MINUTES OF 295th MEETING OF CENTRAL LICENSING BOARD HELD ON 11TH JANUARY 2024

295th meeting of the Central Licensing Board (CLB) was held on 11th January 2024 in the Committee Room, T. F Complex, DRAP, Islamabad. Dr. Muhammad Akhtar Abbas Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Mr. Babar Khan Additional. Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
2.	Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore	Member
3.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa	Member
4.	Mr. Abdul Hafeez Tunio, Chief Inspector of Drugs, Government of Sindh, Karachi (Joined through Microsoft Teams)	Member
5.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
6.	Ms. Mahvish Ansari, Additional Director, representative from QALT, DRAP	Member
7.	Mr. Abdul Hafeez Tunio (online participant), Chief Inspector of Drugs, Government of Sind	Member

Mr. Babar Khan Additional Director/Secretary Licensing Board presented the agenda before the Board. Ms. Ume Liala Deputy Director (Lic), Mr. Mubashir Iqbal, Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Ms. Zunaira Faryad Assistant Director (Lic) and Ms Mahvish Tanveer AD QC assisted the Secretary, Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 294th MEETING**

All members of the Central Licensing Board (CLB) formally confirmed the minutes of 294th meeting of the Central Licensing Board (CLB) held on 27th December, 2023.

A. DRUG LICENSING DIVISION

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSE.

The respective panel of experts for grant of Drug Manufacturing License has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection /	Ranking/ Evaluation	Inspection Panel Members
1	M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd, 1.3-Km (Asil Raiwind Road, Ladhaky Bhular) Lahore. **Sections (03)** 1. Oral Powder Section (General/Antibiotic) (Veterinary) 2. Oral Liquid Section (General/Antibiotic) (Veterinary) 3. Vaccine Section (Veterinary) (Bacterial & Viral) (Evaluator: Ms, Zunaira Faryad, Assistant Director)	29-12-2023	Good	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Dr. Qurban (Vet. Expert). 3. Abdul Rashid Shaikh, Area Federal Inspector of Drugs, DRAP, Lahore.
	QC In-charge	Ms. Sidra Asghar, (Pharm-D)		
	Production In-charge	Ms. Attia Nouman, (Pharm-D)		

Recommendations of the panel: -

Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors is of the opinion to **recommend** the re-grant of Drug Manufacturing License to M/s. Hirra Pharmaceuticals Laboratory, 1.3-km (Asil Raiwind Road, Lodhaky Bhular), Lahore for the following sections:

1. Oral Powder Section (General/Antibiotic) (Veterinary)
2. Oral Liquid Section (General/Antibiotic) (Veterinary)
3. Vaccine Section (Veterinary) (Bacterial & Viral)

It is pertinent to mention here that as per Form-A dated 03-02-2014 Mr. Bakhtiar Ahmed, Mr. Kamran Akhtar & Mr. Muhammad Farooq Shahzad were directors of the firm. Mr. Muhammad Farooq Shahzad passed away on March, 2021. The firm has

	submitted digital certified true copy of Form-29 dated 21-12-2023 in which Kamran Akhtar has been appointed as CEO in place of Mr. Muhammad Farooq Shahzad. Moreover, Mrs. Naheed Akhtar W/o Muhammad Farooq Shahzad submitted a copy of undertaking which is reproduced as under: "It is informed in the most grief that Mr. Muhammad Farooq Shahzad S/o Sheikh Asmat Ullah, Managing Director of Hirra Pharmaceutical Laboratories (Pvt) Ltd, holding CNIC 35202-2902531-9 has passed away on March, 2021 due to Covid- 19. In that perspective we are applying for change of Partner and appointing Mrs. Naheed Akhtar W/O Muhammad Farooq Shahzad holding CNIC 35202- 4493327-0 as a new partner in Hirra Pharmaceutical Laboratories (Pvt) Ltd. Ms. Naheed Akhtar (CNIC: 35202-4493327-0) widow of Muhammad Farooq Shahzad as a partner/shareholder of Hirra Pharmaceutical don't have any objection for DRAP inspection and GMP renewal for continuation of the unit." Vide letter H.PL/13/24 dated 9-01-2024 Dr. Kamran Akhtar CEO of Hirra Pharmaceutical Laboratories (Pvt.) Ltd., has undertaken the responsibility of manufacturing quality products. **Decision of the Central Licensing Board in 295th meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant (afresh) of Drug Manufacturing License by way of Formulation in the name of M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd, 1.3-Km (Asil Raiwind Road, Ladhaky Bhular) Lahore for the following sections. 1. Oral Powder Section (General/Antibiotic) (Veterinary) 2. Oral Liquid Section (General/Antibiotic) (Veterinary) 3. Vaccine Section (Veterinary) The same license No. 000449 shall be allotted to the firm. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The Board also accepted the following management as per form 29 and undertaking till the inclusion of any other director. 1. Dr Kamran Akhtar, CEO			
2	M/s Solaris Life Sciences (Pvt) Ltd, Plot No.08, Street No.S-1, RCCI, Rawat. **Sections (06)** 1. Tablet Section-I (General) 2. Tablet Section-II (General) 3. Capsule Section-I (General)	05-01-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Shamoon Ch. Panel Member. 3. Mr. Umer Latif, Deputy Director, DRAP, Islamabad.

