice for the procurement of drug substance shall be submitted. • Complete analytical record including chromatograms and raw data sheets for	

		analysis performed during stability studies shall be submitted declaring the details of sample and standard solution preparation.	

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

10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd.** **Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18913 dated 27-07-2023
	Details of fee submitted	Rs.75,000/- dated 04-07-2023
	The proposed proprietary name / brand name	**Azi-Rent 200mg/5ml Dry Powder Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin…200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Azomax suspension of M/s AGP.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP specifications

Evaluation by PEC[II]:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Relevant information including valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	
2.	**3.2.S.4**	• Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted form the drug product manufacturer. • Justification shall be submitted for not including test of pH in COA submitted form M/s Winlet Pharma.	

		• COA of relevant batch of drug substance used for the manufacturing of drug product stability batches, shall be submitted.	
3.	**3.2.P.1**	• Justification shall be submitted for variation in qualitative formulation from that of the innovator drug product. • Clarification shall be submitted for the role of "Sodium benzoate" in the applied formulation. • Drug excipient compatibility study shall be submitted since qualitative composition of applied formulation is different form that of the innovator drug product.	
4.	**3.2.P.2.2.1**	Comparative dissolution profile shall be submitted against the innovator/reference product.	
5.	**3.2.P.2.5**	Compatibility study with the reconstitution diluent shall be submitted.	
6.	**3.2.P.5.2**	Analytical procedure from M/s Winlet Pharmaceuticals shall be submitted instead of annexing the extract of USP monograph.	
7.	**3.2.P.5.3**	Complete analytical method verification studies shall be submitted including details of sample and standard preparation for each parameters along with method of analysis.	
8.	**3.2.P.5.4**	Submitted drug product COAs declare manufacturing dates as 08-2021 & 10-2021, while the date of analysis for the same has been declared as 15-10-2021 & 08-12-2021 respectively. Justification shall be submitted for the delay in batch analysis.	
9.	**3.2.P.6**	COA of reference standard/working standard used for the analysis of drug product stability batches, shall be submitted.	
10.	**3.2.P.8.3**	• Commercial invoice for the procurement of drug substance shall be submitted. • Complete raw data sheets for the Assay and Dissolution test performed during stability studies shall be submitted declaring the details of sample and standard solution preparation. • Justification shall be submitted for not performing "Preservative efficacy test" during stability studies.	

		• In-use stability studies for the reconstituted suspension shall be submitted.	
11.		Complete batch manufacturing record declaring the details of dispensed formulation shall be submitted.	

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

11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 10007 dated 13-04-2023
	Details of fee submitted	Rs.75,000/- dated 08-02-2022
	The proposed proprietary name / brand name	**Zaruba 40mg Injection**
	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	MHRA Approved
	For generic drugs (me-too status)	Risek injection of M/s Getz
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.3	• Clarification shall be submitted regarding the manufacturing facility "Dry Powder Injectable (Lyophilized) section" of M/s Safe Pharmaceuticals, whether it is by way of lyophilisation or by way of dry powder filling	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.2.1	Name of drug substance manufacturer declared in this section is different from that mentioned in section 1.6.5	

3.2.S.4	• Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted form the drug product manufacturer. • COA of the relevant batch of drug substance used in the manufacturing of drug product stability batches shall be submitted from the drug substance manufacturer.	
3.2.S.7	Long term stability studies of drug substance shall be submitted as per Zone IV-A.	
3.2.P.1	Details of the reconstitution diluent shall be submitted.	
3.2.P.2.2.1	Limits of test applied in Pharmaceutical equivalence studies are not as per BP monograph of "Omeprazole for injection"	
3.2.P.2.6	Compatibility studies with the reconstitution diluent shall be submitted.	
3.2.P.5.1	• Submitted Drug product specifications are not as per BP monograph of "Omeprazole for injection". • Justification shall be submitted for the Assay limits of drug product.	
3.2.P.5.2	Submitted drug product analytical method is not as per not as per BP monograph of "Omeprazole for injection".	
3.2.P.5.3	Submitted analytical method verification study is not as per BP monograph of "Omeprazole for injection".	
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test. • Justification shall be submitted for not performing stability studies as per BP monograph of "Omeprazole for injection"	

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

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13648 dated 01-06-2023
	Details of fee submitted	Rs.75,000/- dated 25-05-2023
	The proposed proprietary name / brand name	**Berryxib 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin Capsule Contains: Celecoxib…100mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Celbexx capsule of M/s Getz
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	Submitted

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

13.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13649 dated 01-06-2023
	Details of fee submitted	Rs.75,000/- dated 25-05-2023
	The proposed proprietary name / brand name	**Berryxib 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin Capsule Contains: Celecoxib…200mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Celbexx capsule of M/s Getz
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response

3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	Submitted

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

14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals.** **Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13380 dated 30-05-2023
	Details of fee submitted	Rs.75,000/- dated 02-05-2023
	The proposed proprietary name / brand name	**Athpime 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefepime as HCl monohydrate with L-Arginine.….1gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Pimestar 500mg injection of M/s Aulton Pharmaceuticals.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Decision: Approved.

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals.** **Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk, Pakistan**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 13379 dated 30-05-2023

	Details of fee submitted	Rs.75,000/- dated 28-04-2023
	The proposed proprietary name / brand name	**Athpime 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefepime as HCl monohydrate with L-Arginine..…1gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Pimestar 1gm injection of M/s Aulton Pharmaceuticals.
	Proposed Pack size	As per SRO
Evaluation by PEC:		
Decision: Approved.		
16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd.** **E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18084 dated 18-07-2023
	Details of fee submitted	Rs.75,000/- dated 19-07-2023
	The proposed proprietary name / brand name	**Cefadroxil 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Cedrox capsule of Platinum Pharmaceuticals
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.6.5	• Clarification shall be submitted regarding the manufacturer of drug substance since two different manufacturers have been mentioned in section 1.6.5	Two sources were mentioned in dossier since we have two approved sources in our vendor list, while the product was developed with only one source i.e., M/s Pharmagen Ltd.

3.2.S.4.3	Drug substance analytical method verification studies shall be submitted form M/s Platinum Pharmaceuticals.	Submitted
3.2.P.1	Justification shall be submitted for using two different grades of drug substance i.e., compacted and micronized , within the formulation of applied drug product.	The micronized form has been used for development of drug product batches.
3.2.P.8.3	Following shall be submitted: • Documents for the procurement of API with approval from DRAP. • Raw data sheets for the performance of Assay & Dissolution test during stability studies.	Submitted

Decision: Approved.

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Unimark Pharmaceuticals Pvt Ltd. Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 10643 dated 27-04-2023
	Details of fee submitted	Rs.75,000/- dated 06-03-2023
	The proposed proprietary name / brand name	**Vomfran 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml 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	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response

1.3	Evidence of approval of manufacturing facility of "Liquid Injection Ampoule (general) section" from Licensing division of DRAP shall be submitted.	*Firm has not submitted any approval letter from Licensing Division for required manufacturing facility of "Liquid Injection Ampoule (general) section"*
1.6.5	Valid DML/GMP certificate of the drug substance manufacturer shall be submitted.	Submitted
3.2.S.4	Drug substance specifications, analytical procedure and analytical method verification studies shall be submitted from drug product manufacturer.	Submitted
3.2.P.1	Justification shall be submitted for the use of Citric acid monohydrate as preservative in the single dose injectable preparation. Justification shall be submitted for the proposed quantity of "Ondansetron as HCl dihydrate" 4.20mg/ml against the label claim.	Citric acid monohydrate is a widely used multiple excipient in pharmaceutical formulations. It serves multiple functions, including acting as a preservative to ensure the stability and safety of injectable medications. In the case of Vomfran Injection (4 mg per 2 ml), which shares the same formulation as Zofran Injection. Citric acid monohydrate is included as preservative. Citric acid, as an antimicrobial preservative, contributes creating to creating an environment that is less conducive to microbial growth. The acidic environment inhibits the proliferation of bacteria, yeast, and mold, thereby reducing the risk of contamination The based ensuring tolerance on decision key more limits to for round consistent considerations excipient off the and that; citric quantities. accurate acid rounding value dosing. off from to This 0.50 0.46 mg mg minor to 0.50 simplifies adjustment mg the for falls accurate measurement within dispensing acceptable process.
3.2.P.2.2.1	Pharmaceutical equivalence studies have been submitted against the Zofran 8mg/4ml whereas the applied formulation is 4mg/2ml.	*Firm has submitted Biowaiver guidelines while applied formulation is Injectable.*
3.2.P.3.2	Submitted manufacturing method is for the dry powder injection vials, while the submitted product is of liquid injection ampoule.	Firm has submitted revised manufacturing method.

3.2.P.3.5	Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted for not performing terminal sterilisation.	*Ondansetron is known to be sensitive to high temperatures. which can potentially degrade the active pharmaceutical ingredient (APS). Terminal sterilization typically involves exposure in temperatures around 121°C for 15-20 minutes which could compromise the stability and potency of Ondansetron. By utilizing aseptic filling the product is processed and filled in a sterile environment, thus avoiding the thermal stress associated with terminal sterilisation.*
3.2.P.5.2	Submitted drug product analytical procedure for Assay test does not include details of system suitability as recommended by USP monograph.	Firm has submitted revised analytical procedure *but no evidence for performance of system suitability has been submitted.*
3.2.P.8.3	• Justification shall be submitted for not performing sterility test during stability studies. • Raw data sheets including details of sample and standard solution preparation and calculation formula applied for the Assay results , shall be submitted.	Firm has submitted revised stability summary sheets with same dates, incorporating the sterility test, while no microbial reports have been submitted as evidence.
• Justification shall be submitted for dispensing 5% excess drug substance for the formulation of stability batches, as evident form submitted BMRs. • Justification shall be submitted for not performing terminal sterilisation as evident from submitted BMRs.		*Not submitted.*

Decision: Registration Board decided to deferred the application for confirmation of approval of required manufacturing facility of "Liquid Injection Ampoule (general) section" in name of M/s Swiss Pharmaceuticals(Pvt.) Ltd. A/159, S.I.T.E. Super Highway Karachi.

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution. Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15395 dated 19-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule (4ml) Contains: Ondansetron as HCl …….. 8mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.5.2	Revised label claim shall be submitted declaring complete salt form of the drug substance along with applicable fee.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	
3.2.P.3.3	Flow chart submitted for manufacturing procedure is of Liquid vials whereas applied formulation is in ampoule.	
3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Injection.	
3.2.P.3.5	• Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted in this regard. • Submitted process validation protocol does not include any details of sampling plan and critical process parameters.	
3.2.P.5.1	Limits for average volume has been declared as 2ml -2.2 ml , whereas the applied formulation is of 4 ml ampoule.	
3.2.P.5.2	Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	

3.2.P.5.4	• Submitted batch analysis COA of stability batches declare average volume of ampoule as 2ml, whereas applied formulation is of 4ml ampoule. • Submitted batch analysis COA of stability batches does not include performance of particulate matter test.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.7	Type of glass for the ampoule shall be submitted.	
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test.	

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

19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 16610 dated 04-07-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Ondansetron as HCl…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.5.2	Revised label claim shall be submitted declaring complete salt form of the drug substance along with applicable fee.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product.	
3.2.P.3.3	Flow chart submitted for manufacturing procedure is of Liquid vials whereas applied formulation is in ampoule.	
3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Injection.	
3.2.P.3.5	• Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted in this regard. • Submitted process validation protocol does not include any details of sampling plan and critical process parameters.	
3.2.P.5.2	Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	
3.2.P.5.4	• Submitted batch analysis COA of stability batches does not include performance of particulate matter test.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.7	Type of glass for the ampoule shall be submitted.	
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test.	

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

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15686 dated 21-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as Hcl Dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt) Ltd.
	Proposed Pack size	As per SRO

-Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence and CDP studies shall be submitted. • CDP studies have been submitted for 8mg strength instead of 4mg tablet.	
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	

3.2.P.5.2	• Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract. • Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Details of batch size and manufacturing date are different between COAs submitted in section 3.2.P.5.4 and stability sheets in section 3.2.P.8.3 • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay & dissolution test.	

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

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15687 dated 21-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as Hcl Dihydrate…8mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt)

		Ltd.
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence and CDP studies shall be submitted. • CDP studies have been submitted for 4mg strength instead of 8mg tablet.	
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	
3.2.P.5.2	• Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract. • Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	

	• Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay & dissolution test.	

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

22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolution.** **Kala Wala Stop, 20 Km, Lahore Jaranwala Road, Lahore**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 15685 dated 21-06-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg/5ml Syrup**
	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	Innovator's
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	
	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.1	Form 5F has been submitted from the contract manufacturer instead of the contract giver.	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence studies shall be submitted.	

3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Syrup.	
3.2.P.3.5	• Submitted process validation protocol include details for the tablet dosage form instead of the applied syrup.	
3.2.P.5.2	• Submit drug product analytical procedure from M.s Weather folds instead of submitting USP monograph extract.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	
3.2.P.8.3	• Submitted analytical chromatogram does not declare the wavelength upon which the analysis has been performed. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test. • Microbiological reports shall be submitted for the Microbial Enumeration test performed during stability studies.	

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

23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 10003 dated 13-04-2023
	Details of fee submitted	Rs.75,000/- dated 24-01-2023
	The proposed proprietary name / brand name	**Romelo 200mg/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Linezolid…200mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Ecasill Infusion by M/s SAMI Pharmaceuticals

	Proposed Pack size	As per SRO

Evaluation by PEC:

Section#	Observations	Firm's response
1.3	• Submit evidence of validity of DML of the applicant • Submit fresh/valid GMP certificate of GT Pharma or inspection report conducted within last 03 years	
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	
3.2.S.4.1	• Justification shall be submitted for declaring drug substance specifications a sin-house, whereas USP monograph is available for the Linezolid. • Limits for test of "Loss on Drying" are different between the drug substance specifications submitted by M/s GT pharma and drug substance manufacturer. Clarification shall be submitted in this regard.	
3.2.S.4.2	Drug substance analytical procedure shall be submitted from drug substance manufacturer.	
3.2.S.4.3	Justification shall be submitted for adopting UV spectrophotometric method for Assay analysis of drug substance whereas USP monograph of Linezolid has recommended HPLC method.	
3.2.S.6	COA of reference standard/working standard used for analysis of the drug substance by M/s GT pharma shall be submitted.	
3.2.P.2.2.1	• Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator drug product. • Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence studies shall be submitted.	
3.2.P.5.1	• Drug product specifications have been refereed as per "USP standard" , whereas no USP monograph is available for the applied formulation.	
3.2.P.6	COA of reference/working standard, used for analysis of the drug product stability batches, shall be submitted.	

3.2.P.8.3	• Justification shall be submitted for performing Assay analysis for stability studies on UV spectrophotometric method, while HPLC method is available for the applied formulation. • Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance. • Submit raw data sheets for stability studies declaring the concentration of sample and standard preparations in Assay test.	

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

24.	Name, address of Applicant / Marketing Authorization Holder	**M/s Swiss Pharmaceuticals Pvt Ltd.** **A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	GMP status of the manufacturer	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Powder Injection section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission & Details of fee submitted	Dy.No 32570 dated 13-12-2021 Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Hy-Colis 2 MIU Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…2 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size & Unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises

	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Evaluation by PEC:	
	The applied product to be manufactured by M/s Biogen Life Sciences8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan have already been approved by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:	

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	Listim 2MIU Injection

	Decision: Approved.	
25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 17824 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 04-04-2023
	The proposed proprietary name / brand name	**Vonpin 10/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Aspirin (as Enteric Coated Tablet)…100mg Vonoprazan as Fumarate (as Immediate Release Layer)…10mg
	Pharmacotherapeutic Group of (API)	Vonoprazan: Potassium-Competitive Acid Blocker Aspirin: Antithrombotic Agents
	Reference to Finished product specifications	Innovator specification
	The status in reference regulatory authorities	Cabpirin 10/100mg tablet by M/s Takeda Pharmaceutical approved by PMDA of Japan
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
Evaluation by PEC[II]:		
Decision: Approved.		

26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s GT Pharma (Pvt) Ltd.** **713-Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s DeMont Research Laboratories (Pvt) Ltd. 20-km, Lahore-Sharikpur Road, Shekhupura.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18296 dated 20-07-2023
	Details of fee submitted	Rs.75,000/- dated 23-06-2023
	The proposed proprietary name / brand name	**Emprox 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen …500mg Esomeprazole as Magnesium Trihydrate…20mg
	Pharmacotherapeutic Group of (API)	NSAID/PPI
	Reference to Finished product specifications	As per Innovator specifications
	The status in reference regulatory authorities	US FDA approved.
	For generic drugs (me-too status)	Glomov of M/s Global pharmaceuticals
	Proposed Pack size	As per SRO

Evaluation by PEC^{II}:

Sr.#	Section#	Observation	Response of the Firm
1.	**1.5.2**	Submitted label claim shall be elaborated for the Immediate release and delayed release components of the formulation.	
2.	**1.6.5**	Copy of Valid GMP certificate/DML of the drug substance manufacturers shall be submitted.	
3.	**2.3.R**	• Submitted batch manufacturing record declares use of no excessive coating solution for the active layering for Esomeprazole. Justification shall be submitted for achieving the desired content of Esomeprazole as per label claim vide active coating, considering the wastage during coating process. • Dispensed quantity of Esomeprazole magnesium trihydrate shall be justified against the potency determined during drug substance analysis. • Submitted batch manufacturing record does not include any in-process analysis for the Esomeprazole	

		content after active coating process. Justification shall be submitted regarding the measures taken to ensure the content of Esomeprazole before proceeding for the final film coat. • Assay limit for Esomeprazole as magnesium i.e., 90-120% shall be justified.	
4.	**3.2.S.4**	Submit drug substance specifications and analytical procedures of drug substances from drug substance manufacturers.	
5.	**3.2.S.7**	• Drug substance specification for Assay test of naproxen declared in the stability sheets is different from that declared in the drug substance specifications. • Stability studies shall be signed and stamped form the drug substance manufacturer. • Long term stability studies data of Esomeprazole Magnesium trihydrate shall be submitted till claimed shelf life.	
6.	**3.2.P.2.2.1**	• Justification shall be submitted for performance of dissolution of naproxen in dissolution medium of pH=7.4 in Pharmaceutical equivalence studies, instead of Ph 6.8 buffer as recommended by US FDA. • Complete CDP studies in three dissolution mediums of physiological Ph shall be submitted for bot h drug substances.	
7.	**3.2.P.3.5**	• Assay limits of Esomeprazole declared in the process validation protocol shall be justified. • Justification shall be submitted for the dissolution medium of Naproxen. • In-process control for the establishment of Esomeprazole content after active coating shall be incorporated.	
8.	**3.2.P.5**	• Justification shall be submitted for the Assay limits of Esomeprazole as 90-120%.	

		• Justification shall be submitted for no including test for content uniformity by way of Assay for Esomeprazole. • Reference shall be submitted for the dissolution parameters and limits applied for Esomeprazole and Naproxen. • Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component".	
9.	**3.2.P.2.2.1**	Justification shall be submitted for not including sampling time point of "15 minutes" in the performance of CDP studies, as recommended by the relevant guidelines.	
10.	**3.2.P.5.2**	Submitted analytical procedure of Assay test is not as per USP monograph for applied formulation.	
11.	**3.2.P.5.3**	Analytical method verification studies of drug product Assay method have not been performed as per the chromatographic conditions recommended by US monograph. Justification shall be submitted in this regard.	
12.	**3.2.P.8**	• Documents confirming procurements of drug substances issued by DRAP I&E office, shall be submitted. • Complete raw data sheets for the performance of dissolution test including details of standard and sample solution preparation shall be submitted for the stability studies.	

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

M/s Biogen Life Sciences, Rawalpindi was granted New DML w.e.f.13-02-2020.

27.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences.** 8-KM Chakbeli Road ,Rawat, Rawalpindi
	Name, address of Manufacturing site.	**M/s Biogen Life Sciences.** 8-KM Chakbeli Road ,Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML (No. 000911) granted w.e.f. 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14th February 2020 specifying Ampoule Section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13634 dated 01 JUN 2023
	Details of fee submitted	PKR 30,000/- dated 16-02-2023 (Fee Challan / Receipt # 15380526027).
	The proposed proprietary name / brand name	**Tygagen 50mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Tigecycline … 50mg (JP Specifications)
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Tetracycline.
	Pharmaceutical form of applied drug	Powder for Infusion
	Reference to Finished product specifications	USP specs
	Proposed Pack size	5ml x 1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil 50mg powder for solution for infusion of M/s Pfizer Limited, UK (MHRA Approved).
	For generic drugs (me-too status)	Tygacil 50mg Injection (Reg. No. 045642) by M/s Pfizer Pharma.
	Name and address of API manufacturer.	Fuan pharmaceutical group chomming Bosen Pharmaceuticals Co. Ltd. No. 01 Huanan Road, changshou distric Chongqing, 401254 China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 12 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Tygacil 50mg Injection manufactured by Pfizer Pakistan.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuan pharmaceutical group chomming Bosen Pharmaceuticals Co. Ltd. No. 01 Huanan Road, changshou distric Chongqing, 401254 China.
API Lot No.	TI210402
Description of Pack (Container closure system)	USP Type-I glass vial
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 Months Accelerated: 6 Months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T001	T002	T003
Batch Size	500 vial	500 vial	500 vial
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	10-04-2022	10-04-2022	10-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP Certificate No. CQ20180031 issued by CFDA, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Firm has not provided documents for the procurement of API having approval from DRAP.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted. The Firm have mentioned that their HPLC system is not 21 CFR compliant.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm: -

i. Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as “M/s Biogen Life Sciences” whereas the name mentioned on submitted copy of DML is “M/s Biogen Pharmaceuticals”.

ii. Please provide label claim as per the innovator’s product. The mentioned label claim is not as per innovator’s product.

iii. Please provide details of Column used for Analysis of Finished Pharmaceutical Product. Furthermore, the chromatographic conditions (specifically Injection volume and System Suitability) are not as per USP. Please justify.

iv. In Section 2.3.S.7.1, Please justify the stability studies of the drug substance conducted as per zone IV-A conditions, since as per API manufacturer as well as USP the storage conditions is to store the drug substance from 2℃ to 8℃.

v. In Section 2.3.S.7.1 (b), the proposed storage condition of API is mentioned as *"Store below 30℃"* and Expiry period as *"3 years"*, however the same has been mentioned as *"Store between 2℃ to 8℃"*and *"02 years"* by API Manufacturer in Section 3.2.S.7.1. Please justify.

vi. In Section 3.2.P.1, composition has been mentioned as Tigecycline only whereas list of excipients as per innovator include Lactose monohydrate, Hydrochloric acid and Sodium hydroxide (for pH adjustment) as well. Please justify the reason for not using the same in your formulation.

vii. Please provide details (along with supporting evidence) of Reference / Innovator's pack used for Pharmaceutical Equivalence.

viii. Section 3.2.P.8, please justify, with supporting evidence, the reason for not conducting Bacterial Endotoxin Test and Sterility Test at the end of 6th Month Accelerated & Real Time Stability Study Testing.

ix. Please provide documents for the procurement of API having approval from DRAP (for submitted copy of Invoice KSDS20210411 dated 10th September 2021).

x. Section 2.3.R.1.1 Please provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 Section 3.2.P.8.3.

xi. Please provide details of the lyophilizer installed in your premises including details of the minimum and maximum capacity of the equipment.

xii. Please provide evidence of availability of Auto sampler in HPLC, wherein 10℃ temperature conditions could be maintained.

Decision of 330th meeting of Registration Board:

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

Sr. No.	Decision of 330th meeting of Registration Board	Response of The Firm
i.	Please confirm the name of your Firm (along with its supporting evidence) as the same has been mentioned as "M/s Biogen Life Sciences" whereas the name mentioned on submitted copy of DML is "M/s Biogen Pharmaceuticals".	Firm has submitted copy of Change of Title (vide letter No. F.1-2/2019-Lic dated 18th March 2021) to "M/s Biogen Life Sciences".
ii.	Please provide label claim as per the innovator's product. The mentioned label claim is not as per innovator's product.	The firm have submitted that it was as "**drafting error"** and submitted **revised label claim** as follows: **TYGAGEN 50mg Injection** **Each vial contains:** **Tigecycline lyophilized powder … 50mg** **(USP Specifications)**

		Fee for revision of label claim has not been submitted.
iii.	Please provide details of Column used for Analysis of Finished Pharmaceutical Product. Furthermore, the chromatographic conditions (specifically Injection volume and System Suitability) are not as per USP. Please justify.	The firm have submitted that the error was due to a "**typing mistake"** and submitted **revised chromatographic conditions** as follows: Mode: LC Detector: UV 248nm Column: 4.6-mm x 15-cm; 5µm packing L1 Column Temperature: 30°C Flow rate: 1ml/min Injection: 20µl
iv.	In Section 2.3.S.7.1, Please justify the stability studies of the drug substance conducted as per zone IV-A conditions, since as per API manufacturer as well as USP the storage conditions is to store the drug substance from 2°C to 8°C.	The firm have submitted that it was a **"Typographic mistake" and submitted revised 2.3.7.S.3 a) Conclusion of the Stability Studies as follows:** ***The Long Term and accelerated stability study data suggests that the drug substance is stable for 24Months when stored below 2-8°C.***
v.	In Section 2.3.S.7.1 (b), the proposed storage condition of API is mentioned as "Store below 30°C" and Expiry period as "3 years", however the same has been mentioned as "Store between 2°C to 8°C"and "02 years" by API Manufacturer in Section 3.2.S.7.1. Please justify.	The firm have submitted that it was a **"Typographic mistake" and submitted revised 2.3.7.S.1.**
vi.	In Section 3.2.P.1, composition has been mentioned as Tigecycline only whereas list of excipients as per innovator include Lactose monohydrate, Hydrochloric acid and Sodium hydroxide (for pH adjustment) as well. Please justify the reason for not using the same in your formulation.	The firm have submitted that they have imported Tigecycline as **Tigecycline Lyophilized ready to fill Powder.**
vii.	Please provide details (along with supporting evidence) of Reference / Innovator's pack used for Pharmaceutical Equivalence.	Firm has referred to TIGBIO 50mg Injection Batch No. L-409 of M/s Bio-Labs Pharma. **However, no supporting evidence of the claim has been submitted.**
viii.	Section 3.2.P.8, please justify, with supporting evidence, the reason for not conducting Bacterial Endotoxin Test and Sterility Test at the end of 6th Month Accelerated & Real Time Stability Study Testing.	The firm have submitted that they perform Bacterial Endotoxin Test and Sterility Test at initial testing interval and at the end of 24th Month Real Time Stability Study Testing.
ix.	Please provide documents for the procurement of API having approval from DRAP (for submitted copy of Invoice KSDS20210411 dated 10th September 2021).	The firm has submitted as follows: - *"The API was imported in Sep, 2021 for Trials/R&D Studies.* ***There was no strict rule of ADC Clearance by DRAP in our notice at that time. Therefore, the process of ADC Clearance of API was over looked by us. We***

		admit our negligence and request to kindly consider and approve our invoice without ADC Clearance.*"*
x.	Section 2.3.R.1.1 Please provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 Section 3.2.P.8.3.	Trial Manufacturing Records are submitted.
xi.	Please provide details of the lyophilizer installed in your premises including details of the minimum and maximum capacity of the equipment.	**Not provided.** The firm have submitted that they have imported Tigecycline as **Tigecycline Lyophilized ready to fill Powder.**
xii.	Please provide evidence of availability of Auto sampler in HPLC, wherein 10℃ temperature conditions could be maintained.	The firm has submitted as follows: - "*the HPLC system has manual injector. For maintenance of 10℃ temperature. The testing materials / Analyte (sample and standard) placed in refrigerator".*

Decision of 331st Meeting of Registration Board: Registration Board decided to constitute the following panel for onsite investigation for verification / authenticity of the product development and stability data as the data submitted in reply to the shortcoming communicated in 330th meeting has multiple drafting/typographical errors: -

- **Dr. Ghazanfar Ali Khan, Additional Director (QA&LT Field Office) Islamabad.**
- **Muhammad Tahir Waqas, Deputy Director (PEC), Islamabad.**

Report on investigation of genuineness / authenticity of data submitted for registration of TYGAGEN 50mg Injection (Tigecycline) by M/s Biogen Life Sciences, Rawalpindi.