	4. Dry Powder Suspension Section (General) 5. Sachet Powder Section (General) 6. Topical Section General & Steroid Evaluator: Ms, Ume Laila (Deputy Director)			
	QC In-charge	Mr. Bakht Zaman		
	Production In-charge	Mr. Mazhar Ali Khan		

Recommendations of the panel: -

The panel considering that the establishment has the necessary equipment / machinery for manufacturing and testing/analysis of drugs i.e. FTIR, HPLCs, Atomic Absorption, Spectrophotometer, UV-Spectrophotometer, viscometer, stability chambers, hot/cold incubators etc, with the personnel of required qualification and experience, unanimously recommends the grant of Drugs Manufacturing License to M/s Solaris Life Sciences (Pvt) Ltd, Plot No.08, Street S-1, RCCI, Industrial Estate Rawat, Islamabad for the following sections:

1. Tablet Section-I (General)
2. Tablet Section-II (General)
3. Capsule Section-I (General)
4. Dry Powder Suspension Section (General)
5. Sachet Powder Section (General)
6. Topical Section (General & Steroid)

Note:
The establishment has a common section for Topical General and Steroid section with dedicated machinery for steroid section.

Decision of the Central Licensing Board in 295th meeting:

On the recommendations of the panel of experts, the Board considered and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Solaris Life Sciences (Pvt) Ltd, Plot No.08, Street No. S-1, RCCI, Rawat for the following sections:

1. Tablet Section-I (General)
2. Tablet Section-II (General)
3. Capsule Section-I (General)
4. Dry Powder Suspension Section (General)
5. Sachet Powder Section (General)
6. Cream, Ointment, Gel, Lotion Section (General & Steroid)

(The firm fulfills separate area requirements for Cream\Ointment\Gel, and Lotion sections)

Item- III: **GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC.**

The respective panel of experts for grant of additional sections has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle, Kahuta Road, Islamabad. DML No.000860 (Formulation) Section (01): i. Liquid Syrup Section (General) (New) in place of Tablet I (General) (Evaluator: Mr Muhammad Yaqoob)	07-12-2023	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mahwish, Area Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Muhammad Sarfraz, Assistant Director, DRAP, Islamabad.

Recommendations of the Panel:

Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously recommended the grant of following additional section to M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle, Kahuta Road, DML# 000860:

i) Grant of Additional Section

1. Liquid Syrup Section (General) (New) in place of Tablet I (General)

Decision of the Central Licensing Board in 295th meeting:

On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000860 (Formulation) subject to verification of testing equipment (M-290th CLB): -

1. Liquid Syrup Section (General) (New)

The Board also cancelled the Tablet I (General) section.

Item-V: **MISCELLANEOUS**

Case No. 1 CHANGE OF MANAGEMENT OF M/S AGP LIMITED, D-109, S.I.T.E., KARACHI, PAKISTAN UNDER DML NO. 000044 (FORMULATION)

M/s AGP Limited, D-109, S.I.T.E., Karachi, Pakistan has submitted application for change of title of the company under Drug Manufacturing License No. 000044 by way of (Formulation) with relevant fee of Rs. 75,000/. The firm has submitted the notarized copy of certificate of incorporation on change of name issued by the Additional Registrar, SECP, Karachi along with other relevant documents as per approved checklist. The detail of the firm's management is as under:

Previous Management as per Form-29.	New Management as per Form-29.
1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3.	1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. 8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. [Director by virtue of CEO position]

Decision of the Central Licensing Board in 295th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s AGP Limited, D-109, S.I.T.E., Karachi, Pakistan under DML No. 000044 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under;

Previous Management as per Form-29.	**New Management as per Form-29.**

1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3.	1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. 8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. [**Director by virtue of CEO position**]

Case No. 2. <u>CHANGE OF MANAGEMENT OF M/S AGP LIMITED, B-23-C, S.I.T.E., KARACHI, PAKISTAN UNDER DML NO. 000348 (BASIC MANUFACTURER)</u>

M/s AGP Limited, B-23-C, S.I.T.E., Karachi has submitted an application for change of title of the company under Drug Manufacturing License No. 000348 (Basic Manufacturer) with relevant fee of Rs. 75000/. The firm has submitted the notarized copy of certificate of incorporation on change of name issued by the Additional Registrar, SECP, Karachi along with other relevant documents as per approved checklist. The detail of the firm's management is as under:

Previous Management as per Form-29.	New Management as per Form-29.
1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5.	1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5.

7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3.	7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. 8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8.

Decision of the Central Licensing Board in 295th meeting

Based on change of management in SECP, the Board considered and accepted for record the change of management of M/s AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan under DML No. 000348 (Basic Manufacture) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under;

Previous Management as per Form-29.	**New Management as per Form-29.**
1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3.	1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. 8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8.

Case No.3. CORRECTION IN MINUTES OF 292ND MEETING OF CLB (M/S NOVINS INTERNATIONAL (PVT) LTD, KARACHI UNDER DML NO.000541 (FORMULATION:

The case for grant of renewal of DML of M/s Novins International (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi under DML No.000541 (Formulation) was presented in 292nd meeting of CLB as under:

M/s Novins International (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi. DML No. 000541 (Formulation) Period: Commencing on 15-02-23 ending on 14-02-2028.	**17-08-2023** / *by way of Formulation*	**Good**	1. Additional Director, DRAP, Karachi. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.
Production Incharge:		Mr. Qaiser Aziz (B-Pharm)	
QC Incharge:		Ms. Sumaira Shaheen D/o Asghar Ali Khan (M.Sc Chemistry)	

Recommendations of the panel:

"Based on people met, areas visited and commitment of the management for continuous improvement, expansion and export potential, the panel unanimously was of the view to recommend Renewal of Drug Manufacturing License No.000541 as per DRAP, Islamabad letter of even no. dated 26th June' 2023 to the firm M/s Novins International (Pvt) Ltd., situated at A-29, N.W.I.Z., Karachi for following sections:

i. Tablet (General)	ii. Capsule (General)	iii. Ointment (General)

Decision of the Central Licensing Board in 292nd meeting:

The Board considered and approved the grant of renewal of DML No. 000541 by way of Formulation in the name of M/s Novins International (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi on the recommendations of the panel of experts for the period Commencing on 15-02-23 ending on 14-02-2028 for the following sections.

1. Oral Liquid Section (General)
2. Tablet section (General)
3. Capsule Section (General)
4. Dry Powder Suspension (General Antibiotic Section)
5. Capsule Section (Cephalosporin)
6. Dry Powder Suspension Section (Cephalosporin)
7. Dry Powder Injectable Section (Cephalosporin)
8. Liquid Vial Injectable (General Antibiotic)
9. Liquid Ampoule Injectable (General Antibiotic).

In the minutes of 292nd meeting the number of sections approved were inadvertently typed as Nine (09) sections instead of following Three (03) sections in the decision:

i. Tablet section (General)
ii. Capsule Section (General)
iii. Ointment/Cream/ Gel

Decision of the Central Licensing Board in 295th meeting

The Board considered the case and approved the correction for grant of renewal of DML with following sections:

i. Tablet section (General)
ii. Capsule Section (General)
iii. Ointment/Cream/ Gel

Case No.4. CORRECTION IN DML OF 286TH MEETING OF CLB (M/S WIMITS PHARMACEUTICALS (PVT) LTD, LAHORE UNDER DML NO. 000783 (FORMULATION

The case for grant of renewal of DML of M/s Wimits Pharmaceuticals (Pvt) Ltd, Plot No.129, Sunder Industrial Estate, Raiwind Road, Lahore was approved by Central Licensing Board in its 286th meeting. However, in the minutes of 286th meeting, Drug Manufacturing License number was inadvertently typed as 000783 instead 000789 in the decision.