Reference No: F.15-1/2022-PEC dated 14th May, 2024.
Investigation Date: 10th July, 2024.
Investigation Site: Factory premises of M/s M/s Biogen Life Sciences, 8-KM, Chakbeli Road, Rawat, Rawalpindi.

Background:

The case was placed before Registration Board in its 331st Meeting and the Board approved the following panel for on-site investigation to confirm genuineness / authenticity of product development and stability data as the data submitted in reply to the shortcoming communicated in 330th meeting has multiple drafting / typographical errors.

Composition of Panel:

1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT Field Office) Islamabad.
2. Mr. Muhammad Tahir Waqas, Deputy Director (PEC), DRAP Islamabad.

Scope of investigation:

Investigation to confirm genuineness / authenticity of product development & stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

Q. No.	Question	Observation by Panel
1.	Do you have documents confirming the import API including approval from DRAP?	The firm have shown receipt of DHL Import for the said API.
2.	What was the rationale behind selecting the particular manufacturer of API?	Firm informed that they have selected API's manufacturer on the basis of vendor evaluation and qualification (desktop). The criteria include: • Vendor should compile the specification with respect to critical tests. • Vendor should have accreditation from government body and having valid license. • Supplier facility and operation meets the requirements as documented in the Audit Report. • Timely Supply of the products from the vendor.
3.	Do you have documents confirming the import of API reference standard and impurity standards?	Firm does not have documents confirming the import of API reference standard and impurity standards.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Firm have copy of COA of Tigecycline (Lyophilized powder) Batch No. Ti210402 by M/s Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co., Ltd, China, only.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm have GMP certificate of API manufacturer issued by regulatory authority of country of origin.
6.	Do you use API manufacturer method of testing for testing API?	Firm have used API manufacturer's method of testing for testing API.
7.	Do you have stability studies reports on API?	Firm have stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Tests for Impurities & Residual Solvents have been included.

9.	Do you have method for quantifying the impurities in the API?	No
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm does not have remaining quantities of the API and claimed that the Stability Studies have been concluded.
11.	Have you used pharmaceutical grade excipients?	Not applicable. Firm have claimed that no excipients have been used, since ready to fill lyophilized powder will be used for filling only.
12.	Do you have documents confirming the import of the used excipients?	N/A
13.	Do you have test reports and other records on the excipients used?	N/A
14.	Do you have written and authorized protocols for the development of applied product?	Firm have written and authorized protocols for the development of applied product.
15.	Have you performed Drug-excipients compatibility studies?	N/A
16.	Have you performed comparative dissolution studies?	N/A
17.	Do you have product development (R&D) section?	Firm have shown product development (R&D) section.
18.	Do you have necessary equipment available in product development section for development of applied product?	Firm have used equipment available in production area for development of applied product.
19.	Are the equipment in product development section qualified?	N/A
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	N/A
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Firm have trained & qualified staff of 02 Pharmacists, 01 Chemist and 01 Microbiologist involved in Product Development (R&D).
22.	Have you manufactured three stability batches for the stability studies of applied product as required?	Three (03) stability batches have been manufactured for 04-2022 for the stability studies of applied product having batch size of 500 vials each.
23.	Do you have any criteria for fixing the batch size of stability batches?	Batch size fixation based on ICH / Regulatory authority guidelines and the production capacity of area equipment and facilities in manufacturing areas.
24.	Do you have complete record of production of stability batches?	Firm have shown record of production of stability batches.

25.	Do you have protocols for stability testing of stability batches?	Firm have shown protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	Firm have shown method verification studies for testing of stability batches.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	Firm have shown documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.
29.	Is your method of analysis stability indicating?	Degradation products have not been quantified in the Finished Product Testing.
30.	Is your HPLC software 21CFR Compliant?	NO, HPLC systems are not 21 CFR compliant.
31.	Can you show Audit trail reports on stability study testing?	N/A, since HPLC systems are not 21 CFR compliant. Firm have shown manual entries / log books for test / analysis of stability batches.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm does not have remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	Firm does not have stability batches kept on stability testing.
34.	Do you have valid calibration status for the equipment used in production and analysis?	Firm have calibration records for the equipment used in production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	01 Real Time Stability Chamber: o Model No: SC-1000 o Model: MZ Enterprise o QC Equipment No: BLS-QC-016 01 Accelerated Time Stability Chamber: o Model No: SC-MIL o Model: Bio-base Driver o QC Equipment No: BLS-QC-017 Furthermore, manual data loggers were used for temperature monitoring.

36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are as per cGMP compliance.

CONCLUSION:

On the basis of risk based approach the genuineness / authenticity of product development / stability data submitted by the firm for registration of TYGAGEN 50mg Injection (Tigecycline) by M/s Biogen Life Sciences, Rawalpindi, is verifiable to satisfactory level.

The related manufacturing area, equipment, personnel and utilities are as per cGMP compliance.

Additionally, the firm was advised to set up cold storage facility (2°C - 8°C) for storage of commercial consignments of API (Tigecycline Lyophilized Powder).

Submitted for consideration of Board, please.

Decision: Approved.
Registration Board further decided that the Registration Letter will be issued after submission of:

- **Requisite fee for pre-registration revision / correction of data / typographic errors.**

28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted.
	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted, mentioning Tablet (Non-Antibiotic, Antibiotic, Psychotropic, Cephalosporin & Ani-Cancer) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26719 dated 21 SEP 2022
	Details of fee submitted	PKR 30,000/- Dated 06-09-2022 (Challan / Receipt # 19839887999)

	The proposed proprietary name / brand name	**ELSART 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Telmisartan … 40mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C09CA07, Angiotensin II receptor blockers (ARBs), plain.
	Pharmaceutical form of applied drug	White oval shaped, biconvex core tablet plain from both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telmisartan 40mg Tablets of M/s Brillpharma (Ireland) Limited, Health Products Regulatory Authority (Ireland) Approved.
	For generic drugs (me-too status)	TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Rd., Gaochun, Nanjin, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures,

		validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited by performing quality tests (Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against TASMI Tablets 40mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. China.		
API Lot No.	D10011-20190905		
Description of Pack (Container closure system)	Alu-PVC Blisters		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TEL40-SB001	TEL40-SB002	TEL40-SB003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	12-2021	01-2022	01-2022
Date of Initiation	09-02-2022	09-02-2022	09-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Notice of GMP Inspect results of Jiangsu Province No.83/2020 has been enclosed.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. YST19187C dated Dec.19,2019 for import of 4Kgs Telmisartan, cleared by AD(I&E) Lahore vide No. 2399/2020-DRAP dated 14-02-2020, has been submitted.
4.	Data of stability batches will be supported by attested respective	Firm has submitted analytical record for product testing.

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

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm:

	Deficiencies / Shortcomings	Response of the firm
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	The firm have submitted that they have applied for renewal of GMP and are waiting for Inspection.
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	Section approval letter has not been submitted.
iii.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin has not been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical Equivalence & Comparative Dissolution Study.	Submitted.
v.	3.2.P.5.2 Please specify the Dissolution Test 1, 2 or 3.	The firm has mentioned that they have used Dissolution Test 1. Furthermore, the firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
vi.	3.2.P.5.3 Analytical Method has been verified vide Verification Report No. QC/AMV/R/033-01, Effective Date March, 2022, whereas Stability Study was commenced (Initial Testing) in 12-2021 for TEL40-SB001 and 01-2022 for TEL40-SB002 & TEL40-SB003. Please justify.	The firm have submitted that due to unavailability of Reference standard, they were unable to perform verification studies initially, once received, they performed verification studies before third month testing of product on stability.

vii.	3.2.P.5.3 USP in its monograph for Telmisartan Tablets recommends 'Column: 4.0-mm × 4-cm; 5-µm packing L1, Flow rate: 0.7 mL/min' for Assay Analysis whereas you have used 'Column: 4.6-mm × 2.5-cm; 10-µm packing C18', Flow rate: 0.5 mL/min'. Please justify.	The firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
viii.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	Submitted.
ix.	Description of Pack (Container closure system) has been mentioned as 'Alu-PVC Blisters' as well as 'Alu-Alu Blisters' on separate instances within the application dossier. Please clarify.	Typographical error. Container closure system is 'Alu-Alu Blisters'.
x.	Please provide Compliance Record of HPLC software 21CFR.	Submitted.
xi.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	VONOV 10mg and 20mg Tablets.

Decision of 335th Meeting:
Registration Board deferred the case for submission of:

- **Relevant documents as required for points (i) (ii) and (iii) mentioned above.**
- **Data of submitted batches as per revised Method of Analysis.**
- **Requisite fee for pre-registration correction / Typographical Mistake**

29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd., 16-Km Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted.

	Evidence of approval of manufacturing facility	Copy of GMP Certificate Ref. No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020 valid for two years from the date of inspection (04-02-2020) has been submitted, mentioning Tablet (Non-Antibiotic, Antibiotic, Psychotropic, Cephalosporin & Ani-Cancer) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26718 dated 21 SEP 2022
	Details of fee submitted	PKR 30,000/- Dated 06-09-2022 (Challan / Receipt # 77086083419)
	The proposed proprietary name / brand name	**ELSART 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Telmisartan … 80mg (USP Specifications)
	Pharmacotherapeutic Group of (API)	C09CA07, Angiotensin II receptor blockers (ARBs), plain.
	Pharmaceutical form of applied drug	White round shaped, biconvex core tablet plain from both sides.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telmisartan 80mg Tablets of M/s Brillpharma (Ireland) Limited, Health Products Regulatory Authority (Ireland) Approved.
	For generic drugs (me-too status)	TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited.
	Name and address of API manufacturer.	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Rd., Gaochun, Nanjin, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 Months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 Months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited by performing quality tests (Assay, Dissolution, and Uniformity of dosage unit). Firm has submitted CDP results of their product against TASMI Tablets 80mg of M/s Getz Pharma (Pvt.) Limited in 03 dissolution media.
	Analytical method validation/verification of product	Method verification / validation studies have been submitted for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangsu Zhongbang Pharmaceutical Co., Ltd. China.		
API Lot No.	D10011-20190905		
Description of Pack (Container closure system)	Alu-PVC Blisters		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 Months Accelerated: 6 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TEL80-SB001	TEL80-SB002	TEL80-SB003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	11-2021	01-2022	01-2022
Date of Initiation	09-02-2022	09-02-2022	09-02-2022

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	**Not provided.**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Notice of GMP Inspect results of Jiangsu Province No.83/2020 has been enclosed.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. YST19187C dated Dec.19,2019 for import of 4Kgs Telmisartan, cleared by AD(I&E) Lahore vide No. 2399/2020-DRAP dated 14-02-2020, has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing. **However, Compliance Record of HPLC software 21CFR has not been submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The following deficiencies / shortcomings have been communicated to the firm:

	Deficiencies / Shortcomings	**Response of the firm**
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	The firm have submitted that they have applied for renewal of GMP and are waiting for Inspection.
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	Section approval letter has not been submitted.
iii.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin has not been submitted.
iv.	Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical	Submitted.

	Equivalence & Comparative Dissolution Study.	
v.	3.2.P.5.2 Please specify the Dissolution Test 1, 2 or 3.	The firm has mentioned that they have used Dissolution Test 1. Furthermore, the firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
vi.	3.2.P.5.3 Analytical Method has been verified vide Verification Report No. QC/AMV/R/033-01, Effective Date March, 2022, whereas Stability Study was commenced (Initial Testing) in 11-2021 for TEL80-SB001 and 01-2022 for TEL80-SB002 & TEL80-SB003. Please justify.	The firm have submitted that due to unavailability of Reference standard, they were unable to perform verification studies initially, once received, they performed verification studies before third month testing of product on stability.
vii.	3.2.P.5.3 USP in its monograph for Telmisartan Tablets recommends 'Column: 4.0-mm × 4-cm; 5-µm packing L1, Flow rate: 0.7 mL/min' for Assay Analysis whereas you have used 'Column: 4.6-mm × 2.5-cm; 10-µm packing C18', Flow rate: 0.5 mL/min'. Please justify.	The firm have submitted Revised Method of Analysis for Elsart 40mg and 80mg Tablets.
viii.	3.2.P.6 It has been mentioned that Working Standard has been used for analytical testing. Please provide evidence / traceability of the mentioned Working Standard against the USP Reference Standard.	Submitted.
ix.	Description of Pack (Container closure system) has been mentioned as 'Alu-PVC Blisters' as well as 'Alu-Alu Blisters' on separate instances within the application dossier. Please clarify.	Typographical error. Container closure system is 'Alu-Alu Blisters'.
x.	Please provide Compliance Record of HPLC software 21CFR.	Submitted.
xi.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	VONOV 10mg and 20mg Tablets.
Decision of 335th Meeting:		

Registration Board deferred the case for submission of:

- **Requisite fee for pre-registration correction / Typographical Mistake.**
- **Relevant documents as required for points (i) (ii) and (iii) mentioned above.**
- **Data of submitted batches as per revised Method of Analysis.**

The firm have submitted response for **ELSART 20mg and 40mg Tablets** as follows:

Sr. No.	Decision of 335th Meeting	Firm's Response
i.	Requisite fee for pre-registration correction / Typographical Mistake	Elsart 40mg Tablet: Challan No. 92915312 Elsart 80mg Tablet: Challan No. 6411392198
ii.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	**Firm states that they have applied for renewal of GMP and their inspection is awaited.**
iii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	**Not provided.** Copy of letter for Pannel Inpsection has been submitted.
iv.	Please provide valid approval of API/ DML/GMP Certificate of API manufacturer issued by concerned Regulatory Authority of Country of Origin.	API Manufacturer's verification link has been submitted.
v.	Data of submitted batches as per revised Method of Analysis.	**Not Submitted.** **The Firm have claimed that the revised Method of Analysis (MOA) was submitted only to address some typographical errors and not due to technical changes in testing conditions so the query regarding submission of data as per revised MOA was unjustified and have requested to consider previously submitted data as per USP.**

Decision of 339th meeting of the board: Deferred
Registration Board did not accede to the request of the firm and decided that the firm shall submit requisite data as decided in 335th Meeting of Registration Board for ELSART 20mg and 40mg Tablets.

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5260 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 1415475365
	The proposed proprietary name / brand name	**TUGLIF-M 2.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 2.5mg Metformin Hydrochloride … 1000mg
	Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications

EVALUATION OF DATA	
GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated **01-03-2021.**
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of Renewal of DML dated 18th June 2021. The letter specifies Tablet (General) Section.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	SEGLUROMET Tablet 2.5/1000mg (USFDA Approved).
For generic drugs (me-too status)	LOZGIL-M Tablet 2.5/1000mg of M/s Genix Pharma (Private) Limited.
Name and address of API manufacturer.	**Ertugliflozin L-Pyroglutamic acid:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin Hydrochloride:** M/s Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against SEGLUROMET Tablet 2.5/1000mg of M/s MSD

	International GmbH (p.R) LLC, USA, Batch No. U004314, Mfg. 10-2020. Firm has submitted CDP results of their product against SEGLUROMET Tablet 2.5/1000mg of M/s MSD International GmbH (p.R) LLC, USA, Batch No. U004314, Mfg. 10-2020.
Analytical method validation / verification of product	Firm has submitted analytical method validation / verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	Ertugliflozin L-Pyroglutamic acid: L-IG-20211005-D01-IG06-03 Metformin Hydrochloride: A-35212102114 / 5		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	057B22	058B22	059B22
Batch Size	3,000 Tablets	3,000 Tablets	3,000 Tablets
Manufacturing Date	April - 2022	April - 2022	April - 2022
Date of Initiation	06-06-2022	06-06-2022	06-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	GLUSIMET XR 50/500mg Tablets & GLUSIMET 50/100mg Tablets discussed in 296th Meeting of Registration Board.
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic acid:** Copy of GMP Certificate issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone, valid until August 23, 2023 has been submitted. **Metformin Hydrochloride:** Copy of GMP Certificate No. SD20190888 issued by Shandong Food and Drug Administration, valid until **12-03-2024** has been submitted.
Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic acid:** Firm has submitted copy of commercial invoice cleared dated 01-12-2021 for import of 1Kg of API. The invoice is cleared by AD (I&E) DRAP, Karachi. **Metformin Hydrochloride:** Firm has submitted copy of commercial invoice cleared dated 16-04-2021 for import of 3000Kgs of API. The invoice is cleared by AD (I&E) DRAP, Karachi.

Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system & audit trail reports on product testing.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Administration, China.
ii.	**Metformin Hydrochloride:** Please provide valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid until **12-03-2024.**	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06th Month (Accelerated) testing interval from initial test results of Ertugliflozin, Batch No. 058B22. Please justify.	Firm have submitted justification as follows: - • When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. • In the case of small batch sizes, it is important to acknowledge that the results obtained from the stability testing may not fully reflect the true stability profile of the product. • Despite the challenges, all other parameters were satisfactory that shows variation is not as significant.

iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22nd February, 2023.

Decision of 336th Meeting: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accelerated stability studies of Batch no. 058B22 decided to defer the case for submission of stability studies of newly formulated batches.

31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5259 dated 23 FEB 2023
	Details of fee submitted	PKR 30,000/- dated 08-02-2023 Challan / Receipt # 4043535505
	The proposed proprietary name / brand name	**TUGLIF-M 7.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ertugliflozin (as L-Pyroglutamic acid) … 7.5mg Metformin Hydrochloride … 1000mg
	Pharmacotherapeutic Group of (API)	A10BD23, blood glucose lowering drugs, excl. insulins, combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specifications

EVALUATION OF DATA

GMP status of the firm	Firm has submitted copy of GMP certificate of the firm based on inspection dated **01-03-2021.**
Evidence of approval of manufacturing facility	Firm has submitted copy of letter for grant of Renewal of DML dated 18th June 2021. The letter specifies Tablet (General) Section.
Proposed Pack size	As per SRO
Proposed unit price	As per SRO
The status in reference regulatory authorities	SEGLUROMET Tablet 7.5/1000mg (USFDA Approved).
For generic drugs (me-too status)	LOZGIL-M Tablet 7.5/1000mg of M/s Genix Pharma (Private) Limited.
Name and address of API manufacturer.	**Ertugliflozin L-Pyroglutamic acid:** M/s Fuxin Long Rui Pharmaceutical Co., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China.

	Metformin Hydrochloride: M/s Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per module 3.2.S.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A conditions.
Module-III Drug Product:	Firm has submitted data of drug product as per module 3.2.P.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against LOZGIL-M Tablet 7.5/1000mg of M/s Genix Pharma (Private) Limited., Batch No. 0001T416, Mfg. 07-2022. Firm has submitted CDP results of their product against LOZGIL-M Tablet 7.5/1000mg of M/s Genix Pharma (Private) Limited., Batch No. 0001T416, Mfg. 07-2022.
Analytical method validation / verification of product	Firm has submitted analytical method validation / verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
API Lot No.	Ertugliflozin L-Pyroglutamic acid: L-IG-20211005-D01-IG06-03 Metformin Hydrochloride: A-35212102114 / 5		
Description of Pack (Container closure system)	Alu-Alu blister.		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	060B22	061B22	062B22
Batch Size	3,000 Tablets	3,000 Tablets	3,000 Tablets
Manufacturing Date	April - 2022	April - 2022	April - 2022
Date of Initiation	06-06-2022	06-06-2022	06-06-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA	
Reference of previous approval of applications with stability study data of the firm (if any)	GLUSIMET XR 50/500mg Tablets & GLUSIMET 50/100mg Tablets discussed in 296th Meeting of Registration Board.

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin L-Pyroglutamic acid:** Copy of GMP Certificate issued by Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone, valid until August 23, 2023 has been submitted. **Metformin Hydrochloride:** Copy of GMP Certificate No. SD20190888 issued by Shandong Food and Drug Administration, valid until **12-03-2024** has been submitted.
Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin L-Pyroglutamic acid:** Firm has submitted copy of commercial invoice cleared dated 01-12-2021 for import of 1Kg of API. The invoice is cleared by AD (I&E) DRAP, Karachi. **Metformin Hydrochloride:** Firm has submitted copy of commercial invoice cleared dated 16-04-2021 for import of 3000Kgs of API. The invoice is cleared by AD (I&E) DRAP, Karachi.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system & audit trail reports on product testing.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Ertugliflozin L-Pyroglutamic acid**: Please provide approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Liaoning Fuxin Management Committee for Fluoride Industrial Development Zone is not the concerned regulatory authority of country of origin.	Firm have submitted copy of Pharmaceutical Production License number LIAO 20150233, Classification code: Dh, issued by Lioning Province Drug Admistration, China.
ii.	**Metformin Hydrochloride:** Please provide valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP Certificate was valid until **12-03-2024.**	Firm have submitted copy of Pharmaceutical Production License number Lu20160126, Classification code: AhDh, issued by Shandong Medical Products Administration, China.
iii.	3.2.P.8 Significant Change (>5%) have been observed at 06th Month (Real Time)	Firm have submitted justification as follows: -

	testing interval from initial test results of Metformin, Batch No. 060B22. Please justify.	• When working with small batch sizes, there may be instances where variability in results is obtained due to the limited sample size available for analysis. • In the case of small batch sizes, it is important to acknowledge that the results obtained from the stability testing may not fully reflect the true stability profile of the product. • Despite the challenges, all other parameters were satisfactory that shows variation is not as significant.
iv.	Please provide evidence of GMP status of the firm (FPP Manufacturer), not older than 03 years.	Firm have submitted copy of GMP Certificate, issued based on inspection conducted on 22nd February, 2023.

Decision of 336th Meeting: Registration Board while considering the significant change in Assay results of Ertugliflozin, reported in the submitted Accelerated stability studies of Batch no. 060B22 decided to defer the case for submission of stability studies of newly formulated batches.

The firm have submitted following response for **TUGLIF-M 2.5/1000mg Tablets** and **TUGLIF-M 7.5/1000mg Tablets**:

"We have Export Purpose Registration of TUGLIF-M 2.5/1000mg and TUGLIF-M 7.5/1000mg Tablets, therefore, commercial batches for Export were manufactured last year & kept on stability. We are enclosing stability reports of those commercial batches to fulfil the requirement of submission of stability studies of newly formulated batches."

The firm have submitted Stability Study Reports (Summary Sheets) as follows:

Product(s)	Batch Details	Kept on Stability	Completed Intervals
TUGLIF-M 2.5/1000mg Tablets	001F91 35,000 Tablets Mfg. Aug-2023	21-Dec-2023	Accelerated: 06 Months Real Time: 06 Months
TUGLIF-M 7.5/1000mg Tablets	001F92 35,000 Tablets Mfg. Aug-2023	21-Dec-2023	Accelerated: 06 Months Real Time: 06 Months

Decision: Deferred.
Registration Board did not accede to the request of the firm and decided that the firm shall submit requisite data as decided in 336th Meeting of Registration Board for TUGLIF-M 2.5/1000mg Tablets and TUGLIF-M 7.5/1000mg Tablets.

Agenda of Ms. Najia Saleem

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

a. Deferred cases (local)

32.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Amivit Injection 250ml
	Composition	Each ml contains: L-Arginine HCl…1.44mg L-Cysteine HCl…3.20mg L-Glutamine…3.20mg Glycine…3.20mg L-Histidine…1.32mg L-Isoleucine…3.6mg L-Leucine HCl…4.28mg L-Lysine HCl…5.44mg L-Methionine…3.20mg L-Threonine…3.20mg L-Tryptophan…0.86mg L-Valine…3.60mg Vitamin B1...4mg Riboflavin Sodium Phosphate...0.17mg Vitamin B6...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg L-Phenylalnine...5mg
	Diary No. Date of R& I & fee	Dy.No 39620 dated 30-12-2022 Rs.30,000/- dated 30-12-2022 (slip No. 22074538613)
	Pharmacological Group	Vitamin/ Restorative
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	250ml,: Decontrolled
	Me-too status	Aminovital Injection **(50ml, 100ml)** of M/s Star Labs Lahore. (Reg. No. 023491)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Shortcomings:** • Confirmation of relevant manufacturing facility
	Decision of 336th meeting: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
	Updated status: The firm has submitted that Biosign Injection (Reg. No. 122030) and Metagen Injection (Reg. No. 113547) has already been approved **in 500ml pack sizes**. The firm has also provided copies of registration letters.	

	Decision: Approved.

Agenda of Dr. M Haseeb Tariq

Case No. 01 Registration applications of CTD cases

a. New cases

33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29100: 13-10-2022
	Details of fee submitted	PKR 75,000/- : 03-10-2022
	The proposed proprietary name / brand name	**MOXON 5mg Eye Drops (ophthalmic solution)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Moxifloxacin as HCl…5mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Vigamox eye drops by Novartis
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
34.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29101: 13-10-2022
	Details of fee submitted	PKR 75,000/- : 03-10-2022
	The proposed proprietary name / brand name	**OLOPTON 2mg Eye Drops (ophthalmic solution)**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Olopatadine as HCl…2mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Ocudine eye drops by Barret Hodgson
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

b. Deferred case

35.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	G Win 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin Mesylate…320mg
	Diary No. Date of R& I & fee	Dy No. 14805: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in FDA / applicant withdraw its application for Marketing authorization in EMA
	Me-too status	Gemixa tablet by Bosch Pharma
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Gemifloxacin (as mesylate)…320mg
	Decision of 327th RB meeting: Registration Board was apprised that the applied formulation is discontinued in USFDA and the marketing authorization application in EMA has been withdrawn due to negative risk benefit ratio. Based upon the findings of the EMA, the Board decided as under: • Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

	• Directed PE&R Division to present the detailed case in forthcoming meeting of Registration Board along with details of already registered products of same formulation.	
	Submission by the firm: Firm has submitted reference of USFDA approval of applied formulation. As per the review of FDA database, the product marketing status is still discontinued, however with following remarks **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	
	Decision: Approved.	
36.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Wincip 125mg/5ml Granules
	Composition	Each 5ml Granules Suspension Contains: Ciprofloxacin HCl…125mg
	Diary No. Date of R& I & fee	Dy No. 14651: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Registration Board in 269th meeting approved the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension
	Me-too status	Novidat suspension by Sami
	GMP status	The last inspection conducted on 31-01-2022 and report concludes that overall GMP compliance was found good.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml of reconstituted suspension contains: Ciprofloxacin..…125mg
	Decision of 327th RB meeting: Defferred the case. The registration Board discussed and deliberated the case in detail regarding the diluent and decided to constitute an expert working group consisting of members from RB, DRAP, national and International health professionls in the relevant fields, stake holders and member nominated by WHO. This working group will look into the matter considering all the technical aspects and will forward its report to RB for its consideration and decision.	
	Submission by the firm: Firm has requested to reconsider their application in the light of decision of 331st meeting of Registration Board.	
	Decision: Approved.	

Agenda of Ms. Saima Hussain

37.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Ophth Pharma (Pvt.) Ltd. Plot No.241, Sector 24,Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	**M/s. Ophth Pharma (Pvt.) Ltd. Plot No.241, Sector 24,Korangi Industrial Area, Karachi**
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.13764 dated :02-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no. 8256519971 dated 12-05-2023
	The proposed proprietary name / brand name	Travoprost Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each ml contains:** **Travoprost…..0.04mg**
	Pharmacotherapeutic Group of (API)	Prostaglandin $F_{2\alpha}$ Analogue
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Travop ophthalmic solution 0.004% by Alza Reg. # 081621

Remarks of the Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and analytical procedure used for analysis of drug substance by drug product manufacturer.
2.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.
3.	3.2.P.1	Justify for not including the anti-microbial/preservative in the applied formulation since the innovator product used preservative in their formulation.
4.	3.2.P.2.2.1	Since the applied formulation contain Zinc Chloride then how the ophthalmic solution having pH value above 6 be acceptable, when the USP monograph of "**Travoprost Ophthalmic Solution"** recommends that *If labeled to contain zinc chloride as an ingredient the acceptance range of pH is between 5.5–5.9.*
5.	3.2.P.3.2	Storage condition of filled product is up to temperature 30°C as mentioned in the description of manufacturing procedure under section 3.2.P.3.2, justify for keeping the storage temperature above then the recommended temperature as per USP monograph i.e. Store between 2° and 25°.
6.	3.2.P.3.2	Justify, how you maintain the sterility of drug product using non-sterile drug substance and without performing terminal sterilization.
7.	3.2.P.5.1	Acceptance limit of Assay test and pH is not in accordance with USP Monograph of Travoprost Ophthalmic solution, justification is required in this regard.