Decision of the Central Licensing Board in 295th meeting:

The Board considered the case and approved the correction in DML number from 000789 to 000783.

Case No.5. ESTABLISHMENT OF PHARMACEUTICAL UNIT – M/S SINDH INSTITUTE OF ANIMAL HEALTH, KARACHI.

The applicant M/s Sindh Institute of Animal Health, Karachi submitted application for site verification vie letter No. 893 dated 30/1/2010 (Flag A). Additional Director (E&M), DRAP, Karachi was requested to inspect the site situated at Sindh Institute of Animal Health, Karachi vide letter No. F.2-6/2023-Lic dated 16th November, 2023.

In light of above letter, FID, DRAP, Karachi submitted its inception report. Said report and its recommendations is reproduced as under;

"I have the honor to refer to the DRAP Islamabad letter No.F.2-6/2023-Lic dated 16% November, 2023 on the subject mentioned above and to submit that undersigned inspected the site reserved for establishment of pharmaceutical unit M/s. Sindh Institute of Animal Health on dated 06% December, 2023. Following are the observations and recommendations:-

1. *The site is situated at Livestock & Fisheries Department, Government of Sindh Animal) Science Complex, Near Singer Chowrangi, Korangi Karachi in well- developed industrial zone*

2. *Government of Sindh had allocated 18 Acres of land to Sindh Institute of Animal Health in which 02.33 Acres are reserved for obtaining a licensed pharmaceutical unit (Veterinary Drugs and Vaccines) as per requirements of DRAP Act, 2021 and Drugs Act, 1976 as per provided layout plan.*

3. *Inside boundary wall, the institute has provided separate blocks for different types of vaccines already manufactured there, a research QC lab, animal hospital and storage areas,*

4. *All utilities are already available there.*

5. *The plot complies the provisions as laid down under paragraph-1 of Section 1 of Schedule B SRO.470(D/98 dated 15.05.1998) under Rule 16(a) of Drugs (Licensing, Registering & Advertising) Rules 1976 of Drug Act, 1976.*

Keeping in view the observations made during the inspection, the above site is recommended for regularization under rules."

The above case is included in the agenda of authority which shall be placed before DRAP authority in its upcoming meeting for its consideration. However, it is pertinent to mention that the Authority in its 175th meeting held on 3rd November, 2023 has considered a case of similar nature i.e. M/s. Veterinary Research Institute Lahore wherein Licensing Division was advised to process the case of grant of license to M/s Veterinary Research Institute, Lahore. Recommendation /decision of DRAP authority in its 175th meeting was presented before the CLB in its 293rd meeting held on 20th November, 2023 and the Board approved the said site.

The aforesaid decision is case specific, therefore, it is proposed that in larger public interest Board may consider the case subject to decision of the DRAP-Authority.

Decision of the Central Licensing Board in 295th meeting:

The Board considered the case and approved the proposed site situated at Sindh Institute of Animal Health, Karachi of M/s Sindh Institute of Animal Health, Karachi for establishment of pharmaceutical unit subject to decision of DRAP Authority.

Case No.06 **ESTABLISHMENT OF PHARMACEUTICAL UNIT – M/S SINDH INSTITUTE OF ANIMAL HEALTH, SITUATED AT ASV/ARV SEROLOGY LABORATORY AT SAKRAND, SINDH.**

The applicant M/s Sindh Institute of Animal Health, Karachi submitted application for site verification situated at ASV/ARV Serology Laboratory at Sakrand, Sindh. Additional Director (E&M), DRAP, Karachi was requested to inspect the site situated ASV/ARV Serology Laboratory at Sakrand, Sindh, accordingly. Federal Inspector of Drugs-DRAP, Karachi vide letter No. F. 02-07/2023-FID-II(K) dated 01/01/2024 submitted site inspection report. The inception report and its recommendations is reproduced as under;

"I have the honor to refer to the DRAP Islamabad letter No.F.2-7/2023-Lic dated 08th December, 2023 on the subject mentioned above and to submit that undersigned inspected the site reserved for establishment of pharmaceutical unit M/s. Sindh institute of Animal Health (SIAH) on dated 26th December, 2023. Following are the observations and recommendations: -

1. The Sindh Government has allocated this site at Survey No. 4/4 suited at Deh 18 Sakrand in the name of ASV/AVR Serology Lab Sakrand District Shaheed Benazirabad. Furthermore 04 Acres of land to Sindh Institute of Animal Health in which 02.22 Acres are reserved for obtaining a licensed pharmaceutical unit (Veterinary Drugs and Vaccines) as per requirements of DRAP Act, 2021 and Drugs Act, 1976 as per provided layout plan.

2. Inside boundary wall, the institute has provided separate blocks for manufacturing of different types of Sera/vaccines, a research QC lab, animal houses and storage areas.

3. All utilities are already available there.

4. The plot complies the provisions as laid down under paragraph-1 of Section 1 of Schedule B SRO.470(I)/98 dated 15.05.1998) under Rule 16(a) of Drugs (Licensing, Registering & Advertising) Rules 1976 of Drug Act, 1976.

Keeping in view the observations made during the inspection, the above site is recommended for regularization under rules.

The above case is included in the agenda of authority which may be placed before DRAP authority in its upcoming meeting for its consideration. However, it is pertinent to mention that the Authority in its 175th meeting held on 3rd November, 2023 has considered a case of similar nature i.e. M/s. Veterinary Research Institute Lahore wherein Licensing Division was advised to process the case of grant of license to M/s Veterinary Research Institute, Lahore. Recommendation /decision of DRAP authority in its 175th meeting was presented before the CLB in its 293rd meeting held on 20th November, 2023 and the Board approved the said site.

The aforesaid decision is case specific, therefore, it is proposed that in larger public interest Board may consider the case subject to decision of the DRAP-Authority.

Decision of the Central Licensing Board in 295th meeting:

The Board considered the case and approved the proposed site situated at ASV/ARV Serology Laboratory, Sakrand, Sindh of M/s Sindh Institute of Animal Health, Karachi for establishment of pharmaceutical unit subject to decision of DRAP Authority.

Case No.07 WITHDRAWAL OF WAREHOUSE OF M/S HERBION PAKISTAN (Pvt.) LTD., INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD. DML NO. 000937

While considering the case of additional sections and withdrawal of the warehouse facility the Central Licensing Board in its 293rd meeting decided as under.

"The Board deferred the request of the firm for withdrawal of Bulk Warehouse for clarification".

Reply of the Firm:

As far as clarification regarding the withdrawal of the Bulk warehouse is concerned, we wish to inform you that following recommendations from multiple international audits, particularly those conducted by Ministry of Health of Belarus and Uzbekistan, it is recommended to utilize the single main warehouse facility to its maximum available capacity to keep the movement of materials within the building.

Initially, we had faced some challenges in utilizing the entire height of the warehouse due to the absence of required reach truck and stackers. However, we have now invested and already acquired the necessary equipment/machinery (reach truck/stacker) with appropriate safety measures. This has enabled us to optimize the storage space in our main warehouse for products with segregated stacking requirements.

The revised layout (without the outer bulk warehouse) has already been approved from licensing division dated May 23, 2023. During the DRAP inspection on October 12, 2023, the visiting panel has also witnessed that adequate storage capacity is available in the main warehouse. For any future capacity enhancement if required, we will inform you accordingly.

This consolidation is expected to result in a more streamlined warehouse process, improving inventory management and further improvement in better compliance with the requirements of international audit inspections. Additionally, it is important to mention that the outer warehouse is located in a separate building, which has remained unused for the past 1.5 years.

Decision of the Central Licensing Board in 295th meeting:

The Board considered the case and acceded to the request of M/S Herbion Pakistan (Pvt.) Ltd., Industrial Triangle, Kahuta Road, Islamabad. DML No. 000937 (Formulation) for withdrawal Bulk Warehouse.

Case No.08 MANUFACTURING OF ENEMA IN LOTION SECTION

The Central Licensing Board in its 290th meeting constituted following committee for manufacturing of Enema in the topical sections: -

i. Mr. Babar Khan, Secretary Central Licensing Board
ii. Mr. Asif jalil, Incharge, Pharmaceutical Evaluation Cell
iii. Mr. Muhammad Ansar, Deputy Director QA&LT

The meeting was held in the office of Secretary Central Licensing Board on dated 27.11.2023. The committee discussed the possibility of manufacturing of enema formulations in Topical sections: -

i. Rationale of manufacturing.
ii. Cross Contamination.
iii. Section restrictions

Rationale of Manufacturing

Topical sections are meant for the manufacturing of formulations of topical dosage forms that are intended for external use only and are applied mostly on surfaces of skin with ingredients that are safe for topical use only. Formulations that are inserted through rectum for local as well as for systemic actions has difference composition than topical dosage form as they are meant for insertion into body hence does not cover in the section of topical preparations as enemas have formulations totally different from topical.