8.	3.2.P.8	• Provide detailed method and calculation formula for water loss test of the drug product, since ICH guidelines recommend using a particular ratio of water loss for calculation purpose. • Justify for adapting the acceptance criteria of assay test and pH limit different from the recommended acceptance range in the USP monograph of travoprost ophthalmic solution. • According to the chromatogram main peak eluted at retention time of about 7.40 minutes, while the peak area considered while calculating the assay was mentioned against the retention time of 1.6minutes in the table given below the chromatogram, clarify the ambiguity regarding the peak area and retention time pf main peak. • Justify for submitting the same chromatogram and raw data sheets at every time point of each stability batches. • Reference of previous approval of applications with stability study data of the firm (if any) • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Documents for the procurement of API with approval from DRAP (in case of import). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing
9.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		

PREVIOUSLY DEFERRED CASES OF FORM 5-F:

38.	Name, address of Applicant / Marketing Authorization Holder	**M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur**
	Name, address of Manufacturing site.	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	afresh license granted on 10/11/2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Capsules (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 26128 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- Dated 26-10-2023
	The proposed proprietary name / brand name	PTL Tablet 40mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric coated tablet contains: Pantoprazole as sodium sequihydrate…40mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)
	Pharmaceutical form of applied drug	White to off white circular round enteric coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Neege 40mg Tablet by M/s Searle Pakistan, Reg. No. 110185
	Name and address of API manufacturer.	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andra pardesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of

		drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the reference product Neege 40mg Tablet of M/s. Sami Pharma. Firm has submitted CDP results of their product against the reference product Neege 40mg Tablet of M/s. Sami Pharma. in 2 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andrapardesh, India.		
API Lot No.	NA		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA-PT-001	MA-PT-002	MA-PT-003
Batch Size	550 Tablets	550 Tablets	550 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate no. WC-0494 issuing date 26-02-2021 and valid until three years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted

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

Remarks of Evaluator:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
2.	3.2.S.4.3	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
4.	3.2.S.7	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.
5.	3.2.P.1	Justify the formulation which is different in terms of qualitative composition from that of innovator product.
6.	3.2.P.2.2.1	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
7.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 333rd meeting of Registration Board:

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

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Not submitted
2.	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Not submitted

3.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Not submitted
4.	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.	submitted
5.	Justify the formulation which is different in terms of qualitative composition from that of innovator product.	Not submitted
6.	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.	Not submitted
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
8.	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted

Decision OF 336th meeting of Registration Board:

Deferred for submission of following:

- Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2. S.5.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product.
- Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Response of the Firm:

Sr.no.	Decision of 336th meeting of Registration Board	Response of the Firm

1.	Submit data as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm submitted the specification and analytical procedure of drug substance by both drug substance manufacturer and drug product manufacturer.
2.	Submit data as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Firm submitted the analytical verification report of drug substance performed by drug product manufacturer.
3.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Firm submit the COA of working standard of Pantoprazole sodium.
4.	Justify the formulation which is different in terms of qualitative composition from that of innovator product.	Firm submitted review documents of innovator product as an evidence that the qualitative composition of both applied product and innovator product (Protonix 40mg Tablet) is similar.
5.	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.	Firm submitted the detail of comparator product Neege Tablet 40mg ,batch no. 001H, Mfg. date 02-2022, Exp. Date 01-2025 of M/s. Sami Pharmaceuticals, Karachi.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the GMP certificate of API manufacturer which was expired in the Feb,2024.
7.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted

Decision: Deferred for following submissions:

- **Documents for the procurement of API with approval from DRAP.**
- **Compliance Record of HPLC software 21CFR & audit trail reports on product testing.**

Agenda of Dr. Farhadullah

Case No.01 ; Deferred routine registration applications of Human Drugs on Form 5F

39.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3663 dated 08-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#58109440758)
	The proposed proprietary name / brand name	**Sofovel 400/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sofosbuvir…….400mg Velpatasvir……100mg
	Pharmacotherapeutic Group of (API)	Nucleotide polymerase inhibitors / HCV NS5A replication complex inhibitors.
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	EPCLUSA (400mg/100mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Hilvel 400mg/100mg Tablet by M/s Hilton Pharma (Reg# 86973)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)

1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Sofosbuvir and Velpatasvir by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Sofosbuvir and Velpatasvir shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition, and chiral purity in batch analysis of drug substance sofosbuvir by drug product manufacturer as per drug substance manufacturer • Copies of the Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is required. • Justification shall be submitted for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer
3.2.S.7	• Stability study data of velpatasvir at real time conditions till claimed shelf life shall be submitted
3.2.P.1	• Description and Composition of the applied Drug Product shall be submitted
3.2.P.2	• CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted
3.2.P.3.2	• Batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test for sofosbuvir by UV method.
3.2.P.6	• COA of primary / secondary reference standard of sofosbuvir and velpatasvir including source and lot number shall be provided
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).

	• Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

S No.	Deferment Reason	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted valid copy of DML
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter of renewal of DML date 11th June, 2024 specifying Tablet (General) Section • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2024.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Not submitted
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Sofosbuvir and Velpatasvir by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Sofosbuvir and Velpatasvir shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition, and chiral purity in batch analysis of drug substance sofosbuvir by drug product manufacturer as per drug substance manufacturer	• Copies of the Drug substance specifications Sofosbuvir and Velpatasvir by Drug Product manufacturer is submitted. However, Copies of analytical procedures used for routine testing of Sofosbuvir and Velpatasvir by Drug Product manufacturer is not submitted. • Analytical Method Verification studies performed by the Drug Product for Sofosbuvir and Velpatasvir is submitted. However, results of accuracy and specificity test of Sofosbuvir is not submitted in analytical method verification studies • Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is submitted • Not submitted

	• Copies of the Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is required. • Justification shall be submitted for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer	
3.2.S.7	• Stability study data of velpatasvir at real time conditions till claimed shelf life shall be submitted	• Submitted
3.2.P.1	• Description and Composition of the applied Drug Product shall be submitted	• Composition of the applied Drug Product is submitted
3.2.P.2	• CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted	• CDP studies of the applied drug with the innovator / reference / comparator product is not submitted
3.2.P.3.2	• Batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process	• Batch formula for proposed commercial batch size is submitted
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test for sofosbuvir by UV method.	• The firm submitted that content uniformity test is required if API in product is less less than 25mg/tablet. In sofowel both API (sofosbuvir+velpatasvir) more than 25mg/tablet. • The firm submitted that dissolution time is mentioned in analytical procedure but was not mentioned in product specification due to typographical error, it is reattached. Revised specifications is not submitted. • Analytical procedure for API is submitted instead of finished product • The firm submitted that assay of drug product done by HPLC, reports and chromatograms are attached. • Firm submitted that method validation is done by HPLC, and no justification is submitted.
3.2.P.6	• COA of primary / secondary reference standard of sofosbuvir and velpatasvir including source and lot number shall be provided	• COA of secondary reference standard of sofosbuvir and velpatasvir including source and lot number is submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of commercial invoice cleared dated 03-04-2020

	• Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	specifying 0.4Kg Ledipasvir and 1.8kg Sofosbuvir. The invoice is cleared by AD (I&E) DRAP. • Firm has also submitted copy of commercial invoice cleared dated 10-01-2020 specifying 6.5Kg Ledipasvir. The invoice is cleared by AD (I&E) DRAP. • No clarification is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required**
- **Copies of analytical procedures used for routine testing of Sofosbuvir and Velpatasvir by Drug Product manufacturer.**
- **Results of accuracy and specificity test of Sofosbuvir in analytical method verification studies**
- **Justification for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer**
- **Detailed results of CDP studies of the applied drug with the innovator / reference / comparator product**
- **Revised finished product specifications**
- **Analytical procedure for all the tests given in finished product specifications**
- **Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric.**

Case No.02 ; Deferred registration applications of Human Drugs on Form 5F (New section)

40.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17572 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#982634498)
	The proposed proprietary name / brand name	**Vyber 20mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……20mg Sodium Bicarbonate……..1680mg (as buffer)
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 20mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA	
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)
Description of Pack (Container closure system)	**White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.**
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-00.3
Batch Size		500 sachet	500 sachet	500 sachet
Manufacturing Date		06-2022	06-2022	06-2022
Date of Initiation		28-06-2022	28-06-2022	28-06-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted		

Remarks of Evaluator [XI]:

Section	**Observations**
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation

3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	**Observations**	**Firm's Response**
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-02-2024.
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify	• We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP.
1.6.5	• Name and address of API manufacturer of	**Sodium Bicarbonate:**

	sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	TaTa Chemicals Europe Private Limited., Natrium House Winnington Lane, Northwich, Cheshire CW8 4GW Copy of GMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate is not submitted **Omeprazole:** Firm has submitted copy of cGMP certificate of of API manufacturer issued by Drug Control Administration Government of Telangana India valid upto 12-07-2026
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Sodium bicarbonate is used as buffer in applied formulation so drug substance part is N/A for this.
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is submitted. • Copy of Certificate of analysis for Omeprazole B# OME-P/22006 Metrochem API (Pvt) Ltd. is submitted.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.	• Copy of Certificate of analysis for Omeprazole working standard submitted.

3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• We have added sodium bicarbonate as a buffer because the stability of omeprazole is pH-dependent. It is rapidly degraded in acidic media but has acceptable stability under alkaline conditions. According to the FDA label of ZEGERID Powder for Oral Suspension (innovator) by Santarus, Inc., a wholly owned subsidiary of Salix Pharmaceuticals, sodium bicarbonate is described under buffer content in subsection 5.5* of the FDA label for ZEGERID Powder for Oral Suspension. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021849s010021636s0161bl.pdf. Additionally, Risek Insta, a competitor product in Pakistan, has also mentioned sodium bicarbonate as a buffer. • However innovator's product uses it as active ingredient
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph	• According to guidelines provided by the Drug Registration Board in its 293rd meeting, the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPMs, and sampling time) are taken from the FDA dissolution method database. The FDA dissolution database specifies a 30-minute sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. We adopted the 30-minute sampling time from the FDA dissolution database for omeprazole/sodium bicarbonate powder for oral suspension. • We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP. pH limits are selected based on experimental data. Additionally, the product also shows maximum dissolution at pH 7.4, which is the recommended pH for the dissolution test in the FDA dissolution method database. All the results of trial batches lie near pH 7.4. • The product monograph for omeprazole/sodium bicarbonate powder for oral suspension is not included in the USP. A validated testing method (MVL-387 & MVL-387 A) is used for testing omeprazole in the omeprazole/sodium bicarbonate sachet. This method is available in the USP for testing omeprazole. A copy of the USP monograph for omeprazole is submitted for reference.
3.2.P.6	• COA of primary / secondary reference	• Submitted

	standard including source and lot number shall be provided.	
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).	• Detailed raw data sheet for stability testing is submitted • UV absorbance value and spectra for dissolution testing is submitted • Firm has submitted copy of form 6 issued dated 19-04-2022 specifying Sodium Bicarbonate. The invoice is issued by AD (I&E) DRAP. • Documents for procurement of Omeprazole is not submitted

Previous Decision (M-336th-DRB): Deferred for submission of following:

- Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin
- Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
- Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
- Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document
- Justification for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5)
- Documents for the procurement of API with approval from DRAP (in case of import).

Firms Response:

S No.	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin	• Firm has submitted copy of cGMP certificate of API manufacturer (Sodium Bicarbonate) issued by Head of Inspectorate MHRA UK valid upto 27-09-2024
2	• Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Complete drug substance part of module 3 for sodium bicarbonate is submitted
3	• Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• The firm submitted that we have quantitatively added sodium bicarbonate according to innovator's formulation, where it was mentioned as buffer. We have now revised our formulation and updated sodium bicarbonate as an API to ensure compliance with innovator (revised

		formulation is submitted). We have already test and reported the sodium bicarbonate content in the drug product at the finished stage and during stability studies both accelerated and real time.
4	• Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document	• The firm submitted that the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPM, and sampling time) are taken from the FDA dissolution database. The FDA dissolution database specifies a maximum 30-minute sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. Therefore, we have revised the product specifications and updated the sampling time from 30 minutes to 15 minutes. Revised product specifications and method of analysis is submitted.
5	• Justification for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5)	• The firm submitted that we are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension is no longer official. Moreover, the product described in the deleted USP monograph is a compounded omeprazole/sodium bicarbonate suspension. We are adhering to the innovator's specifications (Zegerid (omeprazole/sodium bicarbonate) powder for oral suspension), which is provided in unit dose packets. We follow the innovator's prescribing information for reconstitution and determining the pH of reconstituted sachet. Therefore, our concentration differs from the compounded suspension that is why our pH limits differ from those in the obsoleted USP monograph.

6	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of form 5 issued dated 19-04-2022 specifying Sodium Bicarbonate. The form 5 is cleared by AD (I&E) DRAP. Firm has also submitted invoice, paking list, DHL documents for procurement of 6kg sodium bicarbonate. • Firm has also submitted proforma invoice, and courier documents for procurement of 100gm omeprazole.

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

41.	Name, address of Applicant / Marketing Authorization Holder	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceutical (Pvt.) Ltd., 14-km, Adyala Road, Post Office Dahgal, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate dated 28-08-2020 based on inspection conducted on 25-09-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-18/92-Lic (Vol-III) dated 13-01-2022 specifying Sachet Section (General) New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No 17573 dated 13-07-2023
	Details of fee submitted	Rs.30,000/- dated 20-06-2023 (Deposit slip#307907903)
	The proposed proprietary name / brand name	**Vyber 40mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole……40mg Sodium Bicarbonate……..1680mg (as buffer)

	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1x10 sachet
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID OTC (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
	Name and address of API manufacturer.	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Omeprazole:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 05 ± 3°C for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process

		control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals. CDP has been performed against the same product Risek Insta 40mg sachet by M/s Getz Pharmaceuticals in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor calculated in acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies including specificity, linearity, range, Accuracy, Precision, LOD, LOQ, robustness (Omeprazole).

STABILITY STUDY DATA			
Manufacturer of API	**Omeprazole:** M/s Everest Organics limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist.-502291 Telangana India		
API Lot No.	Omeprazole Powder: OME/E-347/18 (drug substance manufacturer, mfg date07-2018, exp date; 06-21) … OME-P/22006 (drug product manufacturer, mfg date01-2022, exp date; 12-26)		
Description of Pack (Container closure system)	**White color labeled cardboard box contain 1x10 labeled aluminum sachet, filled with shite, mint flavored powder for oral suspension.**		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-00.3
Batch Size	500 sachet	500 sachet	500 sachet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	26-07-2022	26-07-2022	26-07-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Omeprazole:** Firm has submitted copy of cGMP certificate of M/s Everest Organics Limited., Aroor Village, Sadasivapet Mandal, Sangareddy Dist., 502291 Telangana India valid upto 01/08/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.
3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation

3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx5um) for assay test of omeprazole than USP monograph
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • Chromatograms for stability testing at 6th month time point is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-335th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.4	• Submit copy of valid Drug Manufacturing License (DML)	• Submitted
1.3.5	• Submit GMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-02-2024.
1.6.5	• Name and address of API manufacturer of sodium bicarbonate shall be submitted • Valid GMP certificate / DML of Drug Substance manufacturer for	**Sodium Bicarbonate:** TaTa Chemicals Europe Private Limited., Natrium House Winnington Lane, Northwich, Cheshire CW8 4GW Copy of GMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate is not submitted **Omeprazole:** Firm has submitted copy of cGMP certificate of API manufacturer issued by Drug Control Administration Government of Telangana India valid upto 12-07-2026

	omeprazole and sodium bicarbonate issued by relevant regulatory authority of country of origin is required	
1.5.6	• You have applied for innovator's specifications while the applied product is available in USP, clarify	We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP.
3.2.S	• Submit complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Sodium bicarbonate is used as buffer in applied formulation so drug substance part is N/A for this.

3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is required. • Provide COA of relevant batch of Drug Substance omeprazole from Drug substance manufacturer used during product development and stability studies.	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance omeprazole by Drug substance manufacturer and drug product manufacturer is submitted. • Copy of Certificate of analysis for Omeprazole B# OME-P/22006 Metrochem API (Pvt) Ltd. is submitted.
3.2.S.5	• COA of primary / secondary reference standard for omeprazole including source and lot number shall be provided.	• Copy of Certificate of analysis for Omeprazole working standard submitted.

3.2.P.1	• Justification is required as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• We have added sodium bicarbonate as a buffer because the stability of omeprazole is pH-dependent. It is rapidly degraded in acidic media but has acceptable stability under alkaline conditions. According to the FDA label of ZEGERID Powder for Oral Suspension (innovator) by Santarus, Inc., a wholly owned subsidiary of Salix Pharmaceuticals, sodium bicarbonate is described under buffer content in subsection 5.5* of the FDA label for ZEGERID Powder for Oral Suspension. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021849s010021636s0161bl.pdf. Additionally, Risek Insta, a competitor product in Pakistan, has also mentioned sodium bicarbonate as a buffer. • However innovator's product uses it as active ingredient
3.2.P.5	• Justification shall be submitted for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document • Justification shall be submitted for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5) • Justification shall be submitted for using different	• According to guidelines provided by the Drug Registration Board in its 293rd meeting, the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPMs, and sampling time) are taken from the FDA dissolution method database. The FDA dissolution database specifies a 30-minute sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. We adopted the 30-minute sampling time from the FDA dissolution database for omeprazole/sodium bicarbonate powder for oral suspension. • We are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension does not exist in the USP. pH limits are selected based on experimental data. Additionally, the product also shows maximum dissolution at pH 7.4, which is the recommended pH for the dissolution test in the FDA dissolution method database. All the results of trial batches lie near pH 7.4. • The product monograph for omeprazole/sodium bicarbonate powder for oral suspension is not included in the USP. A validated testing method (MVL-387 & MVL-387 A) is used for testing omeprazole in the omeprazole/sodium bicarbonate sachet. This method is available in the USP for testing omeprazole. A copy of the USP monograph for omeprazole is submitted for reference.

	chromatographic conditions (wavelength (280nm), flow rate (0.8ml/min), injection volume (20ul), column specifications (L7, 4.6mmx150umx 5um) for assay test of omeprazole than USP monograph	
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted
3.2.P.8	• Detailed raw data sheet for stability testing is not submitted • Chromatograms for stability testing at 6th month time point is not submitted • UV absorbance value or spectra for dissolution testing is not submitted in stability study • Submit documents for the procurement of API with approval from DRAP (in case of import).	• Detailed raw data sheet for stability testing is submitted • Chromatograms for stability testing at 6th month time point is submitted • UV absorbance value and spectra for dissolution testing is submitted • Firm has submitted copy of form 6 issued dated 19-04-2022 specifying Sodium Bicarbonate. The invoice is issued by AD (I&E) DRAP. • Documents for procurement of Omeprazole is not submitted
Previous Decision (M-336th-DRB): Deferred for submission of following:		

- Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin
- Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation
- Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation
- Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document
- Justification for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5)
- Documents for the procurement of API with approval from DRAP (in case of import).

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of Drug Substance manufacturer for sodium bicarbonate issued by relevant regulatory authority of country of origin	• Firm has submitted copy of cGMP certificate of API manufacturer (Sodium Bicarbonate) issued by Head of Inspectorate MHRA UK valid upto 27-09-2024
2	• Complete drug substance part of module 3 for sodium bicarbonate used in the applied formulation	• Complete drug substance part of module 3 for sodium bicarbonate is submitted
3	• Justification as you have mentioned the use of sodium bicarbonate as inactive ingredient (buffer), while innovator product review document uses it as the active ingredient in the formulation	• The firm submitted that we have quantitatively added sodium bicarbonate according to innovator's formulation, where it was mentioned as buffer. We have now revised our formulation and updated sodium bicarbonate as an API to ensure compliance with innovator (revised formulation is submitted). We have already test and reported the sodium bicarbonate content in the drug product at the finished stage and during stability studies both accelerated and real time.
4	• Justification for selecting the dissolution specifications i.e. NLT Q in 30min in finished product specifications instead of NLT Q in 15min as per innovator product review document	• The firm submitted that the dissolution parameters (i.e., dissolution medium, volume of dissolution medium, dissolution apparatus, RPM, and sampling time) are taken from the FDA dissolution database. The FDA dissolution database specifies a maximum 30-minute sampling time. However, during pharmaceutical equivalence studies, it has been observed that more than 90% dissolution is achieved in 15 minutes. Therefore, we have revised the product specifications and updated the sampling time from 30 minutes to 15

		minutes. Revised product specifications and method of analysis is submitted.
5	• Justification for selecting different limit of pH test (6.5-8.0)in finished product specifications than USP monograph (7.5-8.5)	• The firm submitted that we are following the innovator's specifications because the product monograph for omeprazole/sodium bicarbonate powder for oral suspension is no longer official. Moreover, the product described in the deleted USP monograph is a compounded omeprazole/sodium bicarbonate suspension. We are adhering to the innovator's specifications (Zegerid (omeprazole/sodium bicarbonate) powder for oral suspension), which is provided in unit dose packets. We follow the innovator's prescribing information for reconstitution and determining the pH of reconstituted sachet. Therefore, our concentration differs from the compounded suspension that is why our pH limits differ from those in the obsoleted USP monograph.
6	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of form 5 issued dated 19-04-2022 specifying Sodium Bicarbonate. The form 5 is cleared by AD (I&E) DRAP. Firm has also submitted invoice, paking list, DHL documents for procurement of 6kg sodium bicarbonate. • Firm has also submitted proforma invoice, and courier documents for procurement of 100gm omeprazole.

Decision: Approved with innovator's specifications.

Registration Board further decided that Registration letter will be issued after submission of following:

i. **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Agenda of Mr. Muneeb Cheema

42.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 13-01-2022 specifying Oral Dry Powder Suspension new
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No…. dated 01/06/2023
	Details of fee submitted	PKR 30,000/- Dated 26/05/2023
	The proposed proprietary name / brand name	**CLATHRO 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Clarithromycin……125mg
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	oral suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (60ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 125mg/5ml Dry Suspension Sandoz B.V., Veluwezoom 22, 1327 AH Almere Nederland
	For generic drugs (me-too status)	Klaricid 125mg/5ml Dry Suspension Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Klaricid 125mg/5ml Suspension manufactured by Abbott Laboratories Pakistan Limited Firm has submitted CDP results of their product against the innovator's product Klaricid 125mg/5ml Suspension in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.		
API Lot No.	CTM-1-663		
Description of Pack (Container closure system)	White Plastic Bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 bottles	300 bottles	300 bottles
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	27-08-2022	27-08-2022	27-08-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. (189/2022-DRAP(AD-99778029213) dated 22/10/2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 20-07-2022 specifying 18.5000Kg of clarithromycin. The invoice is cleared by dawn Shaigan Pharmaceuticals Pvt. Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
43.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals Pvt Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-12-2021 based on inspection conducted on 24/11/2021
	Evidence of approval of manufacturing facility	Oral Dry Powder Suspension (General) granted vide DRAP approval 1-18/92-Lic-Vol-III dated 13.01.2022.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16608 dated 04/07/2023
	Details of fee submitted	PKR 30,000/- Dated 26/05/2023
	The proposed proprietary name / brand name	**CLATHRO 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Clarithromycin……250mg

	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Pharmaceutical form of applied drug	Oral Suspension
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (60ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 125mg/5ml Dry Suspension Sandoz B.V., Veluwezoom 22, 1327 AH Almere Netherland
	For generic drugs (me-too status)	Klaricid 125mg/5ml Dry Suspension Abbott Laboratories (Pakistan) Ltd.
	Name and address of API manufacturer.	Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Klaricid 125mg/5ml Suspension manufactured by Abbott Laboratories Pakistan Limited Firm has submitted CDP results of their product against the innovator's product Klaricid 125mg/5ml Suspension in 3 dissolution medias.