Cross Contamination

Topical preparations usually have ingredients that are only meant for external application (Permethrin. Sulfur etc.) and may pose severe adverse effects if they are ingested or taken into body as the rectal areas have excess blood supply, any manufacturing of such enemas in topical section if contaminated by such substances may lead to severe side effects being immediately

absorbed by rectal blood circulation into main blood stream, especially in case of children who has less lean body mass. minute quantity of such drugs can lead to severe adverse effects.

Permethrin

Permethrin is acutely toxic at high doses in animals and humans (LD_{50} for animals is greater than 1 g/kg); the toxicity varies with the cis/trans ratio—the cis isomer being more toxic than the trans isomer. Acute signs of toxicity to the central nervous system include incoordination, ataxia, hyperactivity, convulsions, and finally prostration, paralysis, and death. Permethrin can be an ocular irritant following direct application to the eye, but that would not result from its intended use in BDUs.

The U.S. EPA decided that permethrin was "likely to be carcinogenic to humans" if it was eaten. Permethrin General Fact Sheet (orst.edu)

Section restrictions

Topical sections are meant for the manufacturing of formulations used on external body surfaces, however as enemas are not topical and are intended to be taken internally which shows its effect inside the body (Local or systemic).

Conclusion

The matter was deliberated in detail by the committee as there is high risk for the cross contamination of topical products with enema formulations along with enema formulation are intended for internal use through rectal route the committee recommended that enema formulations may not be allowed in topical sections.

Decision of the Central Licensing Board in 295th meeting:

On the recommendations of the committee and keeping in view of the risk of cross contamination the Board decided that enema preparations shall not be allowed to manufacture in Lotion section.

Case No. 9: APPLICATIONS FOR STEM CELL GMP FACILITY FOR EXPERIMENTAL PURPOSE

The Division of Licensing DRAP has received applications from different centers regarding approval of the layout plan and issuance of License for Experimental Purpose for aseptic isolation/preparation/manufacturing of Stem Cells *in vitro* xeno-free proliferation, and characterization and conducting trials on humans.

- Dr Sheikh Riazuddin, Stem Cell Lab, Jinnah Burn & Reconstructive Surgery Centre, Lahore

The matter was placed before the DRAP Authority meeting dated 11th & 13th Oct 2022, the decision of which is cited below:

1. The Authority decided to refer back the case to Licensing division to suggest a way forward for licensing of stem cells manufacturing facilities in light of international practices.

2. The Authority further decided to send a reference to Health-care commission and Heart & Organ Transplant Authority (HOTA) for their input as per their and DRAP'S scope.

Hence in the light of the decision, the Licensing Division solicited comments from BE&R Division regarding the manufacturing facility requirement for stem cells, in the light of international practices which are as follows:

"It is submitted EMA, WHO & USFDA websites were searched for requirements on manufacturing facilities for manufacturing of stem cell.

a) It is submitted that no concrete requirement has been found on the relevant websites the mentioned regulatory authorities however it has mentioned that manufacturing of stem cell /cell-based medicinal products (CBMPs)/Advanced Therapy Medicinal Product requires a strict control in c-GMP facilities as required for other Biological Drugs along with product specific requirement i.e. justified production & testing facility. For more details, & specific requirement for manufacturing of stem cell, the Licensing division may be requested to obtain expert opinion from relevant expert of the field."

b). Furthermore, in its intended use the applicant has mentioned (as described in para-9/N)

that "*We intend to prepare stem cells for experimental purposes only*" & "*We will employ stem cells for the repair of damaged tissue including but not limited to liver, kidney, skin, cartilage, spinal cord, cornea, and retina in human subjects. For that purpose, the treatment will be totally free of cost and no expenditures will be paid by the patient at any stage of the study. Further, the patient may choose not to take part in the study for any reason at any stage.*" From which it seems that the applicant wants to conduct clinical trial on human subjects therefore the opinion of Pharmacy services division may also be sought in this regard.

It is further submitted that the subject matter is of highly sensitive nature due to direct involvement of the humans during experimental stage and some ethical issues/requirements as per available data on the internet therefore the matter is placed before the Central Licensing Board for deliberation and guidance please.