	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.	
STABILITY STUDY DATA			
Manufacturer of API		Surge Laboratories (Private) Limited Pakistan 10th KM, Faisalabad Road Bikhi, District Sheikhupura –Pakistan.	
API Lot No.		CTM-1-663	
Description of Pack (Container closure system)		White Plastic Bottle	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		T-001	T-002
Batch Size		300 bottles	300 bottles
Manufacturing Date		08-2022	08-2022
Date of Initiation		27-08-2022	27-08-2022
No. of Batches		03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP Certificate No. (189/2022-DRAP(AD-99778029213) dated 22/10/2022 issued by Drug Regulatory Authority of Pakistan. The certificate specifies that the firm is operating at satisfactory level of GMP compliance.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared on 20-07-2022 specifying 18.5000Kg of clarithromycin. The invoice is cleared by dawn Shaigan Pharmaceuticals Pvt. Ltd.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system along with audit trail report for product testing.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	
Remarks: The above products were deferred in 335th meeting of Registraion Board for following and the firm has now submitted reply which is mentioned against each:			

Queries	Reply
Under 1.6.5 (a) you have mentioned M/s Surge Laboratories (Pvt) Limited, Pakistan as API manufacturer, however as per record the aforesaid manufacturer is manufacturing bulk Clarithromycin Granules. You are hereby advised to submit the name and address of API manufacturer rather source of half finished product manufacturer.	The firm has submitted GMP certificate of Zhejiang Better Pharmaceutical Co., Ltd Sanjiang Road, Paojinag Industrial Zone, Shaoxing city, Zhejiang China being API manufacturer.
Under 1.6.5 (b) the approval of manufacturing facility of Clarithromycin API is required rather bulk Clarithromycin Granules.	As mentioned above
The drug substance i.e., Clarithromycin API information need to be submitted under 2.3.S and 3.2.S as required under DRAP guidance document.	The firm has submitted the drug substance data.
The manufacturing of Clarithromycin taste masked granules needs to be included in the Drug Product Modules being the part of drug product manufacturing.	The firm submitted that manufacturing of clarithromycin taste masked granules copied as it is from DMF as the manufacturer mentioned it in drug product module.
3.2. P.1 Justification for adding Citric acid and titanium dioxide in the in the formulation as the granules manufacturer has already added the same in the formulation. Moreover, the composition of plastic bottle along with description and composition of cap needs to be elaborated.	The clarithromycin taste masked granules manufacturer has added citric acid and titanium dioxide in granules and we (FPP manufacturers) added citric acid as acidifier to stabilize the pH of the suspension according to the specifications described in USP monograph of Clarithromycin for oral suspension. Titanium dioxide is added as whitening agent to improve the texture of reconstituted suspension. The same has been used by the Innovator as given in the table#1 The dry suspension is packed in a high-density polyethylene (HDPE) bottle with a child-lock cap (PP and LDPE) and an induction seal. **Table #1** **Ingredients** **Reference Product Biaxin (DS)** Clarithromycin taste masked granules **Citric acid** Aerosil 200 Sucrose Xanthan gum **Titanium dioxide** Fruit punch flavor **Test Product Clarithromycin (DS)** Clarithromycin taste masked granules **Citric acid** Aerosil 200 Sucrose Xanthan gum **Titanium dioxide** Strawberry flavor

<table>
<tr><td>3.2. P.2 Justify that the composition of applied formulation is same as of Innovator/ reference product</td><td>The formulation of Clarithromycin for oral suspension contains the same ingredients as given by the innovator product (Biaxin suspension) see table# 2
Table #2
<table><tr><th>Ingredients
Reference Product
Biaxin(DS)</th><th>Test Product
Clarithromycin (DS)</th></tr><tr><td>Clarithromycin taste masked granules</td><td>Clarithromycin taste masked granules</td></tr><tr><td>Citric acid</td><td>Citric acid</td></tr><tr><td>Aerosil 200</td><td>Aerosil 200</td></tr><tr><td>Sucrose</td><td>Sucrose</td></tr><tr><td>Xanthan gum</td><td>Xanthan gum</td></tr><tr><td>Titanium dioxide</td><td>Titanium dioxide</td></tr><tr><td>Fruit punch flavor</td><td>Strawberry flavor</td></tr></table></td></tr>
<tr><td>3.2.P.2.2.1 Details of the batch (Batch No., Mfg and expiry) of the reference product used for pharmaceutical equivalence and comparative dissolution.</td><td><table><tr><th>Name of reference/ competitor product</th><th>BNo.</th><th>Mfg. Date</th><th>Exp. Date</th><th>Manufacturer’s details</th></tr><tr><td>Klaricid DS 125mg/5ml</td><td>352149XV</td><td>Jan-2022</td><td>Jan-2024</td><td>Abbott Laboratories (Pakistan) Ltd. Karachi.</td></tr><tr><td>Klaricid DS 250mg/5ml</td><td>402567XV</td><td>Apr-2022</td><td>Apr-2024</td><td></td></tr></table></td></tr>
<tr><td>Justification for adding the microbiological enumeration tests and tests for specified</td><td>Microbiological enumeration test and test for specified microorganisms are added in pharmaceutical equivalence studies as a risk base approach at product development</td></tr>
<tr><td>Details of the results on the suggested time points of dissolution of 12 units of innovator and test product with batch No. in a table format of three physiological media for CDP as the submitted details are insufficient and only at 6.8 pH (3.2.P.2.2.1)</td><td>The firm submitted the requisite data.</td></tr>
<tr><td>Reference of specifcations for control of excipients.</td><td>The firm submitted specifcations for control of excipients.</td></tr>
<tr><td>3.2.P.5. Justify specification limits of LOD as the manufacturer providing the granules has limits NMT 5%. and limits for pH 3.5-7.0.</td><td>The limits of LOD and pH of taste masked coated granules are not defined in any pharmacopeia. The manufacturer is following in house specifications. However, in Finished Product formulation we are using these taste masked coated granules along with other excipients that meets the LOD and pH requirements given in USP Pharmacopeia</td></tr>
<tr><td>The Certificate of analysis generated by you vide No. 14650 dated 23.07.2022 has LOD 2.23% for Batch (CTM-1-663) of Clarithromycin granules supplied by the source used for manufacturing of</td><td>We are formulating Clathro Dry Suspension 125mg/5mL by incorporating various excipients with taste-masked coated granules of Clarithromycin. The composition of clarithromycin taste-masked coated granules in the 125mg/5mL dry suspension is 12.99% (w/w), with sucrose being the major excipient at 85.03%</td></tr>
</table>

<table>
<tr><td>product. Please clarify how the LOD was reported less than 2% in the finished product</td><td>(w/w). The limit of loss on drying (LOD) for sucrose is not more than 0.3%. Therefore, in LOD there is major contribution from sucrose having very low LOD percentage. Moreover, the LOD of the formulated Clarithromycin for oral suspension is less than 2.0%, as per the USP monograph for Clarithromycin oral suspension.
We are formulating Clathro Dry Suspension 250mg/5mL by incorporating various excipients with taste-masked coated granules of Clarithromycin. The composition of clarithromycin taste-masked coated granules in the 250mg/5mL dry suspension is 25.25% (w/w), with sucrose being the major excipient at 72.77% (w/w). The limit of loss on drying (LOD) for sucrose is not more than 0.3%. Therefore, in LOD there is major contribution from sucrose having very low LOD percentage. Moreover, the LOD of the formulated Clarithromycin for oral suspension is less than 2.0%, as per the USP monograph for Clarithromycin oral suspension.</td></tr>
<tr><td>Certificate of analysis of reference standards submitted under 3.2. P.6.</td><td>The firm submitted certificate of analysis of reference standards</td></tr>
<tr><td>Justification that quantity per batch is justified w.r.t the tests needed to perform stability for proposed shelf life</td><td>Justification w.r.t the tests needed to perform stability is given in stability protocol Doc# 4/RD/SAS/005 (copy attached) and in stability sample sheet Doc# 4/RD/SAS/008. Number of bottles required for stability testing for the proposed shelf life are 99 bottles; the batch size of each trial is 300 bottles. Details of sample consumption for stability test are given in table#3
Table#3
<table>
<tr><th rowspan="2">Test Parameters</th><th colspan="2">Required Sample Quantity for Stability Studies (bottles)</th></tr>
<tr><th>Accelerated</th><th>Real Time</th></tr>
<tr><td>Description, Identification pH, Assay</td><td>1</td><td>1</td></tr>
<tr><td>Loss on drying</td><td>1</td><td>1</td></tr>
<tr><td>Dissolution</td><td>6</td><td>6</td></tr>
<tr><td>Microbiological testing</td><td>1</td><td>1</td></tr>
<tr><td>Quantity required (one time point)</td><td>9</td><td>9</td></tr>
<tr><td>Total Time points</td><td>2</td><td>7</td></tr>
<tr><td>Total Quantity</td><td>18</td><td>63</td></tr>
<tr><td>Extra Quantity (one time testing)</td><td>9</td><td>9</td></tr>
<tr><td>Grand total</td><td colspan="2">18+63+9+9 = 99 bottles</td></tr>
</table></td></tr>
<tr><td colspan="2">The following information is submitted by M/s Surge Laboratories (Private) Limited Pakistan, 10th KM, Faisalabad Road Bikhi, District Sheikhupura:</td></tr>
</table>

Copies of DRAP attested invoices for purchase of Clarithromycin API along with Certificate of analysis	The firm has submitted the CoA of clarithromycin API for batch No. A042111121 Mfg date 27.11.2021 for 532Kg, however DRAP attested invoice is not submitted.
Composition of Clarithromycin granules needs to be submitted in table format indicating quantities per dosage unit and function of each excipient with its reference to standard	The manufacturer has submitted Composition of Clarithromycin granules
Description of container closure system.	The manufacturer has submitted the description of CCS for primary, secondary and tertiary packing.
Name of the reference/ branded product keeping in view the generic taste masked pellets have been developed.	The manufacturer has submitted that they had developed the formulation keeping view innovator brand i.e. Biaxin Suspension manufactured by Abbott Labs USA.
Justification that the choice excipients is in line with the reference/ innovator product. In case different excipients have been used then justify and submit compatibility studies as well.	The firm has submitted comparative statement w.r.t innovator product.The additional excipients include HPMC-5, PEG, Talcum Powder, Mg Stearate, Ethanol, acetone. The firm has also submitted compatibility study reports.
Optimization studies (if any) for confirming final the quantities of excipients.	The firm didn't respond to the query
Pharmaceutical equivalence studies	The equivalence submitted is with granules of Zhejinag Zongtong Pharmaceutical Pvt Limited. China rather innovator.
Comparative dissolution studies in physiological media.	Since CDP is only applicable to finished formulation and manufacturer is producing Taste masked API and it is not the powder for oral suspension ready to use (Excipients shall be added to manufacture a finished formulation i.e. Powder for oral Suspension) hence CDP is not applicable for Taste masked API)
Manufacturing process development data along with the explanation of manufacturing enteric coated granules. This should be justified with experimental data or with reference literature which indicates that clarithromycin is degradable in gastric pH/ medium. The data of initial trails conducted (wherein 5:3 ratio uncoated granules were good for coating) will be valuable document for review.	The manufacturer submitted that the product has been developed by preparing uncoated granules by granulation and then seal/ barrier coating and then enteric coating. The API clarithromycin is not degradable in acid media but we have to coat it by means of entering coating materials to get its taste masking. This taste making is required to achieve taste masked behaviour of the final dosage form which is suspension for seven days after reconstitution. It we do not enteric coat then taste masking is not achieved which results in very bitter unacceptable taste of the suspension. We have different reference COA which also shows dissolution in both acid and buffer media. COA's are attached for your reference.
Commercial batch formula with quantities of raw materials used.	The firm submitted the batch formula
Manufacturing process flow chart indicating input materials and In-process test.	The firm submitted the Manufacturing process flow chart

Process qualification protocol and process performance qualification report with results of three commercial scale batches.	The firm didn't submit the data and indicated it as restricted part of DMF
Under specifcations, justification is required for mentioning pH limits 3.5-7.0, however USP limits are 4.0-5.4.	The pH limits in the specifications (3.5-7.0) are of taste masked granules which will be used as a raw material for suspension along with other ingredients added by the suspension manufacturer will prepare suspension, its pH should be as per USP monograph (4.0-5.4). So the pH mentioned by the supplier of clarithromycin taste masked granules has no link with pharmacopoeia reference.
Justification for dissolution specifcations for granules in two media and their limits.	The manufacturer submitted that the product has been developed by preparing uncoated granules by granulation and then seal/ barrier coating and then enteric coating. The API clarithromycin is not degradable in acid media but we have to coat it by means of entering coating materials to get its taste masking. This taste making is required to achieve taste masked behaviour of the final dosage form which is suspension for seven days after reconstitution. It we do not enteric coat then taste masking is not achieved which results in very bitter unacceptable taste of the suspension. We have different reference COA which also shows dissolution in both acid and buffer media. COA's are attached for your reference.
Justification for assigning LOD specifications NMT 5% however as per pharmacopeia the specs are NMT 2%. Clarification is also required that in the manufacturing process at step: Drying and Unloading of Coated Granules of Clarithromycin you are drying the granules at 45-55^{0}C till to get LOD NMT 2% however the specs are assigned NMT 5%.	The LOD limits mentioned are of raw material i.e. taste masked granules used. When the manufacturer will prepare suspension its LOD should be as per USP i.e. 2%
Justification for conducting heavy metals test.	Drug product development when specifications were defined, the test was pharmacopeial requirement, hence test was included, however the test is no more required and test will be excluded.
Justification for not specifying the tests for impurities in specifcations.	The manufacturer submitted that they are USP grade API.
Clarification required as Class III solvents are being used in the manufacturing process however their residual limits are not specified in the final specifcations.	The manufacturer submitted that they are residual solvents are controlled by GC, however no testing data submitted.
Copies of monographs of the excipients as per pharmacopeial reference mentioned in dossier	The firm submitted that data for excipients.
Certificate of analysis of reference standards.	Details of USP RS submitted.

Evidence of availability of Gas Chromatograph for testing benzene in Acrypol 934 and EG/PEG in PEG 6000 and other quality tests required testing using Gas Chromatograph of other excipients.	The firm submitted CoA's for testing of EG/PEG in PEG 6000 and other quality tests required testing using Gas Chromatograph of other excipients
Details of PEG batches recently purchased/ imported and tested for DEG/EG impurities in compliance to DRAP directives. CoA need to submitted as evidence.	As mentioned above.
Copy of approval of quota allocation from Control Drugs Division of DRAP for import/ purchase of acetone for batch No. K3587937 Mfg Date 08-2018 and Exp date 12-2022 GRN No: 19120035.	The firm submitted the copy of approval of 75000/- litre purchase of Acetone issued by Ministry of Narcotic control dated 31.05.2019
Stress testing study data as the API has been exposed to 80^{o}C during the manufacturing process form almost 10-12 hours for two times and also at 45-55^{0}C for attaining the desired moisture limits.	The firm didn't submit the stress testing data rather referred to impurities as mentioned in USP monograph
Stability data of last three batches under ongoing stability program.	The firm submitted requisite data.
Decision: Registration Board decided to approve registration of "CLATHRO 125mg/5ml Dry Suspension" and "CLATHRO 250mg/5ml Dry Suspension"	

Agenda of Ms. Maham Misbah

Following three cases of M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) were discussed during 336th meeting of Registration Board held on 4th to 6th June, 2024. However, the decisions against the cases were inadvertently not recorded in the minutes.
The three cases and the decision against each are re-submitted for consideration by the Board, please.

44.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	CARNIL tablet 100mg
	Composition	Each tablet Contains: Metoprolol Tartrate……100mg
	Diary No. Date of R& I & fee	Dy No. 17445 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0815570 dated 06-03-2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code: C07AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's. As per SRO

	Approval status of product in Reference Regulatory Authorities.	Metoprolol Tartrate 100 mg film-coated Tablets. Health Canada approved
	Me-too status	Dronic 100mg Tablets, film coated. Panacea Pharmaceuticals Reg. No. 81425
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
45.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651) Tablet section (General)
	Brand Name +Dosage Form + Strength	BIRONE tablet 5mg Pack size and Demand Price 30's. As per SRO.
	Composition	Each Tablet Contains; Buspirone Hydrochloride …….5 mg
	Diary No. Date of R& I & fee	Dy No. 17422 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 815598 dated 06-03-2019.
	Pharmacological Group	Anxiolytics, Azaspirodecanedione Derivatives. ATC Code: N05BE01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Anziron 5mg Tablet M/s Star Laboratories (Pvt) Ltd., Lahore Reg. No. 23872
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	•
	Decision: Approved.	
46.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd Plot No. 206 &207, Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000651)

		Tablet section (General)
	Brand Name +Dosage Form + Strength	NIMOWIN tablet 30mg
	Composition	Each tablet contains: Nimodipine ……30mg
	Diary No. Date of R& I & fee	Dy No. 17421 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1901426 dated 06-03-2019.
	Pharmacological Group	Calcium channel blocker ATC Code: C08CA06
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved.
	Me-too status	Nidopine M/s Global Pharmaceuticals Pvt Ltd Reg. No. 028367
	GMP status	GMP certificate is issued on the basis of evaluation conducted on 20-02-2024 specifying inter-alia, the following sections: Tablet (General) Liquid Ampule (SVP) Ointment/ Cream (General) Eye/Ear/Nasal drops (Steroid & General) Liquid Syrup (General)
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	

Registration Board 339 Meeting Additional/Supplementary Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**Otsuka Pakistan Limited** F/4-9 Hub industrial Estate, Distt, Lasbella, Balocistan Pakistan (**HB/291/19-R/LASBELA**) Tracking ID: (8RB-UTZ-MGEX, 2024-08-05) Fee Paid: 300000.0 Paid Date: 2024-07-02 Case Category: Short Availability Drugs **(Adil Saeed)**	Proposed Name: **Fatolip** 100 ml of emulsion contain: Soya-bean oil 10.0 g Medium-chain triglycerides (MCT) 10.0 g As per Innovators Specification RRA Status: Germany Me Too Status: Lipofundin MCT/LCT Pack Size(s): 100 ml-As per SRO
	Marketing Authorization Holder (Abroad): Otsuka Pakistan Limited , 30-B, S.M.C.H.S., Karachi., Pakistan **Manufacturer(s):** -Guangdong Otsuka Pharmaceutical Co., Ltd.-No.8, Wenquan Avenue,Conghua, Guangzhou City, Guangdong Province, People's Republic of China-China	
	Evaluation Remarks: Priority as per 184th meeting of Authority regarding shortage of drugs.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Approved as per policy for inspection abroad. The firm shall submit attested Letter of authorization, legalized COPP, legalized GMP certificate before issuance of letter. Further the firm shall write the required storage conditions (do not store above 25? and do not freeze) in both Urdu and English in conspicuous way on label of the product.	
2	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (11W-DXH-B6N3, 2024-06-14) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Dexdo Injection 200mcg/2ml** Each 2ml contains: Dexmedetomidine Hydrochloride eq. to Dexmedetomidine.....200mcg United States Pharmacopeia RRA Status: Precedex® Injection by Pfizer Approved in USFDA Me Too Status: Precedex® Brookes Reg # 88249 Pack Size(s): As per SRO/DPC-As per SRO
	Manufacturer(s): Manufacturing, filli-SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
3	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (131-G3T-BBWW, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ONCE A WEAK TABLET** Each Film Coated Tablet Contains:TICAGRELOR…..……..…60mg As per Innovators Specification RRA Status: MHRA approved Intercept Pharma Ltd. 2 Pancras Square London, N1C 4AG United Kingdom Me Too Status: Anplag 60mg Tablet PharmaEvo Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): manufacturer-M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block A, Phase- V, Industrial Estate Hattar, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
4	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (17B-24L-JXPL, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Linoz** Each vial contains: Linezolid 600mg/300ml As per Innovators Specification RRA Status: USFDA Me Too Status: Pack Size(s): 1'S-As per SRO
	Manufacturer(s): contract -Biogen Life Science Pharmaceuticals-8km Chakbili road Rawat Rawalpindi Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
5	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (1L8-YL4-YL9B, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Destal** Each ml contains: Desloratadine.....0.5mg As per Innovators Specification RRA Status: Neo-clarityn by MSD - Spain Me Too Status: Desora Syrup by Continental Pharma Pack Size(s): 120ml-As per SRO,30ml-As per SRO,60ml-As per SRO,90ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
6	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (211-TAE-WEGJ, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **T-TRON 8MG/4ML** Each 4ml Contains: Ondansetron as Hydrochloride dihydrate = 8MG United States Pharmacopeia RRA Status: FDA appproved Me Too Status: onset 8mg/4ml injection Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
7	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat (**000207**) Tracking ID: (23B-BMV-5U74, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2023-12-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SONOPRAZ** Each fil coated tablet contains: Vonoprazan as fumarate.....20mg (as per innovator specs) As per Innovators Specification RRA Status: VOQUENZA tablet by Phathom Pharmaceuticals,USA Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 2x7-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
8	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (2GT-E5Q-GQ65, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Coledol plus** Each ampoule contains: Cholecalciferol (300,000IU) ..... 7.5mg British Pharmacopeia RRA Status: Brand Name Xarenel® Marketing Authorization holder: Italfarmaco S.p.A. Regulatory Authority: Xarenel® Injection is Approved in AIFA of Italy Me Too Status: D-Strong Injection 7.5mg (300,000IU),,Seraph Pharmaceutical Islamabad Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
9	**GT Pharma Pvt. Ltd** 713- Sundar Industrial Estate, Sundar Raiwind Road, (**000829**) Tracking ID: (379-ERE-DY1X, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-15 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tazipra 2.25g** Each Vial Contains: Piperacillin Sodium USP Equivalent to Piperacillin ……. 2.0 g Tazobactam Sodium USP Equivalent to Tazobactam ……. 0.25 g United States Pharmacopeia RRA Status: MHRA Me Too Status: Tanzo 2.25 g Injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Stallion Pharmaceuticals PVT, LTD.-581-Sundar Industrial Estate, Lahore, Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	
10	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (37R-NW9-9NJ2, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **LAXONATE 2mg** Each Film Coated Tablet contains: Prucalopride as Succinate ….....2mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Prutide Tablet 2mg Reg# 116140 By Weather Folds Pharmaceuticals Pack Size(s): 20’s-As per SRO
	Manufacturer(s): Manufacturer-Wnsfeild Pharmaceuticals-Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
11	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (3AQ-LQ3-P72W, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Onrodine** Each ml contains: Desloratadine……0.5mg (Innovator specs) As per Innovators Specification RRA Status: Neo-clarityn by Merck Sharp & Dohme Ltd Me Too Status: DELEGERIA by Pharmevo Pvt Ltd Pack Size(s): 120ml-As per SRO,60ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
12	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (3WT-DAM-G2ZS, 2024-04-23) Fee Paid: 75000.0 Paid Date: 2024-02-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Loprid 1mg Tablet** Each film coated tablet contains: Prucalopride Succinate…..1mg (Innovator specifications) As per Innovators Specification RRA Status: Motegrity 1mg Tablet Me Too Status: Notogrity 1mg Tablet Pack Size(s): 2x7's-As per SRO
	Manufacturer(s): Contract Manufacturi-SERAPH PHARMACEUTICAL-Plot#210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
13	**The Searle Company Limited** Karachi (**000016**) Tracking ID: (4NN-WYT-QWLY, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Nevan Ophthalmic Suspension** Each ml Contains: Nepafenac …….1mg (Innovator's Specifications) As per Innovators Specification RRA Status: NEVANAC is approved in USFDA Me Too Status: Nevanac 1mg/ml eye drops, suspension. Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Production, Testing,-M/s Cunningham Pharmaceuticals (Pvt.) Ltd.-81-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
14	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (4SY-SDW-PULM, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Isotone 40 mg Capsule** Each soft gel capsule contains: Isotretinoin ……40mg British Pharmacopeia RRA Status: Approved in US-FDA. Me Too Status: Maxitech Pharma Maxinoin 40mg Soft Gel Capsule Pack Size(s): 30's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
15	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (579-Q3V-D8Q1, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MI-D3 7.5mg Injection** Each 1ml ampoule contains:Cholecalciferol .....7.5mg British Pharmacopeia RRA Status: XARENAL 300000 IU/ml (7.5mg/ml) approved y AIFA of Italysolution for Injection Me Too Status: Gen-D3 Injection by Biogen Life Sciences Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	
16	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (5JX-3Q9-NX8X, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **trimethate 34mg dry powder for injection** Each vial Contains: Colistimethate Sodium (1M I.U) eq. to Colistin base activity = 34MG United States Pharmacopeia RRA Status: TGA Approved Me Too Status: colistin 34 mg Pack Size(s): as per DPC-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
17	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (5N1-49P-S6MS, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Metipine** Each film coated tablet contains:Mirtazapine.....30mg(USP Specs) United States Pharmacopeia RRA Status: US FDA approved Me Too Status: Elaxine tablet by Stand Pharma Pvt Ltd Pack Size(s): 1x10's-As per SRO,1x30's-As per SRO,20's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
18	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (5UQ-7HB-X8B4, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MODAX** Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets……..…30mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: Dexilant 30mg Capsule, Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015, USFDA APPROVED Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): 3x10's-As per SRO
	Manufacturer(s): Manufacturer-Wezen Pharmaceuticals-Plot #23 & 24, S-1, RCCI Industrial Estate, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
19	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (691-H7N-PRJH, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ISOTON 10mg Soft Gel Capsule** Each soft gel capsule Contains: Isotretinoin.....10mg British Pharmacopeia RRA Status: Isotretinoin 10 mg soft capsules (MHRA Approved) Me Too Status: Oratane Capsule by Crystolite Pack Size(s): 20's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
20	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat (**000886**) Tracking ID: (6AD-DSL-B4V3, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **DELZO** Each Capsule Contains:Dexlansoprazole as (dual delayed release pelletes)30mg Manufacturer Specification RRA Status: Dexilant Capsule USFDA Approved Me Too Status: DEXCAL 30mg CAPSULE Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Manufacturi-M/s Caliph Pharmaceuticals-Plot #17, Special Industrial Zone ,EPZ ,Risalpur.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
21	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (6RT-RSZ-AU5G, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CURIGEN 10MG/ML INJECTION** Each 5 ml contain: Atracurium besylate…….50mg United States Pharmacopeia RRA Status: Atracurium besylate 10 mg/ml (2.5ml, 5ml, 25ml) solution for injection/infusion, MHRA approved. Me Too Status: Efacurim 50mg/5ml I.V Injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	
22	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (6XN-E3W-W9WX, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CIFER 60MG CAPSULE** Each Capsule contains Duloxetine HCl Enteric coated pellets eq. to Duloxetine …….60mg United States Pharmacopeia RRA Status: CYMBALTA 60mg CAPSULES BY Eli Lilly and co. Inc. USFDA Approved Me Too Status: C-Yalta 60 mg cap BY OBS Pakistan (Pvt.) Ltd Registration Number 076117 Pack Size(s): 10-As per SRO,14-As per SRO
	Manufacturer(s): CONTRACT ACCEPTOR -VARIANT PHARMACEUTICALS (PVT.) LIMITED-Plot No. 5, M2-Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura Sheikhupura-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
23	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (6YB-QP7-R2YE, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **VONAZONE** 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: Cabiprin 10/100mg tablet (Takeda pharma) Me Too Status: NA Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): Manufacturer -M/s WnsFeild Pharmaceutical-Plot #122, Block-A, Phase-V, Industrial Estate Hattar Haripur Kpk Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
24	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (715-26Y-T666, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tamsin Capsule** Each Hard shell capsule contains: Tamsulosin HCl (as SR Pellets).....0.4mg (USP Specs.) United States Pharmacopeia RRA Status: Flomax Capsule by Sanofi Aventis - USFDA Me Too Status: Maxflow Capsule by CCL Pharmaceuticals (Pvt.) Ltd - Pakistan Pack Size(s): 10's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
25	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (7BA-A1B-Z4XD, 2024-06-10) Fee Paid: 75000.0 Paid Date: 2021-12-28 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ERLING** Each Film Coated Tablet containing: Vonoprazan as Fumarate.....20mg As per Innovators Specification RRA Status: VOQUENZA tablet by Phathom Pharmaceuticals,USA Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 2x7-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
26	**Macter International Limited** E-40/A,S.I.T.E.,Karachi-Pakistan (**000641**) Tracking ID: (6Z5-NSQ-S9M2, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tacip 2.25gm Injection** Each Vial contains: Piperacillin as Piperacillin sodium USP……..…2gm Tazobactam as Tazobactam sodium USP……250mg Product complies USP Specifications. United States Pharmacopeia RRA Status: Piperacillin Sodium + Tazobactam Sodium 2.25gm Injection (M/s Sandoz, FDA Approved) Me Too Status: Zoycin 2.25gm Injection (M/s Global Pharmaceuticals Pvt Ltd) Pack Size(s): 1s-As per SRO
	Manufacturer(s): -Global Pharmaceuticals Pvt. Ltd.-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad-Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
27	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (72H-DTJ-XQ8D, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-01-16 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Imicomb 500mg Injection** 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
	Manufacturer(s): -Stallion Pharmaceuticals PVT, LTD-581-Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
28	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha (**000874**) Tracking ID: (7MS-NM2-5XLJ, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2023-12-08 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **solowin 500mg injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone……500mg United States Pharmacopeia RRA Status: Solu-Cortef500mgInjectionshttps://www.accessdata.fda.gov/drugsatfda_docs/label/2009/009866s77s79lbl. Me Too Status: Hy-Cortizone Injection Pack Size(s): 1,s-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing. testi-M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
29	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (**000951**) Tracking ID: (7Z9-78Z-XZ82, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-01-04 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Flopin 5mg + 100mg Tablet** 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
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
30	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (816-UQS-VQ5P, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Empaglif** Each Film coated Tablet contains:Empagliflozin.....10mg As per Innovators Specification RRA Status: US FDA approved Me Too Status: Diampa Tablets by GETZ Pharma Pack Size(s): 14's -As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
31	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan (**000203**) Tracking ID: (83M-SDU-JZ8N, 2024-06-26) Fee Paid: Paid Date: Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SOPRAZONE 10mg Tablet** Each film coated tablet contains: Vonoprazan as Fumarate….10mg (Innovator's specifications) As per Innovators Specification RRA Status: VOQUENZA Tablet (Phathom Pharmaceuticals, USA) Me Too Status: VONOZAN GETZ Pharma Pack Size(s): 14's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals -Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
32	**Albro Pharmaceuticals** 340/s Quiad-e-Azam Industrial Estate Kotlakhpat Lahore (**000175**) Tracking ID: (8LY-XXM-7Z9Z, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Ondabro Syrup** Each 5ml contains: Ondansetron as HCl dihydrate.....4mg (USP Specification) United States Pharmacopeia RRA Status: USFDA (ZOFRAN SYRUP) GSK Me Too Status: Zufran Syrup (GSK) Pack Size(s): 25ml-As per SRO,50ml -As per SRO
	Manufacturer(s): Contract Manufacturi-Bio-Mark Pharmaceuticals. Lahore-527 Sundar Industrial Estate Lahore Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
33	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (8N3-5JT-HSLD, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-01-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Arteject** Each vial contains: Artesunate……..30mg The International Pharmacopeia RRA Status: USFDA Me Too Status: Gen-M Injection Genix Pharma Pack Size(s): 1 vial-Controlled
	Manufacturer(s): Manufacturing & pack-Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	
34	**GT Pharma Pvt. Ltd** 713- Sundar Industrial Estate, Sundar Raiwind Road, (**000829**) Tracking ID: (8N4-3LD-ZB25, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-15 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tazipra 4.5g** Each Vial Contains: Piperacillin Sodium USP Equivalent to Piperacillin ……. 4.0 g Tazobactam Sodium USP Equivalent to Tazobactam……. 0.5 g United States Pharmacopeia RRA Status: MHRA Me Too Status: Tanzo 4.5g Injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Stallion Pharmaceuticals Pvt. Ltd-581-Sundar Industrial Estate, Lahore -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
35	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (8QZ-LQ7-VQ3V, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-01-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Arteject** Each Vial contains:Artesunate……..120mg The International Pharmacopeia RRA Status: USFDA Me Too Status: Gen-M Injection Genix Pharma Pack Size(s): 1 vial-Controlled
	Manufacturer(s): Manufacturing & pack-Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
36	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (8TJ-TZR-B1V3, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Pantowel 40mg Tablet** Each enteric coated tablet contains:Pantoprazole (as sodium sesquihydrate)….40mg(USP Specification) RRA Status: PROTONIX Wyeth-Ayerst Laboratories Tablet is USFDA approved Me Too Status: NEEGE SAMI Pharmaceuticals. Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
37	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha (**000874**) Tracking ID: (942-M71-7PVQ, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2023-03-02 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Farilet** Each ml contains: Iron as Ferric Carboxymaltose…… 50mg As per Innovators Specification RRA Status: Injectafer Injection 50mg/ml MHRA UK Me Too Status: FCM Injection Genix Pharma Pack Size(s): 10ml-Controlled
	Manufacturer(s): Manufacturing & pack-Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
38	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (952-5H1-HNEA, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-03-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Swimero Injection IV 2g** Each vial contains: Meropenem Trihydrate eq.to meropenem …. 2 g (Blended with sodium carbonate) USP Specifications United States Pharmacopeia RRA Status: MEROPENEM Injection by Venus Pharma Germany approved And MHRA approved Me Too Status: Merem 2g Injection by Global Pharmaceutical Pack Size(s): 1's-As per SRO
	Manufacturer(s): Formulation-Biogen Life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi - Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
39	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan (**000203**) Tracking ID: (99R-9ZU-9ZN4, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SOPRAZONE 20mg Tablet** Each film coated tablet contains: Vonoprazan as Fumarate….20mg (Innovator's specifications) As per Innovators Specification RRA Status: VOQUENZA Tablet (Phathom Pharmaceuticals, USA) Me Too Status: VONOZAN GETZ Pharma Pack Size(s): 14's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals -Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
40	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (9QJ-BL2-DJ3E, 2024-06-21) Fee Paid: 75000.0 Paid Date: 2024-05-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **COLESTI-3MIU INJECTION IV** Each vial contains: Colistimethate sodium (3MIU) eq. to. Colistin base activity…….100mg United States Pharmacopeia RRA Status: Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC (MHRA Approved) Me Too Status: Colimethate Inj 3MIU Reg. No. 108905 By: M/s Tabros Pharma Karachi. Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-BIO-LABS (PVT.) LTD,-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
41	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (**000844**) Tracking ID: (9QV-SU1-BJGH, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2023-09-06 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Danzo 4.5gm Injection** Each Vial Contains: Piperacillin as Sodium (USP) …….....4g Tazobactam as Sodium (USP) …….....500mg (USP Specs) United States Pharmacopeia RRA Status: UK MHRA (PIPERACILLIN SODIUM + TAZOBACTAM SODIUM 4.5gm Injection) Me Too Status: TAZOCIN 4.5gm Injection (Wallace Pharma Evolutions) Pack Size(s): 1s-As per SRO
	Manufacturer(s): Manufacturing & Pack-Wallace Pharma Evolutions-Kalawala Stop, 20-Km, Lahore Jaranwala Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
42	**Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, (**000900**) Tracking ID: (9R5-JQ2-6GD8, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Ristro Syrup** Each 5ml contains: Ondansetron (as Hydrochloride Dihydrate)……4mg United States Pharmacopeia RRA Status: Zofran Oral Solution by GSK (USFDA approved) Me Too Status: Zofran Syrup by M/s GSK Pack Size(s): As per SRO / DPC-As per SRO
	Manufacturer(s): Manufacturing & Test-M/s BioMark Pharmaceuticals-Plot No. 527, Sundar Industrial Estate,Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
43	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (9S4-PTG-9EM8, 2024-06-12) Fee Paid: 75000.0 Paid Date: 2024-05-07 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard M Tablets 12.5mg/1000mg** Each film coated tablet contains:Empagliflozin.....12.5mgMetformin Hydrochloride....1000mg RRA Status: Synjardy tablets (USFDA Approved) Me Too Status: Empagen-M Tablet 12.5/1000mg by Ferozsons Laboratories Limited (Reg # 105545) Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
44	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area (**000126**) Tracking ID: (A36-WUP-8SB9, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-02-15 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CPEM 1gm** Each Vial Contains: Meropenem as trihydrate ..... 1gm RRA Status: Meronem IV 1gm - Pfizer Ltd. (MHRA Approved) Me Too Status: Penro Injection - Bosch Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Toll Manufacturing-Nicholas Pharmaceuticals-Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
45	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (A55-THA-VZ41, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TRELAGLE** Each film coated tablet contains: Trelagliptin Succinate Equivalent to Trelagliptin.....50mg As per Innovators Specification RRA Status: PMDA approved Zafatek® Me Too Status: Brand Name: Trelaglip 50 mg tablet Manufacturer: M/s The Searle Company Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): Manufacturer-M/s Wezen Pharmaceuticals-Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.-	
	Evaluation Remarks:	
	Decision: Approved	
46	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat (**000886**) Tracking ID: (A94-1SU-AQRH, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **FERIUM 500MG IRON/ML INJECTION** Each 10ml of ampoule contains:Ferric carboxymaltose corresponding to Iron 500mg As per Innovators Specification RRA Status: US FDA approved Me Too Status: CareInject Injection 50 mg Iron/ml; 10 ml Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Manufacturi-M/s Carer Pharmaceuticals Industries, Rawat-Plot # 27 ,main Road Rawat,Industrial Estate Rawat-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
47	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (ADM-LQX-9232, 2024-06-12) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TRICLO 75MG/3ML SOLUTION FOR INJECTION** Each 3ml Contains: DICLOFENAC SODIUM= 75mg As per Innovators Specification RRA Status: EMA appproved Me Too Status: Dicloran injection Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
48	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (ADS-RZY-EG2Y, 2024-06-12) Fee Paid: 75000.0 Paid Date: 2024-04-04 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TAZOFIX 4.5gm Injection** Each Vial Contains:Piperacillin as Sodium (USP) …….. ..... 4000mgTazobactam as Sodium (USP) …….. .....500mg(Product Complies USP Specs) United States Pharmacopeia RRA Status: Approved by UK MHRA https://www.medicines.org.uk/emc/product/4748/smpc Me Too Status: Zosyn 4.5gm INJECTION (Regent Karachi by Cirin Pharma Hattar)070758 (4.5gm Injection) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): Manufacturer-WALLACE PHARMA EVOLUTIONS -KALA WALA STOP, 20-KM, LAHORE JARANWALA ROAD, LAHORE-	
	Evaluation Remarks:	
	Decision: Approved	
49	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi (**000838**) Tracking ID: (AGJ-2QJ-4SDN, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Vonp-As 10mg 100mg Tablet** 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: PMDA Japan Approved Me Too Status: NA Pack Size(s): As Per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Contract Acceptor-Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
50	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (AHX-4RV-MV1G, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CEPHIXIME** Each 5ml of reconstituted suspension contains:- Cefixime trihydrate equivalent to Cefixime..... 200 mg (Product Complies USP Specs United States Pharmacopeia RRA Status: USFDA approved formulation Me Too Status: Caricef for M/s Sami Pharmaceuticals Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): manufacture -M/s Weather Folds Pharmaceuticals-M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
51	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (APY-792-E9JJ, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2023-12-08 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Methomin Inj (Mecobalamine)** Each 1ml ampoule contains: Mecobalamin.....…….500mcg (Innovator Specification) As per Innovators Specification RRA Status: Methycobal Injection 0.5mg/ml by M/s Eisai Co, Ltd Tokyo, Japan, PMDA Japan Approved. Me Too Status: Biocobal injection 0.5mg/ml by M/s Surge Laboratories (Pvt) Ltd. Reg. No. 033385 Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Manufacturing of Fin-May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
52	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (AZE-4TA-5Y8U, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ONCE A WEAK TABLET** Each film coated tablet containsTricagrelor ..... 90mg As per Innovators Specification RRA Status: US FDA approved Me Too Status: Anplag 90mg Tablet of CCL Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): Formulation-M/s Wnsfeild Pharmaceuticals -Plot No. 122, Block A, Phase- V, Industrial Estate Hattar, Pakistan. -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
53	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (BBJ-PND-1R5W, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-05-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **COLESTI-4.5MIU INJECTION IV** Each Lyophilized vial contains: Colistimethate Sodium 4.5 MIU eq. to. Colistin Base activity (Approx)….....150mg United States Pharmacopeia RRA Status: COLISTIMETHATE SODIUM EQ 150MG BASE/VIAL (USFDA Approved) Me Too Status: CBA 150 Injection Reg. No. 103783 By: M/s Biocare Pharma, Lahore. Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-BIO-LABS (PVT.) LTD,-Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
54	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore (**000655**) Tracking ID: (D2B-TN7-JSDA, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-05-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Nebivia Tablets 10mg** Each film coated tablet contains Nebivolol Hydrochloride Eq. to Nebivolol…….10mg As per Innovators Specification RRA Status: BYSTOLIC 10mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA. Me Too Status: Nebix 10mg Tablets of M/s Highnoon Laboratories Ltd. Pack Size(s): 10's, 14's, 30's -As per SRO
	Manufacturer(s): FP Manufacturing, Te-Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	
55	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (DA4-PXA-WVJU, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Empaglif** Each Film coated tablet contains:Empagliflozin.....25mg As per Innovators Specification RRA Status: US FDA approved Jardiance Tablet by Boehringer Ingelheim Me Too Status: Diampa Tablets by GETZ Pharma Pack Size(s): 3x10's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
56	**UniMark Pharmaceuticals Pvt. Ltd.** Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (**000557**) Tracking ID: (DBJ-BRT-MG2Q, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-05-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Vonokat 10mg Tablet** Each Film-Coated tablet contains Vonoprazan fumarate eq. to vonoprazan .... 10mg As per Innovators Specification RRA Status: Takecab Tablet PMDA Approved Me Too Status: Vonozan tablet of M/S Getz Pharma Pack Size(s): 1X14s-As per SRO
	Manufacturer(s): Manufacturing of Fin-M/S Seraph Pharmaceuticals-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
57	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi (**000838**) Tracking ID: (DEN-9W4-BJJ3, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tazocin 4.5gm Injection** Each Vial Contains: Piperacillin asSodium (USP) …….. 4000mg Tazobactam as Sodium (USP) …….....500mg (Product Complies USP Specs) 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
	Manufacturer(s): Contract Acceptor-Wallace Pharma Evolutions-Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.-	
	Evaluation Remarks:	
	Decision: Approved	
58	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (E1N-S5M-PYTP, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Metipine** Each film coated tablet contains:Mirtazapine.....15 mg(USP Specs) United States Pharmacopeia RRA Status: US FDA approved Remeron 15 mg tablet by ORGANON,USA Me Too Status: Elaxine 15mg tablet by Stand Pharma Pvt Ltd Pack Size(s): 10's-As per SRO,20's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
59	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (E8U-84V-VTUB, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2022-08-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **STALINE** Each ml contains: Citicholine as Sodium.....100mg As per Innovators Specification RRA Status: Citicolina Normon 100 mg/ml oral solution EFG by LABORATORIOUS NORMON,S.A Me Too Status: CITOLIN by Global Pharmaceuticals Pack Size(s): 30ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
60	**UniMark Pharmaceuticals Pvt. Ltd.** Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat (**000557**) Tracking ID: (ENW-36Q-QDPH, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-05-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Vonokat 20mg Tablet** Each Film-coated tablet contains vonoprazan fumarate eq. to vonoprazan 20mg As per Innovators Specification RRA Status: Takecab Tablet PMDA Approved Me Too Status: Vonozan tablet of M/S Getz Pharma Pack Size(s): 1X14s-As per SRO
	Manufacturer(s): -M/S Seraph Pharmaceuticals-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
61	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (G2E-HNQ-ULX2, 2024-06-20) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Zolegen 5mg/100ml Infusion** Each 100ml contains: Zoledronic acid Monohydrate eq. to Zoledronic acid……..5mg (Innovator) As per Innovators Specification RRA Status: USFDA Approved. Reclast 5mg/100ml For Solution For Infusion Me Too Status: Macdronic 5mg/100ml Infusion Registration Number: 079757 Manufactured by: Macter international Limited Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
62	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (G4U-TB8-62DD, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ISOTON 20mg Capsule** Each soft gel capsule Contains: Isotretinoin.....20mg British Pharmacopeia RRA Status: Isotretinoin 20mg soft capsules (MHRA Approved) Me Too Status: Oratane Capsule by Crystolite Pack Size(s): 20's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Biogen Life Sciences -8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
63	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. (**000951**) Tracking ID: (GL2-ZQG-NU2H, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-01-05 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Flopin 15mg + 100mg Tablet** 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
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
64	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (H78-PRY-BPJZ, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TARAZON** Each vial contains: Ceftriaxone sodium (USP) equivalent to ceftriaxone ……500mg United States Pharmacopeia RRA Status: Rocephin 500mg Powder for Solution for Injection or Infusion by Roche Products Limited - UK Me Too Status: Droncef inj by Seraph Pharmaceutical Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Aulton Pharmaceuticals-Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
65	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat (**000886**) Tracking ID: (HGY-ZLE-A6LY, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **DELZO** Each Capsule Contains:Dexlansoprazole as (dual delayed released pelletes)60mg As per Innovators Specification RRA Status: Dexilant Capsule USFDA Approved Me Too Status: DEXCAL 60mg CAPSULE Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Manufacturi-M/s Caliph Pharmaceuticals-Plot #17, Special Industrial Zone ,EPZ ,Risalpur.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
66	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (HHL-A7M-J7UZ, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MODAX 60mg Capsule** Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg As per Innovators Specification RRA Status: Dexilant 60mg Capsule, Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015, USFDA APPROVED Me Too Status: Razodex Capsule by Getz Pharma Pack Size(s): 3x10's-As per SRO
	Manufacturer(s): Manufacturer-Wezen Pharmaceuticals-Plot #23 & 24, S-1, RCCI Industrial Estate, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
67	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (HPT-TBZ-LR5Y, 2024-06-20) Fee Paid: 75000.0 Paid Date: 2024-05-07 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard-L 5mg/10mg Tablets** Each film coated tablet contains:Linagliptin....5mgEmpagliflozin.....10mg RRA Status: Glyxambi Tablets (US FDA Approved) Me Too Status: Empagen-L Tablet 5mg/10mg Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
68	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (HV2-X1U-L8LB, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MARK-D PLUS 7.5MG/ML Injection** One Ampoule contains: Cholecalciferol (vitamin D3) 7.5 mg, which corresponds to 300000 I.U. British Pharmacopeia RRA Status: Xarenel Italfarmaco S.p.A. Xarenel® Injection is Approved in AIFA of Italy Me Too Status: D-Strong Injection 7.5mg (300,000IU) Seraph Pharmaceutical Islamabad Pack Size(s): 1's-As per SRO,5's-As per SRO
	Manufacturer(s): Manufacturing / Pack-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
69	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (HWY-ERV-M5XT, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CEFIME 1GM INJECTION** Each vial contains; Cefepime as HCl with L-Arginine……1000mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: OPIME 1GM INJECTION BY IMCO PHARMA Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
70	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (HXE-NTB-GT4D, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Empaglif-M** Each Film coated tablet contains: Empagliflozin.....5mg Metformin HCl.....500mg As per Innovators Specification RRA Status: Trijardy Tablet by Boehringer Ingelheim Pharmaceuticals Inc. Me Too Status: Diampa-M by Getz Pharma Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
71	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (HXH-HAG-N5SS, 2024-06-20) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **tricomin Injection** Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 1 G United States Pharmacopeia RRA Status: FDA Approved Me Too Status: vancomycin 1g Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
72	**Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA (**000751**) Tracking ID: (HYS-847-SG2D, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Monexi Eye Drops** Each ml contains: Moxifloxacin HCl as Moxifloxacin …….5mg (0.5%) (USP SPECIFICATIONS) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Azlox Opthalmic Solution Alza Pharmaceuticals 081625 Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