Currently, the only stem cell-based treatment that is routinely reviewed and approved by the U.S. Food and Drug Administration (FDA) is hematopoietic (or blood) stem cell transplantation. It is used to treat patients with cancers and disorders that affect the blood and immune system.

The only stem cell-based products that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood.

HEJ research institute of chemistry and Dr Panjwant center for molecular medicine and drug research has also applied for approval of design for stem cell GMP facility. After various discussions division of licensing could not reach on a conclusion due to ethical issues related to the therapy.

Decision of the Central Licensing Board in 295th meeting:

The board decided to form following working group.

1. Dr Obaidullah, Director Pharmacy Services (Chairman)
2. Mr Babar Khan, Additional Director (Lic.)
3. Ms Mahvash Ansari, Additional Director (QC.)
4. Mr Mubashir Iqbal, Deputy Director (Lic.)

TORs of the Working group.

The terms of reference of the working group will include but not limited to the following:

i. The group will consider international references for the requirements of GMP of the Stem Cell manufacturing facilities.
ii. The group will go through the ethical aspects of the clinical trials/experiments.
iii. The group will find out the way forward for regulatory mechanism.
iv. The group will submit its recommendations for the Central Licensing Board for its consideration and final decision in the subject matter.

The Chairman of the Working group may opt any expert / person for assistance and discussion on the subject matter.

Item-III: GRANT OF ADDITIONAL/REVISED SECTION.

1.	M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore. DML No. 000530 (Formulation) **Sections (06):** i. Capsule Section (Cephalosporin) (Revised) ii. Liquid Injectable Ampoule & Vial (General) Section (Revised) iii. Dry Powder Suspension Section (Cephalosporin) (Revised) iv. Cream/Ointment Section (General) (Additional Section) v. Dry Powder Suspension Section (General) (Additional Section) **vi.** Dry Powder Injectable section (Cephalosporin) (Additional Section)	05-01-2024 / *by way of Formulation*	Good	1. Dr. Zaka Ur Rehman , Secretary, Pharmacy Council, Lahore. 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Farooq Aslam, Assistant Director, DRAP, Lahore.
	Production Incharge:		Mr. Hussain Raza	
	QC Incharge:		Mr. Junaid Zafar	
	Recommendations of the panel: Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production, machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors is of the opinion to recommends the renewal of Drug Manufacturing License, Grant of additional & revised sections to M/s Rasco Pharma located at Plot No.27-28, Holiday park Near Ali Raza Abad, 5.5-Km Raiwind Road Lahore for the following sections : **For Renewal of DML:** i. Tablet (General)Section (renewal) ii. Liquid Syrup (General)(Renewal) iii. Capsule Section (General) (Renewal) iv. Tablet (Psychotropic) Section (Renewal) v. Liquid Syrup (Psychotropic) Section (Renewal) **For Revised Section:** vii. Capsule Section (Cephalosporin) (Revised) viii. Liquid Injectable Ampoule & Vial (General) Section (Revised) ix. Dry Powder Suspension Section (Cephalosporin) (Revised) **For Additional Section:**			

	x. Cream/Ointment Section (General) (Additional Section) xi. Dry Powder Suspension Section (General) (Additional Section) **xii.** Dry Powder Injectable section (Cephalosporin) (Additional Section) **<u>Decision of the Central Licensing Board in 295th meeting:</u>** On the recommendations of the panel of experts, the Board considered and approved the grant of following sections in the name of M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore under DML No. 000530 (Formulation) subject to verification of testing equipment's (M-290th CLB): - i. Capsule Section (Cephalosporin) (Revised) ii. Liquid Injectable Ampoule & Vial (General) Section (Revised) iii. Dry Powder Suspension Section (Cephalosporin) (Revised) iv. Cream/Ointment Section (General) (Additional Section) v. Dry Powder Suspension Section (General) (Additional Section) **vi.** Dry Powder Injectable section (Cephalosporin) (Additional Section)