73	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (J5A-8TZ-7RTR, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TRALAGLE** Each Film Coated Tablet Contains: Trelagliptin as Trelagliptin Succinate……..…….100mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: PMDA approved Zafatek Me Too Status: Brand Name: Trelaglip 100 mg tablet Manufacturer: M/s The Searle Company Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): formulation-M/s wezen pharmaceuticals-plot No.23& 24,S-1,RCCI,Industrial estate rawat.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
74	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (J89-NA4-1YAT, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2022-08-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **STOSET** Each 5ml contains:Ondansetron (as Hydrochloride Dihydrate).....4mg United States Pharmacopeia RRA Status: Approved by US FDA Me Too Status: Dysit syrup by Wimits pharmaceuticals Pack Size(s): 50ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
75	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (JB4-D4N-45Z5, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **iMECTA** Each Sachet Contains: Racecadotril……10mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: Registered by UK MHRA Me Too Status: HidrasecSachet Manufacturer Abbott Laboratories Pakistan Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): manufacture -Wnsfeild Pharmaceuticals-Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
76	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (JX9-8QH-VJNT, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-02 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SLECTUM-1GM INJECTION IM/IV** Each vial contains: Cefoperazone as Sodium 500mg + Sulbactam as Sodium……..500mg Any Other RRA Status: PERTAWAY By Betterway Pharmaceutical Group INN. Carson City, NV 89710 USA. (US FDA) Me Too Status: Cefbac Injection 1g By Seraph Pharmaceutical, Islamabad Reg. No.: 086244 Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
77	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (L7R-48T-55JB, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-02 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SLECTUM-2GM INJECTION IM/IV** Each vial contains: Cefoperazone as Sodium.....1000mg + Sulbactam as Sodium……..1000mg Any Other RRA Status: PERTAWAY By Betterway Pharmaceutical Group INN. Carson City, NV 89710 USA. (US FDA) Me Too Status: Cefbac Injection 2g By Seraph Pharmaceutical, Islamabad Reg. No.: 094148 Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
78	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (L9Y-ZUU-JWJA, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **TARAZON** 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 inj by Seraph Pharmaceutical Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Aulton Pharmaceuticals-Plot No. 84/1 Block-A Phase V Industrial Estate Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
79	**The Searle Company Limited** Karachi (**000016**) Tracking ID: (LAY-RT8-BQD2, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Unilat Ophthalmic Solution 0.005%** Each ml Ophthalmic Solution containing: Latanoprost……0.05 mg (Innovator's Specifications) As per Innovators Specification RRA Status: XALATAN 0.05 mg/ml Eye drops, solution by USFDA Me Too Status: XALATAN 0.05 mg/ml Eye drops, solution Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Production, Testing,-M/s Cunningham Pharmaceuticals (Pvt.) Ltd.-81-Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
80	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (LDG-ENZ-EJS6, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **THIO 4mg/2ml INJECTION** Each 2ml ampoule contains Thiocolchicoside…….....4mg As per Innovators Specification RRA Status: Miorel 4mg/2ml , solution for injection (IM) in ampoule, approved by, ANSM France. Me Too Status: Muscoril 4mg/2ml Injection Reg. No. 015501 M/s Sanofi Aventis Pkaistan Pack Size(s): 5-As per SRO
	Manufacturer(s): Manufacturing & Pack-SERAPH Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
81	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha (**000874**) Tracking ID: (LJ3-XB1-39H3, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2023-12-08 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **solowin** Each Vial Contains: Hydrocortisone as Hydrocortisone SodiumSuccinate (USP). ..... 100mg United States Pharmacopeia RRA Status: https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/009866s77s79lbl.pdf Me Too Status: Hy-Cortizone Injection Pack Size(s): 1,s-As per SRO
	Manufacturer(s): Manufacturing. testi-M/s Biogen life sciences -8-km chakbeli road rawat Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
82	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (LN5-P4J-VBAR, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard-M XR 5mg/1000mg Tablets** Each film coated tablet contains:Empagliflozin.....5mg (as immediate release)Metformin Hydrochloride.....1000mg (as extended release) RRA Status: Synjardy XR (US FDA Approved) Me Too Status: Empagen-M XR Tablet 5mg/1000mg Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
83	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (LP8-3Q1-QV95, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Meprin 20mg** Each capsule contains: Omeprazoel (as enteric coated pellets).....20mg United States Pharmacopeia RRA Status: Omeprazole Capsule - USFDA approved Me Too Status: Risek Capsule by Getz Pharma Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
84	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (LSH-8JS-3ANR, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ONZOMET 5/500mg** Each Film coated tablet contains: Empagliflozin 5mg Metformin HCl 500mg As per Innovators Specification RRA Status: Synjardy 5/500mg Boehringer Ingelheim (BI) Phaimaceuticals, Inc. USFDA approved Me Too Status: Diampa 5/500mg Tablet (Getz Pharma) Pack Size(s): 14's-De-Controlled
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals -Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
85	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (M22-1MJ-6NSH, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2024-04-01 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Meronim 2gm Injection** Each vial contains: Meropenem (as trihydrate) ..... 2 g (Blended with sodium carbonate) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Wallace Pharma Evolutions-Kala Wala Stop, 20-Km, Lahore Jaranwala Road, Lahore.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
86	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (MPS-EJJ-694E, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Stalukast** Each Sachet contains: Montelukast (as sodium).....4mg United States Pharmacopeia RRA Status: Singulair Sachet by Merck Research Laboratories Me Too Status: Lucast Sachet by AGP Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
87	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (MR5-8BS-WUAP, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Onlid** Each film coated tablet contains: Linezolid....600mg (USP Specs.) United States Pharmacopeia RRA Status: Zyvox Tablet by Pfizer Inc. - USA Me Too Status: Nezkil Tablet by Continental Pharma - Pakistan Pack Size(s): 10's-De-Controlled,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
88	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (MVW-EDZ-GGPZ, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **LED 25MG TABLET** Each tablet contains Levosulpiride …….25mg (as per innovatorss specs) As per Innovators Specification RRA Status: LEVOPRAID 25mg tablet BY TEOFARMA SRL AIFA ITALY Approved Me Too Status: LEVOPRAID 25 mg tab BY Pacific Pharma Pvt Ltd. Registration Number 021649 Pack Size(s): 10-As per SRO
	Manufacturer(s): CONTRACT ACCEPTOR -VARIANT PHARMACEUTICALS PVT. LTD-Plot No. 5, M2-Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura Sheikhupura-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
89	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (MVW-B43-QVMH, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CEPIME INJECTION** Each vial contains; Cefepime HCl with L-Arginine equivalent to Cefepime……1000mg United States Pharmacopeia RRA Status: Approved by USFDA Me Too Status: OPIME 1GM INJECTION IMCO PHARMACEUTICALS Opime 1gm Injection Each vial contains:- Cefepime (as HCl).. ……..1gm (with L-Arginine) 060122 & 060121 Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): Formulation-M/s. Weather Folds Pharmaceuticals -Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Area, Hattar. DML -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
90	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (NMY-S1J-MXMD, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **COSYDE-4MG INJECTION** Each 2ml ampoule contains: Thiocolchicoside ……. 4mg As per Innovators Specification RRA Status: Myorel 4mg/2ml injection By: LABORATORIO FARMACEUTICO SIT Srl (ANSM FRANCE) Me Too Status: Muscoril Injection 4mg/2ml By: Searle Pharmaceuticals Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
91	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat (**000207**) Tracking ID: (NQ3-4WM-QV8E, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2023-12-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SONOPRAZ** Each film coated tablet contains: Vonoprazan as Fumarate.....10mg (As per innovators specs) As per Innovators Specification RRA Status: VOQUENZA tablet by Phathom Pharmaceuticals,USA Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 2x7-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
92	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (NSW-HZH-XZLS, 2024-06-10) Fee Paid: 75000.0 Paid Date: 2024-04-01 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Mygesto 160mg Tablet** Each Uncoated Tablet Contains: Megestrol Acetate (USP)……..…….160 mg (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Preogace 160mg Tablet by Medinet Pharma Rawalpindi Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
93	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (NTZ-4YU-LNES, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-04-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Meropenem** Each vial contains: Meropenem as trihydrate, 1 g (blended with sodium carbonate) United States Pharmacopeia RRA Status: USFDA Me Too Status: olver injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): Contract acceptor-Wallace Pharma Evolutions-Kala Wala stop,20 km, Lahore Jaranwala Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
94	**Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar (**000574**) Tracking ID: (NWJ-5X1-GXV8, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MERONIM 2gm INJECTION** Each vial contains:- Meropenem (as trihydrate)……..2gm (Blended with sodium carbonate) (Product complies USP Specs) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: NA Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Contract acceptor-M/s Wallace Pharma Evolutions-Kala Wala Stop 20?KM, LAHORE JARANWALA ROAD, LAHORE-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
95	**High-Cure Research Laboratories** 19Km Tayyaba industrial Zone Sheikhupura Road Lahore (**000966**) Tracking ID: (P21-5ET-TGLG, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **KETREX** Each ml contains: Ketororlac tromethamine USP…….30mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Toradol(Barrett Hodgson Pakistan (Pvt.) Ltd) Pack Size(s): 1ml×5’s-As per SRO
	Manufacturer(s): manufacture -Islam Pharmaceuticals-7 kms Pasrur Road, Sialkot -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
96	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore (**000845**) Tracking ID: (P4Q-HSS-RDWM, 2024-06-27) Fee Paid: 150000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Contiflo-D 0.5/0.4mg Capsule** Each hard gelatin capsule contains: Dutasteride (as soft gelatin capsule) …… 0.5 mg Tamsulosin hydrochloride (as modified release pellets) …….0.4 mg As per Innovators Specification RRA Status: Dutasteride/Tamsulosin hydrochloride 0.5 mg / 0.4 mg hard capsules (MillPharm Limited-MHRA) Me Too Status: Maxflow-D Capsule (CCL) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Manufacturi-Biogen Life Sciences - Rawalpindi-8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks: Firm has submitted fee of Rs. 300,000/- as Dutasteride is imported as bulk drug product vide deposit slip nos. 9825110965 (Rs. 75,000/-), 99156875 (Rs. 150000) & 864284815 (Rs. 75,000/-)	
	Decision: Approved	
97	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (P99-QU2-MWDQ, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-11 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Gestron 10mg Tablet** Each film coated tablet contains: Dydrogesterone ..... 10mg United States Pharmacopeia RRA Status: Duphaston 10 mg film-coated tablets is Approved in HPRA of Ireland. Me Too Status: Dydrogest 10mg Tablet of M/s OBS Pakistan Pvt. Ltd. Pack Size(s): As per SRO / DPC-As per SRO
	Manufacturer(s): Manufacturing & Batc-Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
98	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (PQ6-EJR-GY44, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ESPRO 30MG CAPSULE** Each capsule contains Dexlansoprazole Dual Delayed Release Pellets = 30 mg (AS PER INNOVATORS SPECS) As per Innovators Specification RRA Status: DEXILANT 30mg Capsule. BY TAKEDA PHARMS USA. USFDA APPROVED Me Too Status: Razodex 30 mg Capsule BY Getz Pharma Registration Number 086976 Pack Size(s): 30-As per SRO
	Manufacturer(s): CONTRACT ACCEPTOR -VARIANT PHARMACEUTICALS PVT. LTD-Plot No. 5, M2-Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura Sheikhupura-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
99	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (Q5T-YZW-AYYW, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Pepso injection** 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
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
100	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (Q8B-ZEQ-YGHG, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **VILDROP 7.5mg/ml Injection** One Ampoule contains: Cholecalciferol (vitamin D3) 7.5 mg, which corresponds to 300000 I.U British Pharmacopeia RRA Status: Xarenel® Injection(Approved in AIFA of Italy) Me Too Status: D-Strong Injection 7.5mg (300,000IU) Pack Size(s): 1's-As per SRO
	Manufacturer(s): Contract Manufacturi-SERAPH PHARMACEUTICAL-Plot#210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
101	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area (**000126**) Tracking ID: (QDG-E9H-X344, 2024-06-10) Fee Paid: 75000.0 Paid Date: 2024-02-15 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CPEM 500mg** Each Vial Contains: Meropenem as Trihydrate .... 500mg United States Pharmacopeia RRA Status: Meronem IV 500mg - Pfizer Ltd. (MHRA Approved) Me Too Status: Penro Injection - Bosch Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Toll Manufacturing-Nicholas Pharmaceuticals-Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
102	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore (**000655**) Tracking ID: (QR2-16Q-55SQ, 2024-06-05) Fee Paid: 75000.0 Paid Date: 2024-05-15 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Voriza Tablets 20mg** Each film coated tablet contains Vonoprazan as Fumarate ……20mg Product Specs: Innovator's As per Innovators Specification RRA Status: TAKECAB 20mg of Takeda Pharmaceutical Company Limited, Japan approved by PMDA Japan Me Too Status: Vonozan 20mg Tablets of M/s Getz Pharma Pvt Ltd. – Karachi. Pack Size(s): 14's , 28's , 30's-As per SRO
	Manufacturer(s): FP Manufacturing, Te-Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	
103	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (R9Q-RQ8-M6UB, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **tricomin Injection** Each vial Contains: Vancomycin Hydrochloride eq. to Vancomycin = 500mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: vancomycin 500mg Pack Size(s): as per DPC-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
104	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (RAV-J76-NJ4Q, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-02-02 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **IMPOSE-12.5MG/850MG TABLETS** Each film coated tablet contains: Empagliflozin……12.5 mg + Metformin HCl……850mg As per Innovators Specification RRA Status: Synjardy 12.5/850 mg film coated tablet For BoehringerIngelheim Pharma GmbH & Co. KG. Germany (FDA A Me Too Status: Diampa M Tablet 12.5/850 mg By M/s Getz Pharma (Pvt.) Ltd Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
105	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat (**000886**) Tracking ID: (REY-BMY-PLP8, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SEDNO (Desloratadine) 0.5MG/ML Syrup** Each ml of syrup contains:Desloratadine0.5mg As per Innovators Specification RRA Status: US FDA approved Clarinex syrup 0.5mg/ml Me Too Status: Neo-Antial syrup 0.5mg/ml Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -M/s Caliph Pharmaceuticals-Plot #17, Special Industrial Zone ,EPZ ,Risalpur.-	
	Evaluation Remarks:	
	Decision: Approved	
106	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (RHY-8XN-HVBU, 2024-06-12) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **trimethate 150mg dry powder for injection** Each vial Contains: Colistimethate Sodium (4.5M I.U) eq. to Colistin base activity = 150MG United States Pharmacopeia RRA Status: TGA Approved Me Too Status: colistin 150 mg Pack Size(s): as per DPC-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
107	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (RMX-53U-RYGG, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ONKAST Sachet 4 mg** Each Sachet of granules contains: Montelukast sodium eq. to Montelukast…....4mg (USP specification) United States Pharmacopeia RRA Status: Singulair Sachet 4mg (Merck Research Laboratories) USFDA Me Too Status: Josef Sachet Pack Size(s): 14's & 28's-De-Controlled
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Indutrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
108	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore (**000845**) Tracking ID: (RQ7-QYG-S4DZ, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **INSTACID SACHET 20/1680mg** Each Sachet contains Omeprazole …….....20mg Sodium Bicarbonate.....1680mg (USP Specification) United States Pharmacopeia RRA Status: Zegerid® Immediate release Powder for oral suspension of M/s Santarus is USFDA Approved Me Too Status: Carey Sachet 20mg/1680mg of M/s Bio-Mark Pharmaceuticals Pack Size(s): 14-As per SRO,7-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore -	
	Evaluation Remarks:	
	Decision: Approved	
109	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (RVU-H9Z-BM8L, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **PACILINE-4.5GM INJECTION** Each Vial Contains: Piperacillin Sodium USP Eq. to. Piperacillin…….4.0g + Tazobactam Sodium USP Eq. to. Tazobactam…….0.5g United States Pharmacopeia RRA Status: Piperacillin / Tazobactam 4.0 g / 0.5 g Powder for solution for infusion By: Wockhardt Ash Road North, Wrexham Industrial Estate, Wrexham LL 13 9UF. (Reference link: https://www.medicines.org.uk/emc/product/4748/smpc) Me Too Status: Tanzo 4.5 g Injection Reg. No. 039439 By: M/s Bosch / PAKISTAN. Pack Size(s): As Per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturing-STALLION PHARMACEUTICALS (PVT.) LTD.,-581-Sundar Industrial Estate, Lahore-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
110	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (S7Y-8EL-VN9N, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2023-12-08 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Vosset Inj (Ondensteron 8mg/4ml)** Each 4ml ampoule contains: Ondansetron as Hydrochloride dihydrate ……. 8mg (USP Specification) United States Pharmacopeia RRA Status: MHRA Approved. Me Too Status: ONSET Injection 4mg/2ml by M/s Pharmedic Laboratories (Pvt) Ltd. Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Manufacturing of Fin-May & Baker Pharmaceuticals (Pvt.) Ltd.-45 Km, Thokar Multan road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
111	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (S8S-UE9-SSEQ, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CEFIME 500MG INJECTION** Each vial contains; Cefepime as HCl with L-Arginine……500mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: OPIME 500MG INJECTION BY IMCO PHARMA Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
112	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (SA7-144-21P3, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **T-Drop D** Each ml Contains: Vitamin D3 = 5mg As per Innovators Specification RRA Status: ANSM Approved Me Too Status: D-Trees Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
113	**Bio-Next Pharmaceuticals** plot no 50 street no S-10 RCCI Rawat (**000910**) Tracking ID: (SJJ-VSY-DVW2, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2024-05-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Nextone 1gm Injection IM** Each Vial Contains:Ceftriaxone Sodium equivalent to Ceftriaxone..... 1 gm RRA Status: MHRA approved Me Too Status: Topcef Injection Pack Size(s): 1`s-Controlled
	Manufacturer(s): Manufacturing and Pa-Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
114	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (SUB-U2Z-REL6, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2024-05-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard-M XR 25mg/1000mg Tablets** Each film coated tablet contains:Empagliflozin.....25mg (as immediate release)Metformin Hydrochloride.....1000mg (as extended release) RRA Status: Synjardy XR (US FDA Approved) Me Too Status: Empagen-M XR Tablet 25mg/1000mg Pack Size(s): 14's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
115	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE (**000300**) Tracking ID: (SW2-28G-1N8V, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2023-12-07 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **VEPRAZOLE 40 mg IV injection** Each Vial contains: Pre-lyophillized Sterile Powder of Omperazole Sodium eq. to Omperazole ……. 40 mg As per Innovators specs As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Risek 40mg IV by Getz Pharma Pack Size(s): 1s-As per SRO
	Manufacturer(s): Contract Manufacture-Variant Pharma -PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
116	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (T3A-MMV-15MU, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CAFOBACT 1GM INj** Each vial contains;Cefoperazone as sodium…….500mgSulbactum as sodium……..500mg Any Other RRA Status: Sulperazone Intravenous Injection 1g (PMDA Japan Approved) Me Too Status: Cefbac Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): Manufacturing-M/s. Weather Folds Pharmaceuticals- Plot No. 69/2, Phase-II, Industrial Area, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
117	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (TJQ-NYB-A8UY, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **BARTINE 1G INJECTION IV/IM** Each ampoule contains: Levocarnitine …… 1g United States Pharmacopeia RRA Status: Carnitor injection approved by US FDA Me Too Status: Metacartin Injection 1g/5ml (Genome Pharma, Reg.# 103770) Pack Size(s): 5ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	
118	**Fast Pharmaceuticals (Pvt) Ltd.** Plot no.55, Street No. S-4, National Industrial Zone, RCCI-Rawat, Pakistan. (**000954**) Tracking ID: (TLX-PM7-APSN, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-01-29 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Arteject** Each Vial contains: Artesunate……..60mg The International Pharmacopeia RRA Status: USFDA Me Too Status: Gen-M Injection Genix Pharma Pack Size(s): 1 vial-Controlled
	Manufacturer(s): Manufacturing & pack-Bio-Labs (Pvt) Ltd.-Plot 145, Industrial Trangle, Kahuta Road Is;a,abad-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
119	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (TQY-ZHQ-1PE3, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Isotor** Each soft gel capsule contains: Isotretinoin.....20mg (BP Specs.) British Pharmacopeia RRA Status: Isotretinoin 20mg capsule - MHRA approved Me Too Status: Oratane 20mg capsule by Crystolite Pharmaceutical Pack Size(s): 20's-As per SRO,30's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km chakbeli road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
120	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (TXG-87L-52J9, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Ceftix 200mg suspension** Each 5ml of reconstituted suspension contains:- Cefixime trihydrate equivalent to Cefixime ……200 mg (Product Complies USP Specs) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: F-Saf Plus 200mg Suspension by Saaf Pharma Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
121	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (UB2-N88-QP6V, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard-M XR 12.5mg/1000mg Tablets** Each film coated tablet contains:Empagliflozin .... 12.5mg (as immediate release)Metformin Hydrochloride.....1000mg (as extended release) RRA Status: Synjardy XR (US FDA Approved) Me Too Status: Empagen-M XR Tablet 12.5mg/1000mg Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
122	**TRISON RESEARCH LABORATORIES PRIVATE LIMITED** 27-A PUNJAB SMALL INDUSTRIAL ESTATE (**000529**) Tracking ID: (UD6-7RU-EXXG, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-04-19 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Trifer 100mg/5ml INJECTION** Each 5ml Contains: IRON (III) HYDROXIDE SUCROSE COMPLEX Eq. to ELEMENTAL IRON.= 100mg British Pharmacopeia RRA Status: FDA appproved Me Too Status: Ferosoft-S Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-HOUSE NO 23, STREET NO 5 SECTOR B, GHORI BLOCK BAHRIA TOWN, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
123	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (UJM-J43-PE8H, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2024-04-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Meropenem** Each vial contains: Meropenem as trihydrate: 500 mg (blended with Sodium carbonate) United States Pharmacopeia RRA Status: USFDA Me Too Status: olver injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): Contract acceptor-Wallace Pharma Evolutions-Kala Wala stop,20 km, Lahore Jaranwala Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
124	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (USG-VD2-DUJX, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-01-18 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Malron Injection/Infusion 50 mg Iron/ml; 10 ml** Each ampoule contains: Ferric carboxymaltose corresponding to 500 mg iron. United States Pharmacopeia RRA Status: Ferinject.(Vifor Pharma UK Limited.)Ferinject ® Dispersion for Injection/Infusion is Approved in USF Me Too Status: Fercari(Hilton Pharma.) Pack Size(s): As per SRO / DPC-Free of Cost
	Manufacturer(s): Manufacturer-SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
125	**Macter International Limited** E-40/A,S.I.T.E.,Karachi-Pakistan (**000641**) Tracking ID: (V1N-H7W-XV5D, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Tacip 4.5gm Injection** Each vial contains: Piperacillin as Piperacillin sodium USP……..…4gm Tazobactam as Tazobactam sodium USP……500mg Product complies USP Specifications. United States Pharmacopeia RRA Status: Piperacillin Sodium + Tazobactam Sodium 4.5gm Injection (M/s Sandoz, FDA Approved) Me Too Status: Zoycin 4.5gm Injection (M/s Global Pharmaceuticals Pvt Ltd) Pack Size(s): 1s-As per SRO
	Manufacturer(s): -Global Pharmaceuticals Pvt. Ltd.-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad-Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
126	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (VPV-P13-3G18, 2024-06-10) Fee Paid: 75000.0 Paid Date: 2024-05-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **MAREO-2GM INJECTION IV/ IM** Each vial contains: Meropenem Trihydrate eq. to. meropenem….2g United States Pharmacopeia RRA Status: MEROPENEM Injection by Venus Pharm Germany approved And (MHRA Approved) Me Too Status: Merem 2gram Injection By Global Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Sciences-8-KM, Chakbeli Road, Rawat, Rawalpindi-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
127	**Caliph Pharmaceuticals** Plot 17, Special Industrial Zone Risalpur, KPK (**000748**) Tracking ID: (VR2-GWW-2RLU, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **FERICAL 500MG IRON/ML INJECTION** Each 10ml ampoule contains: Ferric carboxymaltose corresponding to elemental iron 500mg As per Innovators Specification RRA Status: Injectafer 500mg Iron /10ml Injection Me Too Status: Ferinject Injection Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Manufacture-Carer Pharmaceuticals Industries-Plot 27, Main Road, Rawat Industrial Estate, Rawat.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
128	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (WJ4-7XL-ENAL, 2024-06-11) Fee Paid: 75000.0 Paid Date: 2021-12-28 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ERLING** Each Film coated Tablet containing: Vonoprazan as fumarate.....10mg As per Innovators Specification RRA Status: VOQUENZA tablet by Phathom Pharmaceuticals,USA Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 2x7-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
129	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (WVX-56Y-65A4, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **IROCELL 100mg/5ml Injection** Each 5ml contains: Iron (III) Hydroxide Sucrose Complex eq. to Elemental Iron--100mg(B.P Specification)(BP Specs) British Pharmacopeia RRA Status: USFDA Me Too Status: Venofer Pack Size(s): 1'S-As per SRO
	Manufacturer(s): contract -Biogen Life Science Pharmaceuticals-8km Chakbili road Rawat Rawalpindi Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
130	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (**000844**) Tracking ID: (X36-1UX-AP4D, 2024-06-10) Fee Paid: 75000.0 Paid Date: 2024-05-07 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Doin Syrup 4mg/5ml** Each 5ml Contains:- Ondansetron hydrochloride dihydrate equivalent to Ondansetron 4mg (USP Specifications) United States Pharmacopeia RRA Status: Approved in MHRA (EMC) (Ondansetron 4 mg/5 ml Syrup, Syri Limited UK) Me Too Status: Onseron Syrup 4mg/5ml (Indus Pharma, Karachi) Pack Size(s): 30ml, 50ml, 60ml, 90-As per SRO
	Manufacturer(s): Manufacturing & Pack-World Biz Pharmaceuticals-Plot No. 340, Industrial Estate,Phase-II, Multan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
131	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (XDJ-HVZ-SZDA, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Osteonic Injection 3mg/3ml** Each 3ml contains: Ibandronate sodium monohydrate eq. to ibandronic acid …… 3mg As per Innovators Specification RRA Status: Ibandronate sodium 3mg/3mlInjection ACCORD HEALTHCARE FDA Approved Drug Me Too Status: Adronil Injection 3mg/3ml by Searle Company Limited, Pakistan Reg.No. 075870 Pack Size(s): As per SRO/DPC-As per SRO
	Manufacturer(s): Manufacturing, filli-SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
132	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat (**000207**) Tracking ID: (XN6-ZZE-QHHD, 2024-06-13) Fee Paid: 75000.0 Paid Date: 2023-12-12 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SAMPMET** Each Film coated Tablet containing: Empagliflozin.....5mg Metformin Hydrochloride.....500mg As per Innovators Specification RRA Status: Synjardy by Boehringer Ingelheim Pharmaceuticals, Inc. Me Too Status: Diampa™ -M By Getz Pharma Pack Size(s): 14's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
133	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (XUZ-EW7-WA1B, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ICOL** Each Film Coated Tablet Contains: Obeticholic Acid…..……..…5mg (Product complies Innovator's Specs) As per Innovators Specification RRA Status: US FDA approved Me Too Status: Ocafib 5mg film-coated tablet Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -M/s Weather Folds Pharmaceuticals-M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
134	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (XV7-8H7-ZGH4, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **CEFOPARA 2GM INJECTION** Each vial contains;Cefoperazone as sodium…….1000mgSulbactum as sodium……..1000mg(Product Complied JP Specs) Any Other RRA Status: ema approved Me Too Status: USZONE INJECTION BY USAWA PHARMA Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
135	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (XVW-M13-ZRUU, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **LAXONATE** Each Film Coated Tablet contains: Prucalopride as Succinate ….....1mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Prutide Tablet 1mg Reg# 116139, By Weather Folds Pharmaceuticals. Pack Size(s): 20's-As per SRO
	Manufacturer(s): Manufacturer-Wnsfeild Pharmaceuticals-Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
136	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (Y2V-PEA-DRJR, 2024-06-25) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **L-KARTIN** Each Ampoule (5mL) Contains: Levocarnitine(USP) …….1000mg (Product complies USP Specs) United States Pharmacopeia RRA Status: Product Name = LEVOCARNITINE1gmINJECTION MHRA Reference: Me Too Status: KEFEI INJECTION R.G. PHARMACEUTICA (PVT) LTD., KARACHI 1gmInjection .EACH Injection CONTAINS:- LEVOCARNITINE FOR INJECTION……..1.0GM (AMINO-ACID). (Reg No. 059054) Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): manufacture -WNSFEILD Pharmaceuticals-PLOT NO.122, PHASE-V, BLOCK-A, INDUSTRIAL ESTATE, HATTAR, KPK, PAKISTAN.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
137	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (Y4V-Y8V-WBWY, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SOSET Syrup** Each 5ml contains: Ondansetron (as hydrochloride dihydrate).....4mg United States Pharmacopeia RRA Status: Zofran Syrup by GSK - USA Me Too Status: Zofran Oral Solution by GSK Pack Size(s): 25ml-As per SRO,50ml-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
138	**The Searle Company Limited** Karachi (**000016**) Tracking ID: (Y71-57R-V52L, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Co-Latan Opthalmic Solution** Each ml Contains: Latanoprost……0.05mg Timolol as Maleate…5mg As per Innovators Specification RRA Status: Xalacom 0.05 mg/ml & 5 mg/ml Eye drops, solution Approved by MHRA of UK Me Too Status: Xalacom eye drops of M/s Pfizer (Reg.# 031386) Pack Size(s): As per SRO/DPC-As per SRO
	Manufacturer(s): Manufacturer of FPP-Cunningham Pharmaceuticals (Pvt.) Ltd-81-Sundar Industrial Estate, Raiwind Road,Lahore, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
139	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (**000614**) Tracking ID: (Y7V-RNM-2VWP, 2024-06-07) Fee Paid: 75000.0 Paid Date: 2024-05-08 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **FLOPIN 100MG/ 15MG Tablet** 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: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209805s000lbl.pdf Me Too Status: Trevia R2 (15/100mg) 14 Tablets By GetZ Pharma Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Formulation-M/S Weather Folds Pharmaceuticals, Hattar-Plot No.69/2, Phase - II, Indutrial Estate, Hattar, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
140	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (**000644**) Tracking ID: (YBV-YRW-H5U7, 2024-06-26) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Isofold 40mg Capsule** Each soft gel capsule Contains: Isotretinoin……40mg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Maxinoin Capsule by Maxitech (Reg # 108920) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Biogen Pharmaceuticals-8Km, Chakbeli Road Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
141	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (YG3-EY4-1VQJ, 2024-06-20) Fee Paid: 75000.0 Paid Date: 2024-05-30 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **PACILINE-2.25GM INJECTION** Each Vial Contains: Piperacillin Sodium USP Eq. to. Piperacillin…….2.0g + Tazobactam Sodium USP Eq. to. Tazobactam…….0.25g United States Pharmacopeia RRA Status: Piperacillin / Tazobactam 2.0 g / 0.25 g Powder for solution for infusion By Wockhardt Ash Road North, Wrexham Industrial Estate, Wrexham LL 13 9UF (Reference link: https://www.medicines.org.uk/emc/product/4748/smpc) Me Too Status: Tanzo 2.25 g Injection Reg. No. 039593 By: M/s Bosch / PAKISTAN. Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-STALLION PHARMACEUTICALS (PVT.) LTD.,-581-Sundar Industrial Estate, Lahore-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
142	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (YGD-E3G-Q9XU, 2024-06-27) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ESONAP** Each Modified Released Tablet Contains: Naproxen as Enteric Coated Core.……..……375mg Esomeprazole as Magnesium Trihydrate as IR……..…....20mg (Product compliesInnovator's Specs) As per Innovators Specification RRA Status: Vimovo delayed release tablet 20/500mg USFDA 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

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): manufacture -M/s WnsFeild Pharmaceuticals- M/s WnsFeild Pharmaceuticals, Plot #122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
143	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway (**000438**) Tracking ID: (YLP-ELW-2VP1, 2024-06-28) Fee Paid: 75000.0 Paid Date: 2024-06-14 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **ISONIDE 40mg Capsule** Each soft gel capsule contains: Isotretinoin ……40mg British Pharmacopeia RRA Status: ACCUTANE 40mg CAPSULE by ROCHE (US - FDA Approved) Me Too Status: Maxinoin 40mg Soft Gel Capsule By Maxitech Pharma (Reg # 108920) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
144	**Bio-Next Pharmaceuticals** plot no 50 street no S-10 RCCI Rawat (**000910**) Tracking ID: (YX9-QW8-T3PE, 2024-06-21) Fee Paid: 75000.0 Paid Date: 2024-05-25 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Zolinext Infusion 600mg** Each 300ml vial contains: Linezolid……600mg As per Innovators Specification RRA Status: USFDA Me Too Status: Nezkil Infusion by SG J pharma. Pack Size(s): 1's-Controlled
	Manufacturer(s): Manufacturing and Pa-Bio-Labs (Pvt) Ltd.,-Plot No. 145, Industrial triangle Kahuta road Islamabad.-	
	Evaluation Remarks:	
	Decision: Approved	
145	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (YUV-7M7-HY4G, 2024-06-24) Fee Paid: 75000.0 Paid Date: 2024-02-02 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **SOLEXIME-100MG DRY SUSPENSION** Each 5ml of reconstituted suspension contains: Cefixime trihydrate equivalent to cefixime 100mg United States Pharmacopeia RRA Status: SUPRAX By Sanofi Limited , UK (Medicines and Healthcare products Regulatory Agency (MHRA) of UK.) Me Too Status: Trispan-100mg/5ml Dry Suspension By Seraph Pharmaceutical, Islamabad Reg. No.: 086231 Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
146	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (ZUM-S52-294G, 2024-06-26) Fee Paid: Paid Date: Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **EMPAWEL 50/500mg Tablet** Each Film coated tablet containing: Empagliflozin……5 mg. Metformin HCl…….500 mg As per Innovators Specification RRA Status: Synjardy Boehringer Ingelheim (BI) Phaimaceuticals, Inc USFDA approved. Me Too Status: Diampa™ -M. Getz Pharma Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
147	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (ZXS-G36-646G, 2024-06-03) Fee Paid: 75000.0 Paid Date: 2024-05-23 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **NEEDRONIC INJECTION** Each 3ml ampoule contains: Ibandronate sodium monohydrate eq. to Ibandronic acid …… 3mg As per Innovators Specification RRA Status: Ibandronate sodium 3mg/3ml injection By: ACCORD HEALTHCARE (FDA Approved) Me Too Status: Adronil Injection 3mg/3ml By Searle Company Limited, Pakistan Reg. No. 075870 Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
148	**sanofi-aventis Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, (**000007**) Tracking ID: (Z5S-5N9-6X9M, 2024-06-20) Fee Paid: 75000.0 Paid Date: 2024-05-07 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Emjard-L 5mg/25mg Tablets** Each film coated tablet contains:Linagliptin.....5mgEmpagliflozin.....25mg RRA Status: Glyxambi Tablets (US FDA Approved) Me Too Status: Empagen-L Tablet 5mg/25mg Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing, Packi-Ferozsons Laboratories Limited-P.O Ferozsons Amangarh, Nowshera Khyber Pakhtunkhwa - Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
149	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (14W-XHV-88LT, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Lotepred-T Eye Drops** Each ml of opthalmic suspension contains: Tobramycin....3mg Loteprednol Etabonate....5mg As per Innovators Specification RRA Status: Zylet Eye Drops Approved By US-FDA Me Too Status: Lotetob Eye Drops by Helix Pharmaceuticals Reg. No. 092853 Pack Size(s): 3ml, 5ml-As per SRO
	Manufacturer(s): Manufacturing-Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
150	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (16Z-MSR-EGPJ, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Meprin 40mg** Each capsule contains: Omeprazole (As enteric coated pellets).....40mg United States Pharmacopeia RRA Status: Omeprazole 40mg Capsule - USFDA Me Too Status: Risek Capsule by Getz Pharma Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
151	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (18P-S92-RQ2X, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **HYCART 500mg Injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…….....500mg United States Pharmacopeia RRA Status: USFDA Me Too Status: Cortizone injection by Global pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Biogen Life Sciences-8-KM, ChakbeliRoad, Rawat, Rawalpindi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
152	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (**000644**) Tracking ID: (1ST-D95-8D2Z, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **SBT 200mcg DPI Capsule** Each Rotacapsule contains: Salbutamol as Sulphate……200mcg British Pharmacopeia RRA Status: UK MHRA Approved Me Too Status: Aerotec 200mcg Capsule Highnoon Laboratories Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
153	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (**000610**) Tracking ID: (26M-B17-3N9S, 2024-07-13) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Isofold 40mg capsule** Each soft gel capsule Contains: Isotretinoin……40mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Maxinoin Capsule by Maxitech (Reg # 108920) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Biogen Pharmaceuticals-8-KM, Chak Beli Road, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
154	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (28Y-SA1-TW3H, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **TICAGFIX 60mg Tablet** Each Film Coated Tablet Contains:Ticagrelor….60mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Anplag (PharmaEvo) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Wnsfeild Pharmaceuticals-Plot #122, Block A, Industrial Estate, Hattar, Haripur, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Drug product monograph is available in BP.	
	Decision: Approved with BP specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
155	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (2HB-4L8-DZ61, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **AZINEX 500mg Tablet** Each Film coated Tablet contains: Azithromycin as dihydrate.....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Azomax tablet by SANDOZ Pack Size(s): 3's-As per SRO,6's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
156	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (2MY-3D4-HTM9, 2024-07-23) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Obsoric** Each soft gel capsule contains: Isotretinoin ……40mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Maxinoin Capsule by Maxitech (Reg # 108920) Pack Size(s): 30(3 X 10s)-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
157	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (2S7-YVE-3AQ1, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Depo 150mg/ml Injectable Suspension** Each 1ml ampoule contains: Medroxyprogesterone acetate.....150mg United States Pharmacopeia RRA Status: DEPO-PROVERA 150 mg/ml Injectable Suspension is Approved in USFDA. Me Too Status: MEDROXY DEPO 150 mg/ml Injection 1ml. Pack Size(s): 1-As per SRO
	Manufacturer(s): Manufacturing & Batc-Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
158	**fleming pharmaceutical** 23-KM Sheikhupura road LAhore (**000936**) Tracking ID: (344-S2R-ZVZS, 2024-02-07) Fee Paid: 30000.0 Paid Date: 2023-12-29 Case Category: Short Availability Drugs **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **FLebenzathine inj. 0.6MIU** Each Vial Contains: Benzylpenicillin Benzathine.....0.6MIU United States Pharmacopeia RRA Status: BENZETACIL 600,000 IU POWDER AND SOLVENT FOR INJECTABLE SUSPENSION (Spain Approved) Me Too Status: Benzibiotic inj. 0.6MIU Pack Size(s): 1,s-As per SRO
	Evaluation Remarks: short molecule as per 178th meeting of the Authority.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
159	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (**000610**) Tracking ID: (3HR-ATQ-LMP4, 2024-07-11) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Combrain 200/6mcg DPI Capsule** Each Rota Capsule contains: Budesonide……200mcg, Formoterol Fumarate……6mcg As per Innovators Specification RRA Status: UK MHRA APPROVED Me Too Status: Combivair capsule by Highnoon Laboratories Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-	
	Evaluation Remarks:	
	Decision: Approved	
160	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (**000914**) Tracking ID: (3MJ-296-8UWN, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VARIVON 20MG TABLET** Each Film coated Tablet contains: Vonoprazan fumarate eqto Vonoprazan ……20mg As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: VOCINTI 20MG TABLET BY SEARLE ration Number 108836 Pack Size(s): 14-As per SRO
	Manufacturer(s): -BIO-MARK PHARMACEUTICALS-PLOT NO. 527, SUNDAR INDUSTRIAL ESTATE LAHORE-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
161	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (4XR-5A4-W25Y, 2024-07-09) Fee Paid: 75000.0 Paid Date: 2024-06-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tobramed Eye Drops** Each ml of solution contains: Tobramycin....3mg United States Pharmacopeia RRA Status: Tobrex Opthalmic Solution by Novartis Pharmaceuticals FDA Approved Me Too Status: Tobrex Opthalmic Solution by Novartis Pharmaceuticals Reg No. 008249 Pack Size(s): 3ml, 5ml-As per SRO
	Manufacturer(s): Manufacturing-Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
162	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (4YM-DPH-QWXU, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **CIFER 30MG CAPSULE** Each capsule contains Duloxetine HCl Enteric coated pellets eq. to Duloxetine …….30mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: C-Yalta 30 mg cap BY BS Pakistan (Pvt.) Ltd Registration Number 076118 Pack Size(s): 10-As per SRO,14 -As per SRO
	Manufacturer(s): CONTRACT ACCEPTOR -VARIANT PHARMACEUTICALS PVT. LTD-Plot No. 5, M2-Pharma Zone, 26-Km, Lahore Sharikpur Road, Sheikhupura Sheikhupura-	
	Evaluation Remarks:	
	Decision: Approved	
163	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. (**000644**) Tracking ID: (5LL-BUN-B6RA, 2024-07-19) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tybro 18mcg DPI Capsule** Each RotaCapsule contains: Tiotropium as Bromide Monohydrate……18 mcg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Apollo-F Capsule Nexus Pharma Karachi. (Reg# 076149) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
164	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (63R-8W9-Y455, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Meropenem 2g Injection** Each vial contains: Meropenem as trihydrate..... 2g (blended with sod. carbonate) United States Pharmacopeia RRA Status: USFDA Me Too Status: N/A Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Wallace Pharma Evolutions-Kala Wala stop,20 km, Lahore Jaranwala Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
165	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (69T-55Q-PUJ5, 2024-07-02) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **MERONIM 2000mg INJECTION** Each vial contains: Meropenem (as trihydrate)…….2gm (Blended with sodium carbonate) United States Pharmacopeia RRA Status: USFDA approved Me Too Status: NA Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): -M/s Wallace Pharma Evolutions-Kala Wala Stop 20-KM, LAHORE JARANWALA ROAD, LAHORE-	
	Evaluation Remarks:	
	Decision: Approved	
166	**idealpharma** 18-km ferozpure road lahore (**000146**) Tracking ID: (6AU-17B-5L9A, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2023-09-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Idelac 30mg/ml Injection** Each ml Contains: Ketorolac Tromethamine.....30mg United States Pharmacopeia RRA Status: FDA Approved Me Too Status: Toradol Injection Pack Size(s): as per DPC-As per SRO
	Manufacturer(s): Manufacturing, Packi-May & Baker Pvt Ltd-45KM Dina Nath, Multan Road Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
167	**M/s Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore (**000576**) Tracking ID: (6MA-H34-LSQ1, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2023-12-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Neugab CR Tablet 82.5mg** Each Extended released Tablet Conatains: Pregabalin.....82.5 mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: NA Pack Size(s): 10's-As per SRO,14's-As per SRO,20's-As per SRO
	Manufacturer(s): MANUFACTURER-wimits Pharmaceutical Pvt Ltd-Plot No.129 Sundar industrial Estate Lahore -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
168	**Health care pharmaceuticals** 40 km lahore Road multan (**000905**) Tracking ID: (6VG-T17-XMV5, 2024-07-13) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **LIV-D 200,000 IU Injection** Each 1ml Ampoule Contains: Cholecalciferol…5mg As per Innovators Specification RRA Status: VITAMIN D3 GOOD 200,000 IU / 1 ml, IM injection solution in ampoule ANSM France Me Too Status: Indrop D Injection by Neutro Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Manufacturer-CARER PHARMACEUTICAL INDUSTRIES-PLOT NO. 27 MAIN ROAD, RAWAT INDUSTRIAL ESTATE, RAWAT-	
	Evaluation Remarks:	
	Decision: Approved	
169	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (6WP-HN1-EUXU, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ONEP 40mg Injection** Each vial contains: Omeprazole sodium eq. to Omeprazole…….40mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Risek Injection by Getz Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio Labs (Pvt) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has applied for innovator's specs, while BP 2024 contains drug product monograph	
	Decision: Approved with BP specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
170	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (6Y5-Z2V-MJWW, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-06-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Dexamed Eye Drops** Each ml of suspension contains: Tobramycin....3mg Dexamethasone....1mg United States Pharmacopeia RRA Status: Tobradex Eye Drops Approved by FDA USA Me Too Status: Tobradex Eye Drops Manufactured by Novartis Pharmaceuticals, Reg. No. 091915 Pack Size(s): 3ml, 5ml-As per SRO
	Manufacturer(s): Manufacturing-Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
171	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (7GY-NNZ-225T, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tapnafix 75mg Tablet** Each Film Coated Tablet contains: Tapentadol (as HCl)…….75mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Tapento mg Tablet(Saami Pharmaceuticals (PVT) LTD) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Welmark Pharmaceuticals-Plot #122, Block B, Phase-V, Industrial Estate, Hattar, Haripur, KPK -	
	Evaluation Remarks:	
	Decision: Approved	
172	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (**000610**) Tracking ID: (7H9-N3W-Y86H, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **SBT 200mcg DPI Capsule** Each Rotacapsule contains: Salbutamol as Sulphate……200mcg British Pharmacopeia RRA Status: UK MHRA APPROVED Me Too Status: Aerotec 200mcg Capsule Highnoon Laboratories (Reg# 044593) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
173	**De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sheikhupura Road, Sheikhupura, Pakistan (**000844**) Tracking ID: (7ML-761-XHR4, 2024-07-04) Fee Paid: 75000.0 Paid Date: 2023-09-06 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Danzo 2.25gm Injection** Each Vial Contains: Piperacillin as Sodium……2000mg, Tazobactam as Sodium…….....250mg United States Pharmacopeia RRA Status: UK MHRA (PIPERACILLIN SODIUM + TAZOBACTAM SODIUM 2.25gm Injection) Me Too Status: TAZOCIN 2.25gm Injection (Wallace Pharma Evolutions) Pack Size(s): 1s-As per SRO
	Manufacturer(s): Manufacturing & Pack-Wallace Pharma Evolutions-Kalawala Stop, 20-Km, Lahore Jaranwala Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
174	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (7S8-E6W-GS2P, 2024-07-23) Fee Paid: 75000.0 Paid Date: 2024-07-23 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Terizan 20 mg Soft Gel Capsule** Each Soft Gel Capsule Contain: Isotretinoin……20mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oratane Capsule by Crystolite Pharma Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
175	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (7VN-Z18-TEQY, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **AZOFIX 80mg Tablet** Each Uncoated Tablet contains: Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil…....80mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Azilazon Tablet (Horizon) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Wnsfeild Pharmaceuticals-Plot #122, Block A, Phase V, Industrial Estate, Hattar, Haripur, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
176	**Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate Raiwind Road Lahore (**000845**) Tracking ID: (7YB-TJ6-EPPY, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **INSTACID SACHET 40/1680mg** Each Sachet contains: Omeprazole……40mg, Sodium Bicarbonate....1680mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Carey Sachet 40mg/1680mg of M/s Bio-Mark Pharmaceutical Pack Size(s): 14's-As per SRO,7's-As per SRO
	Manufacturer(s): -Bio-Mark Pharmaceuticals -Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
177	**Linta Pharmaceuticals Private Limited** Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. Islamabad. (**000810**) Tracking ID: (866-VYM-4WD7, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-04 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Calop 2mg Tablet** Each film coated tablet contains: Prucalopride succinate equivalent to Prucalopride.....2mg As per Innovators Specification RRA Status: Motegrity 2mg Tablet by TAKEDA PHARMS USA, Approved in FDA. Me Too Status: Prutide Tablet by CCL Pharma Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Manufacturer by way -Seraph Pharmaceutical-Plot No 210, Industrial triangle, Kahuta road, Islamabad-Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
178	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (8A3-TN7-G93L, 2024-07-22) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Linzol 200mg/100ml Infusion** Each 100ml of Solution for Infusion contains: Linezolid…… 200mg. As per Innovators Specification RRA Status: Zyvox 2 mg/ml Infusion of Pfizer (USFDA Approved) Me Too Status: Hilid Solution for Infusion. of M/s Hilton Pharma Pack Size(s): 1-As per SRO
	Manufacturer(s): -Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
179	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (8J5-XGR-57T5, 2024-08-01) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **EMPA 25mg Tablet** Each Film coated tablet containing:Empagliflozin…….25 mg As per Innovators Specification RRA Status: Jardiance Tablet by Boehringer Ingelheim Me Too Status: Diampa Tablet by GETZ Pharma Pack Size(s): 14's -As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
180	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (8MJ-LZH-2UNU, 2024-07-26) Fee Paid: 75000.0 Paid Date: 2024-07-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Pregab 82.5mg CR Tablet** Each Film coated Extended release tablet contains: Pregabalin.....82.5mg As per Innovators Specification RRA Status: Lyrica CR 82.5mg Tablet of M/s Pfizer (USFDA Approved) Me Too Status: N/A Pack Size(s): 3 x 10's, 1 x 10's, -As per SRO
	Manufacturer(s): Manufacturing & Batc-Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
181	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (95T-7TV-MGBT, 2024-07-26) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VOZAN 20mg Tablet** Each Film coated tablet containing: Vonoprazan as fumarate…….20mg As per Innovators Specification RRA Status: VOQUENZA tablet by Phathom Pharmaceuticals,USA Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 14's -As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
182	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (9XM-2YU-JB7X, 2024-07-23) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Obsoric** Each soft gel capsule contains: Isotretinoin ……10mg British Pharmacopeia RRA Status: MHRA Me Too Status: Oratane Capsule by Crystolite Pack Size(s): 30(3 X 10s)-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
183	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (A29-QP7-6WP5, 2024-07-24) Fee Paid: 75000.0 Paid Date: 2024-06-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Epime 500mg Injection IV/IM** Each Vial contains:Cefepime HCl with L-Arginine eq. to Cefepime……500mg United States Pharmacopeia RRA Status: Cefepime for injection 500mg/vial of M/s Qilu Pharmaceuticals Co. Ltd. (USFDA Approved) Me Too Status: CefStar for injection 1000mg IV/IM of M/s Barret Hodgson Pakistan (Pvt) Ltd. Pack Size(s): 1x1's,As per SRO-As per SRO
	Manufacturer(s): Manufacturing & Batc-Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
184	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (ABA-8AG-TGWN, 2024-07-15) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Pregvoid 0.75mg Tablet** Each Tablet contains: Levonorgestrel ..... 0.75mg British Pharmacopeia RRA Status: Levonorgestrel Exeltis 0.75 mg EFG tablets. of M/s EXELTIS HEALTHCARE S.L. (AEMPS Approved) Me Too Status: Emkit Tablet 0.75 mg of M/s ZAFA PHARMACEUTICAL LABORATORIES (PVT) LTD Pack Size(s): As per SRO / DPC-As per SRO
	Manufacturer(s): Manufacturing & Batc-Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
185	**Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK (**000610**) Tracking ID: (AJW-VBM-6QXV, 2024-07-11) Fee Paid: 75000.0 Paid Date: 2024-06-24 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tybro 18mcg DPI Capsule** Each RotaCapsule contains: Tiotropium as Bromide Monohydrate……18 Mcg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Apollo-F Capsule Nexus Pharma Karachi. (Reg# 076149) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
186	**Variant Pharmaceuticals (Pvt.) Ltd** Plot # 5 M2-Pharmazone, 26KM lahore-sharaqpur road, sheikhupura (**000914**) Tracking ID: (AMH-GJX-PZNA, 2024-07-14) Fee Paid: Paid Date: Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VARIVON 10MG TABLET** Each Film coated Tablet contains: Vonoprazan fumarate eq to Vonoprazan ……10mg As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: VOCINTI 10MG TABLET BY SEARLE ration Number 108835 Pack Size(s): 14-As per SRO
	Manufacturer(s): -BIO-MARK PHARMACEUTICALS-PLOT NO. 527, SUNDAR INDUSTRIAL ESTATE LAHORE-	
	Evaluation Remarks:	
	Decision: Approved	
187	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (B25-783-JH3G, 2024-07-26) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **EMPAMET 5/500mg Tablet** Each Film coated tablet containing: Empagliflozin……5mg, Metformin HCl……500mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Diampa -M By Getz Pharma Pack Size(s): 14's -As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
188	**FAAS Pharmaceuticals (Pvt)Ltd** F-748 L, S.I.T.E, Karachi (**000767**) Tracking ID: (BGV-RGM-QA6W, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-07-04 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Setzone 8mg/4ml Injection** Each 4 ml ampoule contains: Ondansetron HCl Dihydrate equivalent to Ondansetron……8mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Onset injection of Pharmedic Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
189	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan (**000614**) Tracking ID: (BW9-EY5-48ZW, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-05-08 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **FLOPIN 100MG/ 5MG Tablet** Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate …….100mg, Erugliflozin as L-pyroglutamic Acid ……5mg 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
	Manufacturer(s): Formulation-M/S Weather Folds Pharmaceuticals, Hattar-Plot No.69/2, Phase - II, Indutrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
190	**Invictus Pharmaceuticals** Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad (**000892**) Tracking ID: (D8U-QY3-Y322, 2024-07-31) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Relod Injection** Each ml contains: Iron as Ferric Carboxymaltose…… 50mg As per Innovators Specification RRA Status: Injectafer Solution IV (USFDA Approved) Me Too Status: FCM Injection of M/s Genix Pharma– Karach Pack Size(s): 1's Vail-As per SRO
	Manufacturer(s): -BioLabs (Pvt.) Ltd-Plot No.145, Industrial Triangle, Kahuta Road, Islamabad.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
191	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (DD5-V26-VDAD, 2024-07-31) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Perkol 100ml vial** Each 100ml vial contains: Paracetamol.....1g As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Provas (10mg/ml) Pack Size(s): 1's -As per SRO
	Manufacturer(s): -M/s Biogen Life Sciences - 8km Chakbeli Road Rawat Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
192	**Davis Pharmaceutical Laboratories** Plot No. 121, Industrial Triangle Area, Kahuta Road (**000432**) Tracking ID: (DN3-3B6-NLH4, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Zepenum 500mg Injection** Each Vial Contain: Meropenem Trihydrate equivalent to Meropenem……500 mg United States Pharmacopeia RRA Status: Merrem Injection (USFDA approved) Me Too Status: Merrem Injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8 Km, Chakbeli Road, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
193	**SHAWAN PHARMACEUTICALS** PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (**000627**) Tracking ID: (EED-XRN-Z7E1, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-04-04 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Imiwan 500mg Injection** Each vial contains: Imipenem (as monohydrate)……500mg, Cilastatin (as sodium).....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: cilapen Injection 500/500mg Registration holder: Bosch Pharma Pack Size(s): 1,s-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
194	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (EJX-PPX-9Y3Z, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ESONAP 375/20mg Tablet** Each Modified Released Tablet Contains: Naproxen as Enteric Coated Core.……375mg, Esomeprazole as Magnesium Trihydrate as IR……..20mg 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
	Manufacturer(s): -M/s WnsFeild Pharmaceuticals- M/s WnsFeild Pharmaceuticals, Plot #122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
195	**Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (**000790**) Tracking ID: (G9D-9X1-JDA6, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **CAPRI 4.5MG CAPSULE** Each Capsule Contains: Cariprazine as Cariprazine Hydrochloride…….....4.5mg As per Innovators Specification RRA Status: USFDA approved Me Too Status: Caripra 4.5mg Capsule by Genix Pharma Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Contract accepter-M/s WELCOME PAKISTAN TRADING PHARMA (PRIVATE) LTD-CHAKRI INTERCHANGE, MAIN ROAD, GANGANWALA, RAWALPINDI.-	
	Evaluation Remarks:	
	Decision: Approved	
196	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan (**000203**) Tracking ID: (EW6-4JE-6EDX, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **SARSET 8mg Tablet** Each film coated tablet contains: Ondansetron as (hydrochloride dihydrate).....8mg United States Pharmacopeia RRA Status: Ondansetron 8 mg film-coated Tablet M/s Aurobindo Pharma- Milpharm Ltd. (MHRA approved) Me Too Status: Onset 8mg Tablet M/s Pharmedic Laboratories (Pvt.)Ltd Registration 025989 Pack Size(s): 1x10's, 2x7s, 2x10's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturer and Bat-Wimits Pharmaceuticals (Pvt) Ltd.-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
197	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (GLX-7H4-HTZT, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **IROMED 50MG/ML INJECTION/INFUSION** Each ampoule contains: Ferric carboxymaltose corresponding to 50 mg iron. As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Fercari(Hilton Pharma.) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks: The label claim of the firm is: Each ampoule contains: Ferric carboxymaltose corresponding to 50 mg iron. Required label claim: Each 10ml ampoule contains: Ferric carboxymaltose corresponding to elemental iron.....500mg	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved with following label claim: Each 10ml ampoule contains: Ferric carboxymaltose corresponding to elemental iron.....500mg The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
198	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan (**000203**) Tracking ID: (GWE-NSD-MLNH, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **SARSET 4mg Tablet** Each film coated tablet contains: Ondansetron as (hydrochloride dihydrate).....4mg United States Pharmacopeia RRA Status: Ondansetron 4 mg film-coated Tablet M/s Aurobindo Pharma- Milpharm Ltd. (MHRA approved) Me Too Status: Ondaset 4mg tablet M/s Aspin pharma (Pvt) Ltd. Pack Size(s): 1x10's, 2x7s, 2x10's-As per SRO
	Manufacturer(s): Manufacturer and Bat-Wimits Pharmaceuticals (Pvt) Ltd.-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
199	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi (**000838**) Tracking ID: (H9N-ZT5-S9TJ, 2024-07-01) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Cefket 2.5gm Injection** 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
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
200	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (HQQ-Y5E-6Y75, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **BIRUNATE 30mg Injection** Each vial contains: Artesunate.....30mg The International Pharmacopeia RRA Status: WHO recommended formulation Me Too Status: Arcenate Injection 30mg Reg. no. 100927 M/s Sami Pharma Karachi. Pack Size(s): 1's -As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Labs (Pvt.) Ltd.,-Plot No. 145, Industrial Triangle Kahuta Road, Islamabad-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
201	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (**000823**) Tracking ID: (HYR-BA9-TU64, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-14 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **J-Penem 500mg Injection** Each Vial Contains: Meropenem as trihydrate…… 500mg United States Pharmacopeia RRA Status: MHRA Me Too Status: PENRO 500 mg Injection IV (042106) Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Stallion Pharmaceuticals PVT, LTD.-581-Sundar Industrial Estate, Lahore, Lahore.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
202	**Goodman Laboratories Pvt. Ltd** Plot No. 5, Street S-5, National Industrial Zone, Rawat (**000613**) Tracking ID: (HZH-JP3-VX72, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2023-11-16 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Isolit 20mg Capsule** Each soft gel capsule contains: Isotretinoin.....20mg British Pharmacopeia RRA Status: isotretinoin soft gel capsule . MHRA Me Too Status: Oratane capsule 20mg Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Biogen Life sciences-8 Km , chakbeli road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
203	**Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore (**000228**) Tracking ID: (JLX-8WR-T5VZ, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Laxopride tablet** Each Film Coated Tablet contains: Prucalopride as Succinate…....1mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Prutide Tablet 1mg Reg# 116139 by Weather Folds Pharmaceuticals. Pack Size(s): Alu-Alu Blister furt-As per SRO
	Manufacturer(s): Manufacturing, Quali- Wnsfeild Pharmaceuticals- Plot #122, Block-A, Phase-V, Industrial Estate, Hattar,, Haripur, KPK -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
204	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (LU9-UY2-PMYM, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **MEMRIL 10mg/5ml Oral Solution** Each 5ml contains: Memantine hydrochloride Eq. to Memantine……10mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Afdol 10mg/5ml oral solution((AGP Pharma (PVT) LTD.) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
205	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (MN7-TN1-76AQ, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ICOL 10mg Tablet** Each Film Coated Tablet Contains: Obeticholic Acid…..…10mg As per Innovators Specification RRA Status: UK MHRAReference Me Too Status: Ocafib 10mg tablet Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -M/s Weather Folds-M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks:	
	Decision: Approved	
206	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (MNG-4AX-8ZPN, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **HYCART 250mg Injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone.....250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone injection by Global pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-KM, ChakbeliRoad, Rawat, Rawalpindi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
207	**TN PHARMACEUTICALS** 264-C SUNDAR INDUSTRIAL ESTATE LAHORE (**000868**) Tracking ID: (MSX-QUR-YW1B, 2024-07-01) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **MonTan 4mg Sachet** Each Sachet contains: Montelukast as Sodium .....4mg United States Pharmacopeia RRA Status: Singulair Sachet Merck Research Laboratories USFDA approved. Me Too Status: AEROKAST 4mg Sachet BARRETT HODGSON PAKISTAN LIMITED Pack Size(s): 14's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals -Plot No 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
208	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (MYR-ZWD-31HQ, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **CEFTOBAC** Each Vial Contains: Ceftazidime as Pentahydrate…….2000mg, Avibactam as Sodium Salt……500mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Zavicefta Injection Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -M/s Weather Folds Pharmaceuticals-M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK -	
	Evaluation Remarks:	
	Decision: Approved	
209	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore (**000655**) Tracking ID: (NHP-UEL-LVEV, 2024-07-05) Fee Paid: 75000.0 Paid Date: 2024-05-22 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nebivia Tablets 5mg** Each film coated tablet contains Nebivolol Hydrochloride Eq. to Nebivolol…….5mg As per Innovators Specification RRA Status: BYSTOLIC 5mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA. Me Too Status: Nebix 5mg Tablets of M/s Highnoon Laboratories Ltd. Pack Size(s): 10's, 14's, 30's -As per SRO
	Manufacturer(s): FP Manufacturing, Te-Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
210	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (NJQ-NZT-916Z, 2024-07-03) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Mofloxen** Each 250ml vial contains: Moxifloxacin as Hydrochloride …..400mg As per Innovators Specification RRA Status: USFDA Me Too Status: NDP Pack Size(s): 1'S-As per SRO
	Manufacturer(s): contract -Biogen Life Science Pharmaceuticals-8km Chakbili road Rawat Rawalpindi Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
211	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (NYJ-TBY-25VB, 2024-07-30) Fee Paid: 75000.0 Paid Date: 2024-07-23 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **MIMTIN-10MG/5ML ORAL SOLUTION** Each 5ml contains: Memantine hydrochloride Eq. to Memantine……10mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Afdol 10mg/5ml oral solution By: AGP Pharma (PVT) LTD. Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	
212	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (P6R-S29-YENE, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **DELORT 0.5MG/ML SYRUP** Each ml of syrup contains: Desloratadine ……0.5mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Neo-Antial Syrup 0.5mg/ml(M/s Sami Pharmaceuticals)076064 Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