Item-II: **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.**

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection /</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td rowspan="4">1.</td><td>M/s FAAS Pharmaceuticals (Pvt) Ltd., Plot No. F-7480/L, S.I.T.E., Karachi.
DML No. 000767 (Formulation)
Period: Commencing on 15-02-23 ending on 14-02-2028.</td><td>09-01-2024
/
by way of Formulation</td><td>Good</td><td>1. Chief Drug Inspector, Sindh.
2. Additional Director, DRAP, Karachi.
3. Area FID, DRAP, Karachi.</td></tr>
<tr><td colspan="2">Production Incharge:</td><td colspan="2">Mr. Muhammad Tariq (B-Pharm)</td></tr>
<tr><td colspan="2">QC Incharge:</td><td colspan="2">Ms. Kahkashan Tabassum (B-Pharm)</td></tr>
<tr><td colspan="4"><u>Recommendations of the panel:</u>
“M/s FAAS Pharmaceuticals (Pvt) Ltd., Situated at Plot No. F-7480/L, S.I.T.E., Karachi was and re-inspected in detail on 09-01-2024 in compliance to the directions contained in DRAP, E-Office directions Dated: 05/01/2024 for the grant of renewal of their DML No.000767, as the last panel inspection conducted on 18/12/23 was not concluded due to paucity of time, later on Mr. Abdul Hafeez Chief Drug Inspector Sindh was included into the Panel to complete the task.

The panel inspected the firm in detail including all the manufacturing sections, stores and QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA, and installation qualification of machines, HVAC and other utilities were also seen in place.
Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the grant of renewal of Drug Manufacturing License No.000767 by way of formulation for following sections: -

<table>
<tr><th>S.No.</th><th>Name of Section</th><th>S. No.</th><th>Name of Sections</th></tr>
<tr><td>01.</td><td>Tablet (General)</td><td>02.</td><td>Capsule (General)</td></tr>
<tr><td>03.</td><td>Sachet (General)</td><td></td><td></td></tr>
</table>

<u>Decision of the Central Licensing Board in 295th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000767 by way of Formulation in the name of M/s FAAS Pharmaceuticals (Pvt) Ltd., Plot No. F-7480/L, S.I.T.E., Karachi for the period commencing on 15-02-2023 ending on 14-02-2028 on the recommendations of the panel of experts for the following sections subject to verification of testing equipment (M-290th CLB).

i. Tablet (General)
ii. Capsule (General)
iii. Sachet (General)</td></tr>
</table>

2.	M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore. DML No. 000530 (Formulation) Period: Commencing on 26-01-2024 ending on 25-01-2029.	**05-01-2024** / *by way of Formulation*	**Good**	1. Dr. Zaka Ur Rehman, Secretary, Pharmacy Council, Lahore. 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Farooq Aslam, Assistant Director, DRAP, Lahore.
	Production Incharge:		Mr. Hussain Raza	
	QC Incharge:		Mr. Junaid Zafar	

Recommendations of the panel:

Keeping in view the manufacturing facilities like building and availabilities of HVAC system, sanitation, production, machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors is of the opinion to recommends the renewal of Drug Manufacturing License, Grant of additional & revised sections to M/s Rasco Pharma located at Plot No.27-28, Holiday park Near Ali Raza Abad, 5.5-Km Raiwind Road Lahore for the following sections :

For Renewal of DML:

i. Tablet (General)Section (renewal)
ii. Liquid Syrup (General)(Renewal)
iii. Capsule Section (General) (Renewal)
iv. Tablet (Psychotropic) Section (Renewal)
v. Liquid Syrup (Psychotropic) Section (Renewal)

For Revised Section:

i. Capsule Section (Cephalosporin) (Revised)
ii. Liquid Injectable Ampoule & Vial (General) Section (Revised)
iii. Dry Powder Suspension Section (Cephalosporin) (Revised)

For Additional Section:

i. Cream/Ointment Section (General) (Additional Section)
ii. Dry Powder Suspension Section (General) (Additional Section)
iii. Dry Powder Injectable section (Cephalosporin) (Additional Section)

Decision of the Central Licensing Board in 295th meeting:

The Board considered and approved the grant of renewal of DML No. 000530 by way of Formulation in the name of M/s Rasco Pharma, Plot No.27, Holiday Park, Near Ali Raza Abad, 5.5-Km, Raiwind Road, Lahore for the period commencing on 26-01-2024 ending on 25-01-2029 on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for psychotropic section and subject to verification of testing equipment (M-290th CLB) for following sections:

	i. Tablet (General)Section (renewal) ii. Liquid Syrup (General)(Renewal) iii. Capsule Section (General) (Renewal) iv. Tablet (Psychotropic) Section (Renewal) v. Liquid Syrup (Psychotropic) Section (Renewal)