213	**SHAWAN PHARMACEUTICALS** PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (**000627**) Tracking ID: (PJ9-ESV-N4VW, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-04-04 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Imiwan 250mg Injection** Each vial contains: Imipenem (as monohydrate)……250mg, Cilastatin (as sodium).....250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: cilapen Injection 500/500mg by Bosch Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
214	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (PLG-P1Q-S6LT, 2024-07-01) Fee Paid: Paid Date: Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Montiwel 4mg Sachet** Each Sachet contains: Montelukast sodium eq. to Montelukast…....4mg United States Pharmacopeia RRA Status: Singulair Sachet Merck Research Laboratories USFDA approved Me Too Status: AEROKAST BARRETT HODGSON Pack Size(s): 14's-As per SRO,28's-As per SRO
	Manufacturer(s): -Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore -	
	Evaluation Remarks:	
	Decision: Approved	
215	**Health care pharmaceuticals** 40 km lahore Road multan (**000905**) Tracking ID: (Q86-DUL-JRXE, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **TRETIN 20mg Capsule** Each soft gel capsule contains: Isotretinoin ……20mg British Pharmacopeia RRA Status: Isotretinoin 20 mg Soft Capsules MHRA Approved Me Too Status: Oratane Capsule by Crystolite Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Manufacturer-Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
216	**Daneen Pharma Pvt Limited** plot no: 27 sunder industrial estate, sunder raiwind road, lahore (**000688**) Tracking ID: (Q9S-W2N-VJ3D, 2024-07-25) Fee Paid: 75000.0 Paid Date: 2024-06-03 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Risdan Oral Disintegrating Tablet 4mg** Each disintegrating tablet contains: Risperidone……4mg United States Pharmacopeia RRA Status: RISPERDAL®M-TAB® Me Too Status: Gradon Flash Tablet mfg. by Grays Pharmaceuticals (Reg. 102702) Pack Size(s): 7’s, 10’s, 14’s, 20-As per SRO
	Manufacturer(s): Contract Manufacturi-Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
217	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (QGR-NUJ-6AJL, 2024-07-24) Fee Paid: 75000.0 Paid Date: 2024-06-12 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Calsofin 0.5mcg soft gelatin Capsule** Each soft gelatin capsule contains: Calcitriol……0.5mcg British Pharmacopeia RRA Status: FDA Approved. ROCALTROL (calcitriol) Me Too Status: Rocaltrol Capsules 0.5mcg Pack Size(s): 3x10's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-Km Chakbeli Road Rawat Rawalpindi -Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
218	**BF Biosciences Limited** 5-KM Sundar Raiwind Road, Raiwind, Lahore (**000655**) Tracking ID: (QM7-YSP-M7H2, 2024-07-09) Fee Paid: 75000.0 Paid Date: 2024-06-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Oxxo 1% Cream** Each gm Contains: Oxiconazole Nitrate eq. to Oxiconazole ……10mg As per Innovators Specification RRA Status: OXISTAT of Fougera Pharmaceuticals Inc. Melville, NY 11747 USA approved USFDA Me Too Status: Xirconi 1 % Cream of M/s Ferozsons Laboratories Limited Pack Size(s): 15g, 30g, 60g-As per SRO
	Manufacturer(s): FP Manufacturing, Te-Ferozsons Laboratories Limited-P.O Ferozsons, Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
219	**STALLION PHARMACEUTICALS PVT LTD** Plot#581 Sundar Industrial Estate Lahore (**000783**) Tracking ID: (R6V-3NZ-2E7P, 2024-07-26) Fee Paid: 75000.0 Paid Date: 2024-07-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Pregab 330mg CR Tablet** Each Film Coated Extended Release tablet contains: Pregabalin……....330 mg As per Innovators Specification RRA Status: Lyrica CR 330mg Tablet of M/s Pfizer (USFDA Approved) Me Too Status: N/A Pack Size(s): 3 x 10's, 1 x 10's, -As per SRO
	Manufacturer(s): Manufacturing & Batc-Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
220	**SHAWAN PHARMACEUTICALS** PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT (**000627**) Tracking ID: (RHZ-7QY-X7YZ, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-07-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tretiwan 40mg capsule** Each soft gel capsule contains: Isotretinoin……40mg British Pharmacopeia RRA Status: (USFDA Approved). Me Too Status: Maxinoin Capsule by Maxitech (Reg # 108920) Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
221	**jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi (**000838**) Tracking ID: (RJ2-YJ8-XGA7, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Tazocin 2.25gm Injection** Each Vial Contains: Piperacillin as Sodium…....2000mg, Tazobactam as Sodium……..250mg 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
	Manufacturer(s): Contract Acceptor-M/S Wallace Pharma Evolutions-Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
222	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (RRE-UNU-2Q6G, 2024-07-31) Fee Paid: 75000.0 Paid Date: 2024-07-23 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ABSTEN-5MG/5ML SYRUP** Each 5ml contains: Ebastine……5mg As per Innovators Specification RRA Status: EBASTEL 1mg/1ml oral solution Spain Approved. Me Too Status: Simstine 5mg/5ml Syrup By M/s Simz Pharmaceuticals (Pvt.) Ltd. Lahore Reg. No. 074206 Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Manufacturing-Seraph Pharmaceuticals-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-PAKISTAN.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
223	**fleming pharmaceutical** 23-KM Sheikhupura road LAhore (**000936**) Tracking ID: (RZ3-9MZ-VQ2R, 2024-02-07) Fee Paid: 30000.0 Paid Date: 2023-12-29 Case Category: Short Availability Drugs **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **FLebenzathine inj. 1.2 MIU** Each Vial Contain: Benezylpenicillin Benzathine.....1.2MIU United States Pharmacopeia RRA Status: BENZETACIL 1,200,000 IU powder and solvent for suspension for injection Spain Approved) Me Too Status: Benzibiotic inj. 1.2 MIU Pack Size(s): 1,s-As per SRO
	Evaluation Remarks: short molecule as per 178th meeting of the Authority.	
	Decision: Approved	
224	**Nimrall Laboratories** Plot No. 24, Street SS-3, Rawat Industrial Estate, Rawat (**000611**) Tracking ID: (S45-TX6-TXS1, 2024-07-11) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Betanim Cream** Each gram contains: Betamethasone as dipropionate.....0.5mg (0.05%w/w), Gentamicin as Sulphate.....1mg (0.1% w/w) As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Gentanix-B Cream, Biogen pharma, Reg. No. 070201 Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-KM chekbeli Road Rawat Rawalpindi-	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
225	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (S6Y-Q6J-1LW6, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **DRISDOL 7.5mg/ml Injection** Each ampoule contains: Cholecalciferol.....7.5mg (corresponding to 300,000IU) British Pharmacopeia RRA Status: Swissmedic Approved Me Too Status: NA Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
226	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (S88-7AX-QHSX, 2024-08-01) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **VOZAN 10mg Tablet** Each Film coated tablet containing: Vonoprazan as fumarate……10 mg As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: VONOZAN tablet by GETZ Pharma Pack Size(s): 14's -As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Evaluation Remarks:	
	Decision: Approved	
227	**Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat (**000871**) Tracking ID: (SA6-Q6Z-TY7A, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-07-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Risot 40mg Soft gel Capsules** Each soft gel capsule Contains: Isotretinoin……40mg British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Maxinoin Capsule by Maxitech (Reg # 108920) Pack Size(s): 30's-As per SRO
	Manufacturer(s): -M/s Biogen Life Sciences- 8-KM, Chak Beli Road, Rawat-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
228	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (SJZ-YMT-6VXS, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **HYCART 100mg Injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone……..... 100 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone injection by Global pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Biogen Life Sciences-8-KM, ChakbeliRoad, Rawat, Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
229	**Davis Pharmaceutical Laboratories** Plot No. 121, Industrial Triangle Area, Kahuta Road (**000432**) Tracking ID: (SM5-M48-BNZW, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Devicort 250mg Injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to Hydrocortisone…… 250 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Sciences-8 Km, Chakbeli Road, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
230	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (SZ9-XSR-W5DY, 2024-07-26) Fee Paid: 75000.0 Paid Date: 2024-07-25 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **EMPA 10mg Tablet** Each Film coated tablet containing: Empagliflozin……10mg As per Innovators Specification RRA Status: Jardiance Tablet by Boehringer Ingelheim Me Too Status: Diampa Tablet by GETZ Pharma Pack Size(s): 14's -As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
231	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (T47-XJB-YYB1, 2024-07-17) Fee Paid: 75000.0 Paid Date: 2024-06-12 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Calsofin 0.25mcg soft gelatin Capsule** Each soft gelatin capsule contains: Calcitriol ……0.25mcg British Pharmacopeia RRA Status: FDA Approved. ROCALTROL (calcitriol) Me Too Status: Rocaltrol Capsules 0.25mcg Pack Size(s): 30's,100s-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8-Km Chakbeli Road Rawat Rawalpindi -Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
232	**Davis Pharmaceutical Laboratories** Plot No. 121, Industrial Triangle Area, Kahuta Road (**000432**) Tracking ID: (T5T-PQW-1W18, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **IsoSoft 20mg Capsule** Each soft gel capsule contains: Isotretinoin……20mg British Pharmacopeia RRA Status: Isotretinoin 20mg soft capsules (MHRA Approved) Me Too Status: Oratane 20mg Soft Gel Capsule Pack Size(s): 10'S-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Sciences-8 Km, Chakbeli Road, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	
233	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. (**000750**) Tracking ID: (T82-Z3U-LY75, 2024-07-31) Fee Paid: 75000.0 Paid Date: 2024-07-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Gufprazan 10mg Tablets** Each film coated tablets contains: Vonoprazan Fumarate equivalent to Vonoprazan……10mg As per Innovators Specification RRA Status: PMDA Japan Approved Me Too Status: Vonozan 10mg tablet Pack Size(s): 14's-As per SRO
	Manufacturer(s): -Linta pharmaceuticals(Pvt.)Ltd.-Plot No.3,Street S-5, National industrial zone, Rawat-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
234	**Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad (**000572**) Tracking ID: (TMP-U8T-YVB8, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **TICAGFIX 90mg Tablet** Each Film Coated Tablet Contains: Ticagrelor…..…90mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Anplag (PharmaEvo) Pack Size(s): As per SRO -As per SRO
	Manufacturer(s): -Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-	
	Evaluation Remarks: Product monograph is available in BP	
	Decision: Approved with BP specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
235	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (U1D-UT1-Q1A2, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **AVIDIME 2.5gm Injection** Each Vial Contains: Ceftazidime as Pentahydrate……2000mg, Avibactam as Sodium Salt……500mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: ZAVICEFTA 2.5GM INJECTION PFIZER Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Weather Folds Pharmaceuticals -Plot No. 69/2, Block B, Industrial Estate, Hattar-	
	Evaluation Remarks:	
	Decision: Approved	
236	**Siam Pharmaceuticals** Plot No 217 Industrial Triangle Kahuta Road Islamabad (**000711**) Tracking ID: (UGH-SVJ-8W6P, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-13 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Fenes 1% Lotions** Each gm contains: Terbinafine hydrochloride…..10mg As per Innovators Specification RRA Status: Netherland Approved Me Too Status: Cutis Lotion of M/s Tabros Pharma Pack Size(s): 1x1-Controlled
	Manufacturer(s): -Biogen Pharmaceuticals-8km Chakbili road Rawat Rawalpindi Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
237	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (UGT-29D-VL7Q, 2024-07-04) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **IMECTA 30mg Sachet** Each Sachet Contains: Racecadotril……30mg As per Innovators Specification RRA Status: MHRA Reference: Me Too Status: Hidrasec 10mg Sachet by M/s Abbot Laboratories (Pakistan) Ltd., Landhi, Karachi, Pakistan. DRAP Approved. Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -M/s WnsFeild Pharmaceuticals,-M/s WnsFeild Pharmaceuticals, Plot #122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
238	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (V64-SNB-8613, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **BIRUNATE 120mg Injection** Each vial contains: Artesunate…….....120mg The International Pharmacopeia RRA Status: WHO recommended formulation. Me Too Status: Arcenate Injection 120mg Reg. no. 100929 M/s Sami Pharma Karachi Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Labs (Pvt.) Ltd.,-Plot No. 145, Industrial Triangle Kahuta Road, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	
239	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (VG8-3PU-VBBR, 2024-07-17) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ORNATE 60mg Injection** Each vial contains:Artesunate. ……60mg The International Pharmacopeia RRA Status: WHO recommended formulation Me Too Status: Gen-M by Genix Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio Labs (Pvt) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
240	**AsianContinental (Pvt.) Ltd.** D-133, Tipu Sultan Road, KDA Scheme No.1, Karsaz, (**000643**) Tracking ID: (VJW-1EB-1RB7, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-06-11 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Acdiva 500mg CR** Each Extended release Tablet contains:Divalproex Sodium equivalent to Valproic acid.....500mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Epival CR 500mg Tablet (M/s Abbott Laboratories Pakistan Limited) Pack Size(s): 5 x 10's-As per SRO
	Manufacturer(s): Manufacturing & Batc-Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
241	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (W2R-2G1-GH9P, 2024-07-09) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ORNATE 120mg Injection** Each vial contains: Artesunate……120mg The International Pharmacopeia RRA Status: WHO recommended formulation Me Too Status: Gen-M by Genix Pharma Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Bio Labs (Pvt) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
242	**Islam Pharmaceuticals** 7km Pasrur Road Sialkot (**000885**) Tracking ID: (WT9-LGR-DU39, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-21 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **CEFOBACT** Each vial contains; Cefoperazone as sodium…….1000mg Sulbactum as sodium……..1000mg (Product Complied JP Specs) Any Other RRA Status: Approved by EMA Me Too Status: Cefbac injection by Seraph Pharmaceuticals Pack Size(s): as per SRO-As per SRO
	Manufacturer(s): -M/s Weather Folds Pharmaceuticals-M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
243	**Davis Pharmaceutical Laboratories** Plot No. 121, Industrial Triangle Area, Kahuta Road (**000432**) Tracking ID: (XJB-QGN-29TD, 2024-07-12) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Zepenum 1g Injection** Each Vial Contain: Meropenem Trihydrate equivalent to Meropenem……1g United States Pharmacopeia RRA Status: Merrem Injection (FDA approved) Me Too Status: Merrem Injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Biogen Life Sciences-8 Km, Chakbeli Road, Rawat-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
244	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (XU5-TRE-HR1G, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **BIRUNATE 60mg Injection** Each vial contains: Artesunate…….....…..60mg The International Pharmacopeia RRA Status: WHO recommended formulation. Me Too Status: Arcenate Injection 60mg Reg. no. 100928 M/s Sami Pharma Karachi. Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Labs (Pvt.) Ltd.,-Plot No. 145, Industrial Triangle Kahuta Road, Islamabad-	
	Evaluation Remarks:	
	Decision: Approved	
245	**M/s Pak Risen Pharmaceuticals** Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar (**000573**) Tracking ID: (Y2X-YHT-H8SL, 2024-07-16) Fee Paid: 75000.0 Paid Date: 2024-07-08 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Danzo 4.5gm Injection** Each Vial Contains: Piperacillin as Sodium……4000mg, Tazobactam as Sodium…….....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
	Manufacturer(s): Contract Acceptor-Wallace Pharma Evolutions-Kala wala stop, 20-KM, Lahore Jaranwala Road Lahore.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
246	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala (**000987**) Tracking ID: (YAS-WPL-M4B5, 2024-07-15) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Ettirox 60mg Tablet** Each Film Coated Tablet Contains: Etoricoxib…....60mg As per Innovators Specification RRA Status: UK MHRA Me Too Status: Starcox Tablet by Getz Pharma Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Wnsfeild Pharmaceuticals-Plot NO. 122, Block-A, Phase-V, Industrial Estate, Hattar, KPK. -	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
247	**M/s Levon Pharmaceuticals** Plot ; 13.5 Sheikhupura Sharakpur Road ,Sheikhupura (**000976**) Tracking ID: (YD7-LHM-TQQ4, 2024-07-11) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Sun-D3 Injection (Cholecalciferol 7.5 mg, which corresponds to 300000 I.U.)** Each Ampoule contains: Cholecalciferol (vitamin D3).....7.5 mg (corresponding to 300,000I.U) British Pharmacopeia RRA Status: Swissmedic Approved Me Too Status: NA Pack Size(s): As per SRO-As per SRO
	Manufacturer(s): -Seraph Pharmaceutical-Plot # 210 Industrial Triangle Kahuta Road, Islamabad.-	
	Evaluation Remarks:	
	Decision: Approved	
248	**Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock (**000699**) Tracking ID: (YDB-EDS-DBBP, 2024-07-19) Fee Paid: 75000.0 Paid Date: 2024-06-05 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nepa Eye Drops** Each ml of suspension contains: Nepafenac.....1mg As per Innovators Specification RRA Status: Ilevro Eye Drops by Novartis Pharma Approved in MHRA Me Too Status: Nepanac Opthalmic Suspension by Remington Pharma Reg. No. 069177 Pack Size(s): 3ml, 5ml-As per SRO
	Manufacturer(s): Manufacturing-Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
249	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (YEZ-U6M-ZG3V, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **ONENO** Each Vial Contains: Esomeprazole as sodium……40mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Esso injection by Shaigan Pharmaceuticals Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio Labs (Pvt) Ltd-Plot No. 145,Industrial Triangle Kahuta Road Islamabad- Pakistan-	
	Evaluation Remarks: Product monograph is available in BP.	
	Decision: Approved with BP specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
250	**M/s Pak Risen Pharmaceuticals** Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar (**000573**) Tracking ID: (YGQ-9LL-HVSZ, 2024-07-19) Fee Paid: 75000.0 Paid Date: 2024-07-08 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Nebrise 2.5mg Tablet** Each uncoated Tablet Contains: Nebivolol as Hydrochloride……..…2.5mg As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Nabiz Tablet by Wnsfeild Pharma Pack Size(s): As Per SRO-As per SRO
	Manufacturer(s): Contract Acceptor-Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Estate, Hattar.-	
	Evaluation Remarks:	
	Decision: Approved	
251	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura (**000823**) Tracking ID: (YLD-SJ7-ZA4B, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-06-14 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **J-Penem Injection 1gm** Each Vial Contains: Meropenem as trihydrate …… 1g United States Pharmacopeia RRA Status: MHRA Me Too Status: PENRO 1g Injection IV (042107) Pack Size(s): 1's-As per SRO
	Manufacturer(s): -Stallion Pharmaceuticals PVT, LTD.-581-Sundar Industrial Estate, Lahore, Lahore.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
252	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (YU9-1TP-5AVB, 2024-07-15) Fee Paid: 75000.0 Paid Date: 2024-06-10 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Pregvoid 1.5mg Tablet** Each Tablet contains: Levonorgestrel ..... 1.5mg British Pharmacopeia RRA Status: LEVONORGESTREL SANDOZ 1.5 MG EFG TABLET is Approved in AEMPS. Me Too Status: Emkit DS Tablet 1.5 mg of M/s ZAFA PHARMACEUTICAL LABORATORIES (PVT) LTD Pack Size(s): As per SRO / DPC-As per SRO
	Manufacturer(s): Manufacturing & Batc-Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
253	**Nimrall Laboratories** Plot No. 24, Street SS-3, Rawat Industrial Estate, Rawat (**000611**) Tracking ID: (ZAG-EWA-3LGY, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Isoral 20mg Capsule** Each soft gel capsule Contains: Isotretinoin.....20mg British Pharmacopeia RRA Status: Isotretinoin 20mg soft capsules (MHRA Approved) Me Too Status: Oratane 20mg Soft Gel Capsule, Crystolite Pharmaceutical Pack Size(s): 10's, 30's-As per SRO
	Manufacturer(s): Contract manufacture-Biogen Life Sciences-8-KM chekbeli Road Rawat Rawalpindi-	
	Evaluation Remarks:	
	Decision: Approved	
254	**Davis Pharmaceutical Laboratories** Plot No. 121, Industrial Triangle Area, Kahuta Road (**000432**) Tracking ID: (ZB9-J5E-42LQ, 2024-07-10) Fee Paid: 75000.0 Paid Date: 2024-06-28 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Devicort 100mg Injection** Each vial contains: Hydrocortisone Sodium Succinate equivalent to Hydrocortisone…… 100 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cortizone injection Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Sciences-8 Km, Chakbeli Road, Rawat-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
255	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore (**000863**) Tracking ID: (ZN9-6GH-A6G2, 2024-07-14) Fee Paid: 75000.0 Paid Date: 2024-06-26 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **IBANDRO 3mg/3ml Injection** Each 3ml ampoule contains: Ibandronate sodium monohydrate eq. to Ibandronic acid …… 3mg As per Innovators Specification RRA Status: Ibandronate sodium 3mg/3ml injection ACCORD HEALTHCARE FDA Approved Drug. Me Too Status: Adronil Injection 3mg/3 ml Searle Company Limited,Pakistan Reg.No. 075870 Pack Size(s): 1-As per SRO
	Manufacturer(s): Manufacturing & Pack-Seraph Pharmaceuticals -Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.-	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
256	**Biogen PHarma** 8-KM, Chak Beli Road, Rawat, (**000639**) Tracking ID: (ZRD-RPA-BRRM, 2024-07-18) Fee Paid: 75000.0 Paid Date: 2024-06-12 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Biothate 3M.I.U** Each vial contains: Colistimethate sodium eq. to Colistin base activity……..(3MIU)100mg United States Pharmacopeia RRA Status: MHRA Approved Me Too Status: Manufacturer: M/s Tabros Pharma Karachi Brand Name: Colimethate Powder for Solution for Injection / In Reg No. 108905 Pack Size(s): 1's-As per SRO
	Manufacturer(s): Manufacturing-Biogen Life Science -8-km, Chakbeli Road, Rawat, Rawalpindi -	
	Evaluation Remarks:	
	Decision: Approved	
257	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra (**000440**) Tracking ID: (Z7D-2D1-HQTB, 2024-07-08) Fee Paid: 75000.0 Paid Date: 2024-06-27 Case Category: Contract Manufacturing **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Isotor** Each soft gel capsule contains: Isotretinoin.....10mg British Pharmacopeia RRA Status: Isotretinoin 10mg capsule - MHRA approved Me Too Status: Oratane 10mg capsule by Crystolite Pharmaceutical Pack Size(s): 20's-As per SRO,30's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Biogen pharmaceuticals-8-km chakbeli road, Rawat, Rawalpindi-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
258	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, (**000449**) Tracking ID: (3MJ-ZMS-2PVX, 2024-08-02) Fee Paid: 30000.0 Paid Date: 2024-08-02 Case Category: New Section **(Najia Saleem)**	Proposed Name: **HIRRA AMOX-80 POWDER** Each 100gm powder containsAmoxicillin as Trihydarte-------20gColistin sulphate----------80MIU As per Innovators Specification RRA Status: NA Me Too Status: AMOXITIN-C W/S POWDER (071062) M/S ATTABAK PHARMACEUTICALS ISLAMABAD Pack Size(s): 100 g-De-Controlled,1000 g-De-Controlled,250 g-De-Controlled,500 g-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Licensing Division has sent a File on e-office No.F.1-10/94-Lic(Vol-II) / Subject: M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd) to Division of PE&R wherein Additional Director (Drug Licensing) has stated vide para 55/N of the said file that "The inspection report of firm regarding Penicillin (oral - Vet) section was considered by the CLB in the 298 meeting. The Board endorsed the recommendations of the panel. The minutes are however under draft." Furthermore, the Director (Drug Licensing)/ Chairman Licensing Board vide para 58/N has stated that "The CLB has approved the additional section during the meeting and minutes of the meeting are under process. The approval of the minutes may take few more days. O?nce approved, the final minutes shall be shared accordingly, please. "	
	Decision: Approved The Board approved the product subject to issuance of new section letter of *Oral Powder (Penicillin)(veterinary) from* Licensing Division as the section has already been approved by CLB in 298th meeting as informed by the Chairman CLB.	
259	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (7QP-LGA-84XM, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Tetralet Plus Aerosol Spray** Each mL ContainsOxytetracycline HCL 40 mgGentian Violet 4 mgPermethin 10 mgCitronella 20 mg As per Innovators Specification RRA Status: N/A Me Too Status: Teragen Plus Aerosol Spray (063623) Star Pack Size(s): 100 mL-De-Controlled,150 mL-De-Controlled,200 mL-De-Controlled,250 mL-De-Controlled,300 mL-De-Controlled,50 mL-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
260	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (7ZS-Y99-EWU7, 2024-05-25) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **onefone Water Soluble Powder** Each Gram Contains Trichlorfon 980 mg As per Innovators Specification RRA Status: GRDR Trichlorfon 98% powder Me Too Status: Ectoned(071071) Selmore. 2. Trifon (049662) SJ&G Pack Size(s): 1.0 kg-De-Controlled,10 gm-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm -De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Group: Insecticide Line: Livestock & Poultry	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
261	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (8PZ-STB-T26D, 2024-05-24) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Sulphamin k3 Oral Powder** Each 100 Gram ContainsSulphaquinoxaline Sodium 16 gmDiaverdine 4.0 gmVitamin A 0.40MIUVitamin K3 1.0 gm As per Innovators Specification RRA Status: Diaxalin . veitnam Me Too Status: Cocoplus (046604) Intervac Pack Size(s): 1.0 kg-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: Poultry: Calves, goatlings Sheep, goat	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
262	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (9X9-Y69-GB7G, 2024-05-24) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Oxymytin Oral powder** Each 1000 Gram ContainsOxytetracycline HCL 250 gmNeomycin Sulphate 250 gmColistin Sulphate 300 MIU As per Innovators Specification RRA Status: Nifulin OP Ukraine Me Too Status: Colicyclin N (089829) vetz Pack Size(s): 1.0 kg-De-Controlled,10 .0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: calves aged 4 to 8 weeks, lambs, kids under the age of 4 months, , poultry (chicken), as well as dogs and cats	
	Decision: Approved	
263	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (ARQ-RHQ-WZ16, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Tetrasone Aerosol Spray** Each mL ContainsOxytetracycline HCL 5 mgHydrocortisone 1.6 mg As per Innovators Specification RRA Status: N/A Me Too Status: Cortisel Aerosol Spray (071079) Star Pack Size(s): 100 mL-De-Controlled,150 mL-De-Controlled,200 mL-De-Controlled,250 mL-De-Controlled,300 mL-De-Controlled,50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Cattle, sheep, goat	
	Decision: Deferred Firm shall submit evidence of separate dispensing booth for steroids	
264	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (AYW-29T-X3XD, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Tetralet Aerosol Spray** Each mL Contains: Oxytetracycline HCL 40 mgGentian Violet 4 mg As per Innovators Specification RRA Status: Desi Spray O.L.K.R Animal Health, Ukraine. Me Too Status: Oxyviolet Spray (088093) Selmore Pack Size(s): 100 mL-De-Controlled,125 mL-De-Controlled,150 mL-De-Controlled,200 mL-De-Controlled,250 mL-De-Controlled,300 mL-De-Controlled,50 mL-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
265	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (D31-PH4-Z77M, 2024-05-25) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Onegizer oral powder** Each Gram Contains Lysozyme 220mgVitamin E 5mg As per Innovators Specification RRA Status: imugin WS Me Too Status: Liso-10 (049566) Mallard Pack Size(s): 1.0 kg-De-Controlled,10 gm-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 Kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: Poultry	
	Decision: Approved	
266	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (GQB-R44-RNVN, 2024-05-25) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Nefratone oral powder** Each Kg ContainsMethenamine 950 gmVitamin B1 8000 mgVitamin B2 9200 mgVitamin k3 2000 mg As per Innovators Specification RRA Status: Methavet , Syria Me Too Status: Diurile (017948) Manhattan Pharma Pack Size(s): 1.0 kg-De-Controlled,10 gm-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Poultry, Ruminants and horses, Dogs and cats	
	Decision: Approved	
267	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (JML-WZY-VZYP, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Milk Boost Oral Powder** Each Kg ContainsCobalt 10 mg Copper 600 mgIron 1000 mg Zinc 3000 mgCalcium 155 gm Magnesium 55 gmManganese 2000 mg Sodium 45 gmPhosphorus 135 gm Iodine 40 mg Selenium 3 mg As per Innovators Specification RRA Status: N/A Me Too Status: Milk Magic (053967) Mallard. Pack Size(s): 1.0 kg-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target Animals : Calves Cattle Cows Goats Sheep	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
268	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (UBU-Y8S-ZNA1, 2024-05-29) Fee Paid: 30000.0 Paid Date: 2024-05-22 Case Category: New License **(Najia Saleem)**	Proposed Name: **Chlor One Aerosol Spray** Each mL ContainsChlortetracycline HCL 15.2 mg As per Innovators Specification RRA Status: Cyclo Spray. Netherland Me Too Status: BioChlor Aerosol Spray (0088094) Selmore. Pack Size(s): 100 mL-De-Controlled,150 mL-De-Controlled,211 mL-De-Controlled,300 mL-De-Controlled,50 mL-De-Controlled
	Evaluation Remarks: target species: sheep, cattle	
	Decision: Approved	
269	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (V3J-YN1-WGSZ, 2024-05-24) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Erycozone Oral powder** Each Gram ContainsTrimethoprim micronized 20 mgSulphadiazine Base 100 mgErythromycin Thiocyanate 100 mg As per Innovators Specification RRA Status: ThrosulCare . USA Me Too Status: erythroprim-S (081728) ICI Pack Size(s): 1.0 kg-De-Controlled,10 .0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target Species: Poultry	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
270	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (WTZ-3W3-54MT, 2024-05-24) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **Neotamins Oral powder** Each Kg ContainsOxytetracycline Hcl 250 gmNeomycin Sulphate 100 gmSodium Sulphate 60 gmVitamin A 250,000 IUVitamin D3 500,000 IUVitamin C 100 gmVitamin E 1 gm As per Innovators Specification RRA Status: Uvemycin plus, Jordan. Me Too Status: NSV_4 (088092) Selmore Pack Size(s): 1.0 kg-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 -De-Controlled,2.5 kg-De-Controlled,20 gm-De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: Chicken, Turkey, Calves	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
271	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (XQR-NY9-XHGS, 2024-05-25) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **N.C.Line oral powder** Each Kg Contains Neomycin Sulphate 70 gmColistin Sulphate 4 gmChlortetracycline HCL 80 gm As per Innovators Specification RRA Status: N/A Me Too Status: Mycol Powder (062200) Univet Pharmaceuticals Pack Size(s): 1.0 kg-De-Controlled,10 gm-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm -De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: Sheep and Goat	
	Decision: Approved	
272	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. (**000993**) Tracking ID: (Z2T-GYW-L348, 2024-05-25) Fee Paid: 30000.0 Paid Date: 2024-05-13 Case Category: New License **(Najia Saleem)**	Proposed Name: **C- One oral powder** Each Gram ContainsVitamin C 100% W/W As per Innovators Specification RRA Status: VITAMIN C PG 100%. PHARMAGAL, Slovak, Europe. Me Too Status: C-Vit Forte (025315) symans Pharma Pack Size(s): 1.0 kg-De-Controlled,10 gm-De-Controlled,10.0 kg-De-Controlled,100 gm-De-Controlled,15.0 kg-De-Controlled,2.5 kg-De-Controlled,20 gm -De-Controlled,25.0 kg-De-Controlled,250 gm-De-Controlled,5.0 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: mammals, poultry	
	Decision: Approved	
273	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, (**000449**) Tracking ID: (YY6-Y37-A8PV, 2024-04-04) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Hirra Amoxy-N Water Soluble Powder** Each 1000gm powder contains. Amoxicillin ----------10%(100GM)Colistin sulphate ----------50MIU(50GM)NEOMYCIN SULPHATE---------20%(200GM) Manufacturer Specification RRA Status: NA Me Too Status: AMCOCIN W/S POWDER, M/S SALMORE PHARMACEUTICAL PVT(LTD) Pack Size(s): 100's-De-Controlled,1000's-De-Controlled,250's-De-Controlled,500's-De-Controlled
	Evaluation Remarks: Licensing Division has sent a File on e-office No.F.1-10/94-Lic(Vol-II) / Subject: M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd) to Division of PE&R wherein Additional Director (Drug Licensing) has stated vide para 55/N of the said file that "The inspection report of firm regarding Penicillin (oral - Vet) section was considered by the CLB in the 298 meeting. The Board endorsed the recommendations of the panel. The minutes are however under draft." Furthermore, the Director (Drug Licensing)/ Chairman Licensing Board vide para 58/N has stated that "The CLB has approved the additional section during the meeting and minutes of the meeting are under process. The approval of the minutes may take few more days. Once approved, the final minutes shall be shared accordingly, please. "	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved The Board approved the product subject to issuance of new section letter of *Oral Powder (Penicillin)(veterinary) from* Licensing Division as the section has already been approved by CLB in 298th meeting as informed by the Chairman CLB.	

Meeting ended with vote of thanks to and from the chair.

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